IFS Food Version 6

Guideline

Typical auditor questions, examples for KO/Major and cross references for IFS requirements

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Preface

Aim

The implementation of the IFS requirements often depends on the situation of the respective company. IFS improves the audit quality by providing explanations and examples for the IFS requirements. **This guideline shall be used as a tool for auditors to perform the audits in compliance with IFS requirements and it supports companies preparing an IFS audit.**

Focusing on products

IFS provides a product certification scheme, therefore the respective audit is focussed on products/ processes. Therefore any objective evidences are closely related to products and processes. The products that the auditor chooses as “the audit trail” for the questioning during the audit are important. If the auditee can prove with objective evidences that these products – selected by the auditor in an appropriate number - are produced according to the agreed specification in a safe manner, it provides a reliable assessment of the auditee. The listed typical questions in the guideline are closely linked to the checks of products. The auditor should ask these questions in order to get a maximum of information about a representative sample of products (retailer branded products) and about the auditee.

Incompleteness

The listed questions are just examples and can not give the auditor a complete survey. The auditor shall adapt his audit to the specific situation of the company case by case. The audit is not automatically complete if the auditor asks every question of the list. It establishes just a minimum survey the auditor should fulfill.

The cross references with the regarding legislation provide additional information for the auditor and the audited company. **IFS clearly states that the legal references are only indicative, but not exhaustive.** The cross references should be seen as an introduction to the European and the US American legislations. It should be considered that additional and specific regulations can exist in certain countries. The list shows the current legal situation and will be out of date when new regulations apply. **It is the responsibility of the auditor and the auditee to be kept informed about any changes of relevant legislation.**

Improvements

The IFS is dedicated for improving the guideline continuously. Therefore IFS would like to give the auditors as well as the certification bodies and the audited companies the opportunity to support IFS. If you have comments or ideas on the basis of own experiences that could help IFS to improve the guideline please do not hesitate to contact the IFS offices.

N°	IFS Requirements	What do you have to check? What must be asked?	KO / Major	Cross reference (IFS requirements, important european directives, other comments, US american legislation)
1	**Senior Management Responsibility**			
1.1	**Corporate policy / Corporate principles**			
1.1.1	The senior management shall draw up and implement a corporate policy. This shall consider as a minimum: - customer focus - environmental responsibility - sustainability - ethics and personnel responsibility - product requirements (includes: product safety, quality, legality, process and specification). The corporate policy shall be communicated to all employees.	• How and where is corporate policy documented? • What are the contents of the corporate policy? • How was corporate policy communicated to all employees? <corporate policy>, <posters> <documented evidence of corporate policy communication> Environmental responsibility and sustainability are included in the IFS Food standard, even if it is a food safety and quality standard, in order to initiate/develop in companies processes of awareness for both topics.		
1.1.2	The content of the corporate policy shall have been broken down into specific objectives for the related departments. The responsibility and the time scale for achievement shall be defined for each department of the company.	• What short, medium and long term quality objectives are addressed? • How are the objectives attained? • What is the time frame to attain the objectives? • Who is responsible for objectives attainment? • What actions are taken by specific departments, e.g. purchase, to attain the objectives? <written review meeting minutes>, <list of attendees at review meeting>, < quality objectives>		
1.1.3	From the corporate policy, the quality and food safety objectives shall be communicated to the employees in the respective departments and shall be effectively implemented.	• What quality objectives are defined? • Are these objectives known by concerned employees? • What tools are used to measure that the objectives have been attained? <list of attendees at review meeting>, <mailing list of review meeting minutes>, <posters showing the different department objectives>		
1.1.4	The senior management shall ensure that the achievement of all objectives is regularly reviewed, as a minimum at least once a year.	• When is objective achievement reviewed? • How often is this review performed? <review>, <review minutes>,<internal audit report>	There is basically no review / other rating of objectives available.	Product specific regulations (e.g. 21 CFR 106, 21 CFR 107) 21 CFR 110 Current Good manufacturing practice in manufacturing, packaging or holding human food
1.1.5	All relevant information related to food safety and quality shall be communicated effectively and in a timely manner to the relevant personnel.	• How is relevant information transmitted to concerned persons? <posters>, <distribution of meeting minutes>	A Food Safety and Legality issue occurs due to missing communication within the company.	

1.2	Corporate structure			
1.2.1	An organisation chart shall be available showing the structure of the company.	• Is an organisation chart available? • How is the organisation structured? <Organisation chart>		1.2.8 The responsibility of Quality Assurance Department, and to whom QA Department reports shall be particularly taken into account.
1.2.2	Competences and responsibilities, including deputation of responsibility shall be clearly laid down.	• For which positions do written job descriptions exist? • What is regulated in the job descriptions? • Who, for example substitutes QA manager during his absence? <Responsibility description for important key staff "dedicated to a specific person", e.g. QA Manager, Production Manager, Shift Leader….. >	When a Food Safety and Legality issue occurs due to failure to define responsibilities for existing company regulations.	21 CFR 110.80 21 CFR 120.10
1.2.3	Job descriptions with clearly defined responsibilities shall exist and shall be applicable for employees whose work has an effect on product requirements.	• What is the content of the job descriptions? • For which positions do job descriptions exist?		
1.2.4 KO	**KO n°1: The senior management shall ensure that employees are aware of their responsibilities related to food safety and quality and that mechanisms are in place to monitor the effectiveness of their operation. Such mechanisms shall be clearly identified and documented.**	• How is it ensured that employees know their responsibilities? • How does senior management ensure that employees know their responsibilities? • Who is responsible for food safety?	When senior management does nothing to ensure that employees know their responsibilities. When during the audit the Auditor has evidence that key employees are not aware of their responsibilities and this leads to a Food Safety and/or Legality issue.	
1.2.5	Employees with influence on product requirements shall be aware of their responsibilities, and shall be able to demonstrate their understanding of their responsibilities.	• Interview of at least: QAM, person responsible for labelling, person responsible for product development, person responsible for production, person responsible for monitoring CCP´s	Key employees are not aware of their responsibilities	
1.2.6	The company shall have an IFS representative nominated by senior management.	• Who is the IFS representative? • What are the responsibilities of the IFS representative • Is the function of the IFS representative clearly laid down? <job description>, <Organigram>	No IFS representative exists.	
1.2.7	The senior management shall provide sufficient and relevant resources to meet the product requirements.	• How were the necessary resources defined? <budget plan>	When senior management doesn´t provide enough resources and this leads to a Food Safety and/or Legality issue.	
1.2.8	The department responsible for quality and food safety management shall have a direct reporting relationship to the senior management.	• Who is the QMD manager? • To whom does the QMD manager report? <job description>, <Organigramm>		1.2.1

1.2.9	The company shall ensure that all processes (documented and undocumented) are known by the relevant personnel and are applied consistently.	• What criteria are used to ensure process control? • What is done to ensure that processes are known to relevant personnel (incl. permanent staff and temporary/ seasonal workers)? Processes can be understood as ISO processes (see also chapter 2.3, Part 1 of the standard)	When key personnel have no process knowledge and this leads to a Food Safety and/or Legality issue.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.80 Processes and controls
1.2.10	The company shall have a system in place to ensure that it is kept informed of all relevant legislation on food safety and quality issues, scientific and technical developments and industry codes of practice.	• How does management ensure that all relevant food safety laws are in place and known? E.g. • How does management ensure that purchased products comply with all relevant legislation? • How does management ensure that manufactured products comply with all relevant legislation? <food laws subscription>, < training>	When absence of legal knowledge and information on relevant laws lead to a Food Safety and/or Legality issue.	178-2002-EU (General Food Directive) 852-2004-EU (General Food Hygiene) 853-2004-EU (animal related food directive) 854-2004-EU (Regulatory Authorities) 1998-83-EU (Drinking Water) 2073-2005-EU (Food Safety Criteria) 1441/2007 (microbiological criteria for foodstuffs) 1935-2004-EU (General Packaging Directive) 10/2011-EU (Plastic Food contact Materials) 2023-2006-EU (GMP for Food Packaging Producers) 90/496/EEC (Labelling) 2008/100/EC (Labelling) 2008/5/EG (Labelling) 2000-13-EU (Labelling+Allergens) 68/2007/EC (Allergens) 2003/83 (Allergens) 1924-2006-EU (Health Claims) 1829-2003-EU (GMO) 1830-2003-EU (GMO) 2001-95-EU (General Product Safety) 37/2005 (Temperature controll) 1881-2006-EU (Contaminants) 37/2010 (pharmacologically active substances) 1925/2006 (addition of vitamins and minerals and other substances) 1331/200 (foods additives, enzymes and flavourings) 1332/200 (food enzymes) 1333/200 (food additives) 1334/200 (food flavourings) General: 21 CFR Food is mentioned mostly in Part: 1 – 190 Product specific regulations: 21 CFR Part: 105, 106, 107, 111, 113, 114, 115, 119, 123, 129, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160,

				161, 163, 164, 165, 166, 168, 169, (Animal Food: 21 CFR Part: 500 – 589) See: http://www.fda.gov/ Food Allergen Labeling and Consumer Protection Act of 2004 (Title II of Public Law 108-282) Different Allergens in US and EU Important: 21 CFR 189 Substances prohibited from use in human food.
1.2.11	The company shall inform its customers, as soon as possible, of any issue related to product specification, in particular of all non-conformity(ies) identified by competent authorities related to products which could have, has or has had a defined impact on safety and/ or legality of respective products. This could include, but are not limited to cautionary issues.	For example, if Regulatory Bodies come to the company and identify that something is wrong (related to legality/quality/safety) on a private label product, the company shall inform the relevant customer accordingly. If this product is also manufactured for other customers and if the identified deviation/non-conformity also has an impact on the other private labels, the company shall also inform these other relevant customers.		FSMA Title II Sec 211, Sec. 204 Title 1 Sec 103 a-g
1.3	**Customer focus**			
1.3.1	A documented procedure shall be in place to identify fundamental needs and expectations of customers.	• How are customer needs and expectations identified? • How often are these identified? <questionnaire/survey regarding customers' needs and expectations>		
1.3.2	The results of this procedure shall be evaluated and considered to determine quality and food safety objectives.	• What were the results of the last customer survey? <analysis of customer surveys> • How these results were evaluated regarding quality objectives? <quality objectives> • Have identified needs influence on the production process? <survey analyses>		
1.4	**Management review**			
1.4.1	Senior management shall ensure that the quality and food safety management systems are reviewed at least annually or more frequently if changes occur. Such reviews shall contain, at least, results of audits, customer feedbacks, process compliance and product conformity, status of preventive and corrective actions, follow up actions from previous management reviews, changes that could affect the food safety and quality management systems and recommendations for improvement.	• when is the quality management system reviewed and evaluated? • How often was the system reviewed last year? • What was the result of the review? <review report> • Does the management review take into consideration, as a minimum, the assessment of the following: - documents from the previous management review, - results from internal and external audits, as well as inspections, - performance indicators for customers, complaints and withdras/recalls,	When the quality management system is not reviewed regularly and there is no assurance that it works properly	Title 1 Sec 418 a-e

		- incidents, corrective actions, results out of specifications and non confomring materials, - process performance and product compliance, - review of HACCP system and changes which may affect quality and food safety system, - evolutions of scientific information related to products, - improvement of quality system efficiency anf production process, - improvement of product, related to customer requirements, - needs in ressources (including investments)?		
1.4.2	This review shall include the evaluation of measures for the control of the quality and food safety management system and for the continuous improvement process.	Based on the review result, have any actions for improvement been taken? <improvement actions>		
1.4.3	The company shall identify and review regularly (e.g. by internal audits or on-site inspection) the infrastructure needed to achieve conformity to product requirements. This shall include, as a minimum, the following: - buildings - supply systems - machines and equipment - transport. The results of the review shall be considered, with due consideration to risk, for investment planning.	• When is infrastructure (building, machinery, transport) evaluated? • What was the result of infrastructure evaluation? <audit report> • Who evaluated infrastructure? • What were the results of the infrastructure assessment? <corrective actions> <investment plan> • Were the results used for further infrastructure planning? <investment plan> • What risks were identified according to the results of infrastructure assessment? <risk analysis> • What are infrastructure related investments for the near future? <investment plan>	When infrastructure is not evaluated and therefore a risk for legality, safety and quality of products occurs	Internal audits 5.1.1 On site inspections 5.11.2 FSMA Sec 307
1.4.4	The company shall identify and review regularly (e.g. by internal audits or on-site inspection) the work environment needed to achieve conformity to product requirements. This shall include, as a minimum the following: - staff facilities - environmental conditions - hygienic conditions - workplace design - external influences (e.g. noise, vibration). The results of the review shall be considered, with due consideration to risk for investment planning.	• When is the work environment (staff facilities, environmental conditions, safety and security at work, hygienic conditions, workplace design etc.) evaluated? • What was the result of work environment evaluation? <audit report> • Who evaluated work environment? • What were the results of the work environment assessment? <corrective actions> <investment plan> • Were the results used for further work environment planning? <investment plan> • What risks were identified according to the results of the work environment assessment? <risk analysis> • What are work environment related investments for the near future? <investment plan>	When work environment is not evaluated and therefore a risk for legality, safety and quality of products occurs	Internal audits 5.1.1 On site inspections 5.11.2 FSMA Sec 307

2.	**Quality and Food Safety Management System**			
2.1	**Quality management**			
2.1.1	**Documentation requirements**			FSMA Titel I Sec 103
2.1.1.1	The system for food safety and quality management shall be documented and implemented, and shall be retained in one location (food safety and quality manual or electronic documented system).	• Where is documentation concerning the quality system for quality assurance and food safety retained? <procedure for document control>	When there is no quality system for quality assurance and food safety in place	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food (111 for dietary supplements) 110.110 Natural or unavoidable defects in food for human use that present no health hazard. FSMA Titel I Sec 103
2.1.1.2	A documented procedure shall exist for the control of documents and their amendments.	• What rules exist regarding document control? • Do the documents have an identification code? • How is the identification code structured? • How can a revision be identified? • Who is responsible for changes <procedure for documents>	When documents do not state clearly which exist, are in use and valid.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food (111 for dietary supplements) 120.7 Hazard Analysis
2.1.1.3	All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times.	• Are all documents legible? • Are the documents unambiguous? • Are the documents available at the right places? Also after office hours? • How do relevant employees have access to documents? • How are document changes communicated to relevant employees? • Are there any distribution lists for documents? <Examples>, <procedure>, <distribution lists>	When documents are unavailable and this endangers legality, safety or quality of the product.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food (111 for dietary supplements) 120.7 Hazard Analysis
2.1.1.4	All documents which are necessary for compliance with the product requirements shall be available in their latest version.	• How is document validity identified? • How is it ensured that only valid documents are in circulation?	When void/obsolete or out-of date documents are not identified as such and thus endanger legality, safety or quality.	Regulation 852/2004 Art. 5, para. 4 b
2.1.1.5	The reason for any amendments to documents critical for the product requirements shall be recorded.	• Are the reasons for any amendments to documents, critical for the product requirements recorded? <examples>		
2.1.2	**Record keeping**			
2.1.2.1	All relevant records necessary for the product requirements shall be complete, detailed and maintained and shall be available on request.	• What records exist? • Are the records complete? • Are the records available?	When insufficient or no records are made and thus endanger legality, safety or quality.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food (111 for dietary supplements) 120.13 Hazard Analysis
2.1.2.2	Records shall be legible and genuine. They shall be maintained in a way that subsequent manipulation of records is prohibited.	• Are records plausible? • Are records legible? • What kind of assurance is given that records cannot be subsequently manipulated? • Are the records reviewed by a supervisor?	When records are illegible and therefore no evidence exists for legally required checks/inspections	

2.1.2.3	All records shall be kept in accordance with legal requirements and for a minimum of one year after the shelf life. For products which have no shelf life, the duration of record keeping shall be justified and this justification shall be documented.	• Where are records stored? • Who stores records? • How long are records kept? On what basis were record storage times defined? • For products with a short shelf- life, was record storage time definition based on risk analysis? <procedure documents>, <risk analysis>	When records are not stored in accordance to legal requirements	Risk analysis Regulation 852/2004 Art. 5, para. 4 c and para. 5
2.1.2.4	Any amendments to records shall only be carried out by authorised persons.	• How are amendments to records carried out? • Who is authorized to make amendments? • How are amendments authorized?	When a general problem exists regarding record changes/amendments in the company	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils FSMA Title I Sec 101, 103, 111, Title II Sec 204
2.1.2.5	Records shall be securely stored and easily accessible.	This requirement has been added in order to comply with GFSI Guidance Document version 6.		21 CFR Part: 120 – Hazard Analysis and Critical Control Point (HACCP) system FSMA Title I Sec 112 120.07 Hazard Analysis
2.2	**Food safety Management**			21 CFR Part: 120 – Hazard Analysis and Critical Control Point (HACCP) system 120.07 Hazard Analysis
2.2.1	**HACCP system**			21 CFR Part: 120 – Hazard Analysis and Critical Control Point (HACCP) system 120.07 Hazard Analysis
2.2.1.1	The basis of the company's food safety control system shall be a fully implemented, systematic and comprehensive HACCP system, based upon the Codex Alimentarius principles. It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The HACCP system shall be implemented at each production site.	• The company's HACCP plan is based on what principles? • Has every site/plant a separate HACCP plan? • Which specific regulations are taken care of in HACCP plan? <HACCP plan> • are the legal requirements of the destination country are known, especially the labeling regulation?	If there is no HACCP plan. If legal requirements are not included in HACCP plan If there is no HACCP plan for each individual site/plant	Regulation 852/2004 Article 5 No. 1 - 3
2.2.1.2	The HACCP system shall cover all raw materials, products or product groups as well as every process from goods into dispatch, including product development and product packaging.	• Does HACCP plan cover all product groups and processes incl. product development and product packaging? • Which processes are performed? <product group overview>, <flow chart> • are processes for DEL-Products available?	When the HACCP plan does not cover all product groups and processes	Regulation 852/2004 Article 5 No. 1 - 3 21 CFR Part: 120 – Hazard Analysis and Critical Control Point (HACCP) system FSMA Title I Sec 112 120.07 Hazard Analysis
2.2.1.3	The company shall ensure that the HACCP system is based upon scientific literature, or technical verified specifications relating to the manufactured products and procedures. This shall be maintained in line with new technical process development.	• Is the HACCP plan based upon scientific literature or technically verified specifications relating to the manufactured products and procedures? • How are new technical developments taken care of? <references of used literature, etc.> • Does the HACCP system meet all applicable regulatory requirements of the country in which it is established, including the required and applicable risk assessments and supporting documentation? (Where applicable, such regulatory requirements will supercede requirements of the standard. Related to Canadian and US law, certain	When HACCP plan is not based on scientific literature or technically verified data about products and processes and therefore causes a food safety or legality risk.	21 CFR Part: 120 – Hazard Analysis and Critical Control Point (HACCP) system 120.07 Hazard Analysis

		forms and formats are required.)		
2.2.1.4	HACCP system shall be reviewed and necessary changes shall be made when any modification is made in the product, process or any step.	The update of HACCP system was missing in IFS Food version 5, therefore it has been added in version 6.		21 CFR Part: 120 – Hazard Analysis and Critical Control Point (HACCP) system 120.07 Hazard Analysis
2.2.2	**HACCP team**			
2.2.2.1	**Assemble HACCP team (CA Step 1)** The HACCP team shall be multidisciplinary and include operational staff. Personnel appointed as HACCP team members shall have specific knowledge of HACCP, product and process knowledge and the associated hazards. Where competent knowledge is not available, external expert advice shall be obtained.	• Who is member of the HACCP team? • Which departments/functions are included in the HACCP team? • How was qualification for HACCP team membership verified? <evidences for education, advanced training> • What hazards are connected to the product? • Does a contract exist with an external expert? <service contract>	Although there is a lack of product knowledge no external expert has been consulted and this results in food safety and legality risk.	2.2.2.2 21 CFR Part: 120 – Hazard Analysis and Critical Control Point (HACCP) system 120.08 HACCP Plan
2.2.2.2	Those responsible for the development and maintenance of the HACCP system shall have an internal team leader and shall have received adequate training in the application of the HACCP principles.	• What is the content of a HACCP training course? <HACCP training proofs> • When was the last HACCP training course held? <training proofs> • Who participated in the HACCP training course? <training proofs>		2.2.2.1 Regulation 852/2004 Annex 2 chapter XII
2.2.2.3	The HACCP team shall have strong senior management support and shall be well known and established across the whole facility.	• Who is member of the HACCP team? • Is the team well known across the company? How was it announced? <job descriptions>, <team matrix>, <blackboard notice> <presence of management in any HACCP brief> <result of HACCP rewiew include in Management review> <Attribution of resources>	When no HACCP team exists or no person has been appointed HACCP team leader	
2.2.3	**HACCP analysis**			
2.2.3.1	**Describe product (CA Step 2)** A full description of the product including all relevant information on product safety exists such as: - composition - physical, organoleptic, chemical and microbiological parameters - legal requirements for the food safety of the product - methods of treatment - packaging - durability (shelf life) - conditions for storage, method of transport and distribution.	• Does a complete product description exist for each product? • What is included in the product description? <product description> <product specification>	When there are no product descriptions for each product. When product descriptions do not provide essential product data. When essential information does not match legislation (e.g. microbilogical test values).	Regulation 852/2004
2.2.3.2	**Identify intended use (CA Step 3)** The intended use of the product shall be described in relation to the expected use of the product by the end consumer, taking into account vulnerable groups of consumers.	• What is the intended use of the product? • The product is unsuitable for which consumer group? • Is the product suitable for children, pregnant women, senior persons? <product description>	When there is a food safety risk for consumers due to lack of definition for whom the product is suitable/unsuitable.	Regulation 852/2004
2.2.3.3	**Construct flow diagram (CA Step 4)** A flow diagram shall exist for each product, or product	• Are flow charts available for all products? • Are the flow charts dated?	Flow charts are unavailable for any of the products,	Regulation 852/2004 21 CFR Part: 120 – Hazard Analysis and

	group, and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall be dated, and clearly identify each CCP with the number assigned to it. In the event of any changes the flow diagram shall be updated.	• Are all CCP's identified on the flow chart? • Have all CCP's a number? • Are all flow charts with CCP's up-to date? <flow charts for all products>	charts or are not conform to the specifications	Critical Control Point (HACCP) system 120.10 Corrective actions 5.11.2 FSMA Title I Sec 418 e
2.2.3.4	**On-site confirmation of the flow diagram (CA Step 5)** The HACCP team shall verify the flow diagram, by on-site checks, at all operation stages. Amendments to the diagram shall be made, where appropriate.	• Was the flow chart confirmed during a HACCP meeting? <meeting minutes>	When flow charts are not validated	Regulation 852/2004 21 CFR Part: 120 – Hazard Analysis and Critical Control Point (HACCP) system 120.11 Process validation 5.3 FSMA Title I Sec 418 f
2.2.3.5	**Conduct a hazard analysis for each step (CA Step 6 – Principle 1)**			21 CFR Part: 120 – Hazard Analysis and Critical Control Point (HACCP) system 120.12 Records FSMA Title I Sec 418 g
2.2.3.5.1	A hazard analysis shall be available for all physical, chemical and biological hazards, including allergens, which may reasonably be expected.	• Does a hazard analysis exist for each step? <hazard analysis> • Does it include every hazard? • Which biological, physical and chemical hazards can be expected? <hazard analysis>	When a hazard analysis was not performed for each step. When hazards were not properly assessed or not all significant hazards were taken into account and a safety issue exists.	Regulation 852/2004 Art. 5, para. 2 a Directive 68/2007/EC Annex 3
2.2.3.5.2	The hazard analysis shall consider the likely occurrence of hazards and severity of their adverse health effects.	• Does a risk analysis for all product groups including harm and likelihood exist? <risk analysis>	When, due to lack of a risk analysis, a safety risk exists.	
2.2.3.6	**Determine critical control points (CA Step 7 – Principle 2)**			
2.2.3.6.1	The determination of relevant critical control points (CCP's) shall be facilitated by the application of a decision tree or other tool(s), which demonstrates a logical reasoned approach.	• Which CCPs were defined? • How many CCPs exist • On the defined CCPs, can the process be influenced in order to prevent, eliminate or reduce a food safety hazard? <hazard analysis> <flow chart>, <HACCP plan>, <decision tree>	When CCPs were not identified as such and/or they are not under permanent control so that a safety risk exists.	Regulation 852/2004 Art. 5, para. 2 b
2.2.3.6.2	For all steps which are important for food safety, but which are not CCP's, the company shall implement and document control points (CP's). Appropriate control measures shall be implemented.	• Which CPs are defind? • Which prerequisite measures were taken regarding CPs? • Which prerequisite measures are documented? • How are the measures documented? <hazard analysis> <flow chart> <decision tree> <prerequisite measures>	When, due to missing prerequisite measures not all CPs are covered and this leads to a safety risk	Regulation 852/2004 Art. 5 21 CFR 11 Electronic Records, Electronic Signatures
2.2.3.7	**Establish critical limits for each CCP (CA Step 8 – Principle 3)** For each CCP, the appropriate critical limits shall be defined and validated in order to clearly identify when a process is out of control.	• Is a critical limit defined for each CCP? • What critical limits are defined? • How were the critical limits determined? <HACCP plan>	When there are no critical limits for each CCP or they are insufficient and this causes a safety risk.	Regulation 852/2004 Art. 5, para. 2 c 21 CFR 11 and product specific regulations 21 CFR 7 Enforcement policy
2.2.3.8	**Establish a monitoring system for each CCP (CA**			

	Step 9 – Principle 4)			
2.2.3.8.1 KO	**KO N° 2: Specific monitoring procedures shall be established for each CCP to detect any loss of control at that CCP. Records of monitoring shall be maintained for a relevant period. Each defined CCP shall be under control. Monitoring and control of each CCP shall be demonstrated by records. The records shall specify the person responsible as well as the date and result of the monitoring activities.**	• How are CCPs monitored? • Are the CCPs under control? • How is the monitoring of each CCP documented? • Who documents? • Are date, time, responsible employee and result/reading documented? • How long will records be stored? • Where are records stored? <CCP records>	If CCPs are not monitored and the measurements are not documented If company is unaware of loss of control at a CCP If records don't clarify who, when and where a measure is done or with what results If records are not stored for an adequate time period	Regulation 852/2004 Art. 5, para. 2 d
2.2.3.8.2	The operative personnel in charge of the monitoring of CCP's shall have received specific training/ instruction.			21 CFR 11 Electronic Records, Electronic Signatures FSMA Title I Sec 418 h
2.2.3.8.3	Records of CCP's monitoring shall be checked.			
2.2.3.8.4	The CP's shall be monitored and this monitoring shall be recorded.	Management of CP's has been added, in order to align with ISO 22000		21 CFR 11 and product specific regulations Risk analysis
2.2.3.9	**Establish corrective actions (CA Step 10 – Principle 5)** In the event that the monitoring indicates that a particular CCP or CP is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any non-conforming products.	• What corrective actions exist for each CCP? • When was a corrective action carried out? • Where are corrective actions documented? • Who documents the taken corrective actions? <CCP records> <corrective actions> Monitoring shall be understood as defined in Codex Alimentarius (The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control). This is enlarged to CP as well in IFS.	When there are no corrective actions defined or no corrective actions are taken. When corrective actions are not documented.	5.11.2 Regulation 852/2004 Art. 5, para. 2 e
2.2.3.10	Establish verification procedures (CA Step 11 – Principle 6) Procedures of verification shall be established to confirm that the HACCP system is effective. Verification of the HACCP system shall be performed at least once a year. Examples of verification activities include: - internal audits - analysis - sampling - evaluations - complaint by authorities and customers. The results of this verification shall be incorporated into the HACCP system.	• How often is the HACCP plan verified? • What was the date of the last verification? • What was the result of the last verification? • Does the HACCP plan reflect the results of the verification? • What was the last date when the HACCP plan was changed? <audit reports or other reports for validation>	When no verification was carried out and this leads to a safety risk.	5.6.1 Regulation 852/2004 Art. 5, para. 2 f FSMA Title 1 Sec 418 h
2.2.3.11	**Establish documentation and record keeping (CA Step 12 – Principle 7)** Documentation shall be available covering all	• What HACCP plan related documents exist? • Do these documents include processes, procedures and results?	When HACCP plan is not sufficiently documented and this leads to a legality	Regulation 852/2004 Art. 5, para. 2 g

	processes, procedures, control measures and records. Documentation and record keeping shall be appropriate to the nature and size of the company.	<inspection plans>, <records>, <product descriptions>, <hazard analysis>, <risk analysis>	issue	
3.	**Resource Management**			
3.1	**Human resources management**			
3.1.1	All personnel performing work that affects product safety, legality and quality shall have the required competence by education, work experience and/ or training, commensurate with their role, based on hazard analysis and assessment of associated risks.	• How is it assured that new employees have the right capabilities for the job?	When, due to lack of education, experience or training the legality or safety of the product is jeopardized	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel HACCP team, IFS manager, pest controller, cleaning & sanitation, maintenance
3.2	**Human resources**			
3.2.1	**Personnel hygiene**			
3.2.1.1	There shall be documented requirements relating to personnel hygiene. These include, as a minimum, the following fields: - protective clothing - hand washing and disinfection - eating and drinking - smoking - actions to be taken in case of cuts or skin abrasions - fingernails, jewellery and personal belongings - hair and beards. The requirements shall be based on hazard analysis and assessment of associated risks in relation to product and process.	• What is the policy regarding personal hygiene? <hygiene rules for employees> • The rules regarding personnel hygiene include hand cleaning, food and beverages, smoking, handling of injuries, finger nails and jewellery, hair and beards? • Are the rules based on a risk analysis? <risk analysis> • Where is it allowed to smoke? • How should lesions be treated/covered? • What kinds of hair restraints are needed in which areas? Example of result from the hazard analysis and assessment of associated risks: if gloves are used, then hand disinfection is not required for low risk production.	When insufficient rules for personal hygiene cause a safety risk. When no correspondent risk analysis exists.	Risk analysis 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel
3.2.1.2 KO	**KO N° 3: The requirements for personnel hygiene shall be in place and applied by all relevant personnel, contractors and visitors.**	• How is the hygiene policy communicated? <hygiene rules for employees> • Are personnel hygiene rules also followed by external service providers/workmen and visitors? <hygiene rules for visitors> • How is it assured that external persons know the relevant hygiene rules? <hygiene rules for visitors> • How are employees monitored during work? <hand swab tests, etc.> • Is employee compliance to hygiene rules checked on a regular basis? <minutes site inspection>, <list of identified failures>, etc.	When, during the audit major violations of the rules are identified that lead to a safety risk.	
3.2.1.3	Compliance with personnel hygiene requirements shall be checked regularly.	This requirement was formerly part of the KO requirement in version 5 and has been placed in an individual requirement in version 6.		21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel
3.2.1.4	Visible jewellery (incl. piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated by hazard analysis and	• Is it allowed to use jewellery and watches in production areas? <personnel hygiene rules> • Is allowance based on risk hazard analysis?	When wearing jewellery or a watch causes a food or employee safety risk.	Risk analysis 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing,

	assessment of associated risks in relation to product and process. This shall be effectively managed.	<risk analysis>		packaging or holding human food 110.10 Personnel
3.2.1.5	Cuts and skin abrasions shall be covered by a coloured plaster/ bandage (different from the product colour) – containing a metal strip, where appropriate – and in case of hand injuries, in addition to a plaster/bandage, a single use glove shall be worn.	• What colour is plaster and where is it used? • Does the plaster contain a metal strip? • What is an employee required to observe in case of hand injury? <personnel hygiene rules>	When hand injuries ensue a product safety risk (e.g. an uncovered purulent wound that comes into contact with the product)	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel
3.2.2	**Protective clothing for personnel, contractors and visitors**			
3.2.2.1	Company procedures shall exist to ensure that all personnel, contractors and visitors are aware of the rules regarding the management of wearing and changing of protective clothing in specified areas in accordance with product requirements.	• What are the rules regarding protective clothing? <personnel hygiene rules> • Are the protective clothing rules based on risk analysis? <risk analysis> • When must protective clothing be changed? <personnel hygiene rules> • examples of areas: catering, changing rooms, smoking area, toilets, high risk areas, etc.	When the lack of protective clothing ensues a product safety risk	Risk analysis 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel
3.2.2.2	In work areas where wearing headgear and/ or beard snood (coverings) is required, the hair shall be covered completely, so that product contamination is prevented.	• In which production areas is wearing of protective headgear and/or beard snood mandatory? • What kind of headgear is used? • How shall headgear be used? <personnel hygiene rules>	When incorrect wearing or absence of headgear and/or bear snood ensues a product safety risk	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel
3.2.2.3	Clearly defined usage rules shall exist for work areas/ activities where it is required to wear gloves (coloured differently from the product colour). Compliance with these rules shall be checked on a regular basis.	• In which production areas is wearing of gloves mandatory? <personnel hygiene rules> • What kinds of gloves are used? When must gloves be changed? • How is the compliance with these rules checked? <glove swab test results > <on site inspections>	When missing or unclean gloves ensue a product safety risk	Check-list 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel
3.2.2.4	Suitable protective clothing shall be available in sufficient quantity for each employee.	• How many protective suits/uniforms are at the disposal of each employee? • How often is an employee supposed to change his/her protective suit/uniform?	When employees do not have protective clothing and therefore a product contamination risk exists	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel
3.2.2.5	All protective clothing shall be thoroughly and regularly laundered. Hazard analysis and assessment of associated risks, together with consideration given to the processes and products of the company shall determine if clothing shall be washed by a contract laundry, on site laundry or by the employee.	• How is protective clothing laundered? <personnel hygiene rules> • Are there any employees who launder their protective clothing at home? • Is protective clothes laundering based on a risk analysis? <risk analysis>	When insufficient laundering ensues a product contamination risk	Risk analysis 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel
3.2.2.6	Guidelines shall exist for laundering of protective clothing and a procedure shall be in place for checking its cleanliness.	• How is the laundering procedure checked for effectiveness? <protective clothes swab test results> • What guidelines exist regarding protective clothes laundering? <personnel hygiene rules>		Check list 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel

3.2.3	**Procedures applicable to infectious diseases**			
3.2.3.1	There shall be written and communicated measures for personnel, contractors and visitors to declare any infectious disease which may have an impact on food safety. In case of declaration of infectious disease, actions shall be taken in order to minimize risk of contamination of products.	• How shall personnel and visitors behave in case or suspicion of an infectious disease? • How is it ensured that personnel and visitors know the guidelines? <personnel hygiene rules> <visitors hygiene rules>	When due to an employee's infectious disease a product safety risk is given and no preventive steps are taken by the company	Infectious disease prevention law chapter VIII of Regulation (EC) n° 852/2004 about personnel hygiene
3.3	**Training and instruction**			21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.10 Personnel A lot of training references are made in the product specific regulations. (e.g. 113.10: 123.10) 21 CFR Part: 120 HACCP System 120.13 Training
3.3.1	The company shall implement documented training and/ or instruction programs with respect to the product requirements and the training needs of the employees based on their job and shall include: - training contents - training frequency - employee's task - languages - qualified trainer/ tutor - evaluation methodology.	• Who is responsible for training? <training proof> • What are the evidences for the trainer's qualification? • What was the content of the last training session? <training program> • How are foreign employees trained/instructed? • Who participates in the training sessions? • How are the instruction necessities for each employee determined? • How often are training sessions held? <training schedule>	When due to lack or insufficient training a product safety or legality risk exists. When legally required food safety instructions are not undertaken	Regulation 852/2004 Annex 2 chapter XII No. 1+3 21 CFR Part: 120 HACCP System 120.13 Training 120.10 Corrective action 2.2.2.1
3.3.2	The documented training and/ or instruction shall apply to all personnel, including seasonal and temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained in accordance with the documented training/instruction programs.	• Are prospective employees (incl. seasonal and temporary workers) trained/instructed upon employment? • Which employees are trained/instructed upon employment? What is the content of these instructions? <training proofs>		Infectious disease prevention law
3.3.3	Records shall be available of all training/instruction events, stating: - list of participants (this shall include their signature) - date - duration - contents of training - name of trainer/ tutor. There shall be a procedure or program in place to prove the effectiveness of the training and/ or instruction programs.	• Which training courses are undertaken? • Are there any special training courses? • Are training courses documented? • What has been documented? • Have participants signed the training proofs? • How often are hygiene training sessions held? • What was the content of the last hygiene training session? <training proofs>	No training proofs exist to confirm that employees were trained/instructed	
3.3.4	The contents of training and/ or instruction shall be reviewed and updated regularly and take into account company's specific issues, food safety, food related legal requirements and product/ process	• How are training contents reviewed? <review test> • When are training contents reviewed? • When was the latest training content update done?	During the on-site audit evidence was given that employees did not act according to knowledge	

	modifications.	• What was the content of the latest update? <audit results> • specific issues: non-conformitites, failure, complaints, etc	transmitted in the training sessions and this lead to a product safety risk	
3.4	**Sanitary facilities, equipment for personnel hygiene and staff facilities**			
3.4.1	The company shall provide staff facilities, which shall be proportional in size, equipped for the number of personnel and designed and operated so as to minimise food safety risks. Such facilities shall be kept in clean and good condition.	• How many employees are there? • Do they have access to a cafeteria? • Are there locker-rooms? • Where are the restrooms? • Are there bathing facilities? <plant lay-out> • Staff facilities = e.g. changing room, smoking area, dining room, etc.	When social facilities are underequipped or are out of proportion to the number of employees so that a safety issue arises	
3.4.2	The risk of product contamination by foreign material from staff facilities shall be evaluated and minimised. Consideration shall also be given to food brought to work by personnel and personal belongings.	• May employees bring food from home? <personnel hygiene rules> • May employees take medicine along to their work place? <personnel hygiene rules> • Does a risk analysis exist regarding foreign bodies from social facilities? <risk analysis>		
3.4.3	There shall be in place rules and facilities to ensure the correct management for personnel belongings and for food brought to work by personnel, food coming from dining room and from vending machines. The food shall only be stored and/ or used in designated areas.			
3.4.4	The company shall provide suitable changing rooms for personnel, contractors and visitors. Where necessary, outdoor clothing and protective clothing shall be stored separately.	• Are there locker-rooms for employees and visitors with separation for outdoor and protective clothing?	When no locker-rooms exist or there is no separation between outdoor and protective clothing although high risk products are being processed	Regulation 852/2004 Annex 2 chapter I No. 9 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.37 Sanitary facilities and controls (additional requirements in the standard)
3.4.5	Toilets shall not have direct access to an area where food products are handled. The toilets shall be equipped with adequate hand washing facilities. Sanitary facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.	• Do toilets open directly into production areas?	When toilet exhaustion poses a contamination risk	Regulation 852/2004 Annex 2 chapter I No. 3+6 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.37 Sanitary facilities and controls 2.2.2.1
3.4.6	Adequate hand hygiene facilities shall be provided at access points to and within production areas, as well as at staff facilities. Based on hazard analysis and assessment of associated risks, further areas (e.g. packaging area) shall be similarly equipped.	• Are there enough hand washing facilities available at the entrance to processing areas and in social areas?	When a contamination problem occurs due to lack of hand washing facilities	Risk analysis Regulation 852/2004 Annex2 chapter I No4 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.37 Sanitary facilities and controls
3.4.7	Hand washing facilities shall provide as a minimum: - running potable water at an appropriate temperature - liquid soap - appropriate equipment for hand drying.	• Are all hand washing facilities provided with appropriate equipment for hand drying, liquid soap and disinfectant? • Are all hand washing facilities provided with running potable water at an appropriate temperature?		Regulation 852/2004 Annex2 chapter I No4 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food

				110.37 Sanitary facilities and controls FSMA Title I Sec 105
3.4.8	Where highly perishable food products are handled, the following additional requirements regarding hand hygiene shall also be provided: - hand contact-free fittings - hand disinfection - adequate hygiene equipments - signage highlighting hand hygiene requirements - waste container with hand contact-free opening.	• Are all areas where highly perishable food products are handled provided with hand contact-free fittings, hand disinfection devices and signs or pictograms? <signs/pictograms>	When a contamination problem occurs due to lack of appropriate hand washing facilities	
3.4.9	Based on hazard analysis and assessment of associated risks, there shall be a program to control effectiveness of hand hygiene.			
3.4.10	Changing rooms shall be situated so that they allow direct access to the areas where food products are handled. Based on hazard analysis and assessment of associated risks, exceptions shall be justified and managed.	• Are there cleaning facilities for boots and protective aprons? • Do locker-rooms give direct access to processing areas? • How is protective clothing handled during breaks/intervals? <personnel hygiene rules> • Does a risk analysis exist for locker-rooms with no direct access to processing areas? <risk analysis>	When a contamination occurs due to locker-room location which leads to food product safety problem	Risk analysis
3.4.11	Where the hazard analysis and assessment of associated risks show the necessity, cleaning facilities shall be available and used for boots, shoes and further protective clothing.			
4.	**Planning and Production Process**			
4.1	**Contract agreement**			
4.1.1	The requirements which are defined between the contract partners shall be established, agreed upon and reviewed concerning their acceptability before a supply agreement is concluded. All clauses related to quality and food safety shall be known and communicated to each relevant department.	• What assurances are given that customer requirements and own specifications are in accordance with each other? • Do written supply agreements with customers exist? • Do specific customer requirements for purchased products exist? • Who checks and approves specifications? • Who ensures that the proper raw materials are available whenever needed?	When there are no approved specifications and no clarity exists if required product can be delivered.	Specifications
4.1.2	Changes of existing contractual agreements shall be documented and communicated between the contract partners.	• How is it ensured that customers are informed about product changes? • Who checks and approves specifications?		
4.2	**Specifications and formulas**			
4.2.1	**Specifications**			
4.2.1.1	Specifications shall be available and in place for all finished products. They shall be up to date, unambiguous and be in compliance with legal and customer requirements.	• How are specifications compiled, checked and approved? • Are there specifications for all final products? • How are up to date specifications recognizable?	When not all specifications for final products are up to date and in conformance with legal requirements	2.2.3.1 Statements given in Regulation 2008/5/EC to be included on labels of certain foodstuffs in addition to those given in

		<specifications>		Directive 2000/13/EC Guidelines for foodstuffs Regulation (EC) N°1925/2006 on the addition of vitamins and minerals and of certain other substances 21 CFR 189 Substances prohibited from use in human food. 21 CFR 182 Substances generally recognized as safe 21 CFR 185 Direct food substances affirmed as generally recognized as safe (GRAS) 21 CFR 186 Indirect food substances affirmed as generally recognized as safe 21 CFR 101 Food labeling 21 CFR 130 Food Standards: General
4.2.1.2 KO	**KO N° 4: Specifications shall be available and in place for all raw materials (raw materials/ ingredients, additives, packaging materials, rework). Specifications shall be up to date, unambiguous and be in compliance with legal requirements and, if existing, with customer requirements.**	• Are specifications available for all raw materials, ingredients, additives, packaging materials and rework? • What assurance is given that specifications are followed? <proof of specification compliance, e.g. lab results> • What assurance is given that specifications are in conformance with legal requirements? • Who writes, checks and approves specifications?	When not all raw materials, ingredients, additives, packaging materials and rework have specifications. When specifications do not comply with legal requirements.	
4.2.1.3	Where required by customers, product specifications shall be formally agreed.			
4.2.1.4	Specifications and/ or their contents shall be provided in the relevant location and accessible to all relevant personnel.	• Who has access to specifications?	When key employees do not have access to specifications and a product safety and/or legal requirement issue ensues.	2.1.1.2
4.2.1.5	There shall be a procedure for the creation, the modification and approval of specifications for all parts of the process, which shall include the preliminary acceptance of the customer, if specifications have been agreed with customers.	• Who writes, amends, checks and approves specifications?	When specifications are used but have not been properly approved and it is not clear if they can be complied with.	
4.2.1.6	The specification control procedure shall include the update of finished product specification in case of any modification: - of raw material - of formula/ recipe - of process with influence on the final products - of packaging with influence on the final products.			
4.2.2	**Formula/ recipes**			
4.2.2.1	**KO N° 5: Where there are customer agreements in relation to the product formula/ recipe and technological requirements, these shall be complied with.**	• What assurance is given that specified recipe is followed? • How is recipe compliance checked? • If no specific technological requirements and/ or	When there is evidence that recipe and finished product specifications do not fit together.	

		formulas are agreed between the contract partners, the formula of the supplier is the basis. In this case the requirement shall be rated with N/A	When during a traceability test there is evidence that agreed upon recipe is not complied with.	
4.3.	**Product development/ Product modification/ Modification of production processes**	The requirements for product development have to be checked even if there are only product modifications (new ingredient used, changes in packaging) or modifications of production processes.		
4.3.1	A procedure for product development shall be in place which incorporates the hazard analysis principles, in accordance with the HACCP system.	• How are the processing procedures for product development built up? • Do processing procedures for product development also contain a hazard analysis? <hazard analysis>	When no processing procedures were established for product development and a food safety and/or legal issue ensues.	2.2.3.5 Regulation 852/2004 Art. 5 para. 2 last sentence 21 CFR 120 HACCP
4.3.2	Product formulation, manufacturing processes, process parameters and the fulfilment of product requirements shall be established and shall have been assured by factory trials and product testing.	• What do product development procedures look like? <product development procedures> • What tests are made while a product is developed? <test results> • Is developed product submitted to trial runs? <trial run documentation>	When new processing procedures, recipes and product requirements are not ensured by tests and trial runs and enter directly into production and this entails a food safety and/or legality issue which cannot be corrected.	5.6.1.
4.3.3	Shelf life tests or adequate processes shall be carried out and consideration given to product formulation, packaging, manufacturing and declared conditions; “Use by” or “Best before” dates shall be established accordingly.	• How are shelf lives determined? <microbiological tests> • Are products submitted to shelf-life tests? <shelf-life test results>	When no proof for defined shelf-life exists and a safety issue can occur.	Test plan
4.3.4	When establishing and validating the shelf life of the product (including long shelf life product i.e. labelled with a “best before date”), the results of organoleptic tests shall also be taken into account.	• Are organoleptic test results considered for shel life determinations?		FSMA Title III Sec 309
4.3.5	Product development shall consider the results of organoleptic assessments.	• How often are organoleptic tests made? • Who participates in organoleptic tests? • Are organoleptic tests documented? • How are the results from organoleptic tests taken into consideration during product development? <organoleptic test results evaluation>		
4.3.6	A process shall be in place to ensure that labelling complies with current legislation of destination country and customer requirements.	• Export goes to which countries? Which countries have special requirements? • Who issues the labels? • Who approves labels? • How is conformity of the product and label reviewed?	Product and labelling are not in conformity with each other, thus creating a legality problem.	Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs Directive 90/496/EEC on Nutrition Labelling for Foodstuffs Directive 2008/100/EC amending Council Directive 90/496/EEC on nutrition labelling for foodstuffs as recommended daily allowances Regulation (EC) N°1924/2006 on nutrition and health

				claims made on foods
4.3.7	Recommendations for preparation and/ or use of the food products shall be established. Where appropriate, customer requirements shall be included.	• How are preparation recommendations and/or product use established? • How are consumer requirements taken into consideration during product development? <example>	When a safety issue ensues due to wrong or lack of preparation recommendations and/or product use. (e.g. recommendation to heat packed product in microwave oven but no according test results are available; frying/cooking times are too short so that for example broilers are not properly done)	Directive 2000/13 relating to the labelling, presentation and advertising of foodstuffs Article 3 No. 9 and Article 11 21 CFR Part: 101, 102, 104 (Color additive 21 CFR Part: 70, 71, 80, 81, 82)
4.3.8	The company shall demonstrate through studies and/ or perform relevant tests in order to validate nutritional information or claims which are mentioned on labelling. This applies both for a new product and during all its period of sale.			FSMA Title I Sec 113
4.3.9	The progress and results of product development shall be properly recorded.	• Are all steps and test results for product development properly recorded? <product development documentation>	When steps and results from product development are not reproducible due to lack of documentation	
4.3.10	The company shall ensure that in the event of changes to product formulation, including rework and packaging material, process characteristics are reviewed in order to assure that product requirements are complied with.	• Who reviews and ensures that specifications are met in the event of recipe or processing changes?	When it is not sure if a safety or legality issue occurs due to applied changes.	
4.4	**Purchasing**			21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food Subpart B Production and Process control
4.4.1	**General purchasing**			
4.4.1.1	The company shall control purchasing processes to ensure that all externally sourced materials and services, which have an impact on food safety and quality, conform to requirements. Where a company chooses to outsource any process that may have an impact on food safety and quality, the company shall ensure control over such processes. Control of such outsourced processes shall be identified and documented within the food safety and quality management system.	• How is it ensured that purchased products and services conform to specifications?	When purchased products do not conform to specifications and thus entail a safety or legality problem	4.2.1.1 Procedures regarding mandatory veterinary controls during the import or transport of foodstuffs of animal origin from third countries as well as the import of other third country foodstuffs Regulation 852/2004 Articel 10 21 CFR 189 Substances prohibited from use in human food. 21 CFR 182 Substances generally recognized as safe 21 CFR 185 Direct food substances affirmed as generally recognized as safe (GRAS)

				21 CFR 186 Indirect food substances affirmed as generally recognized as safe 21 CFR 101 Food labelling 21 CFR 130 Food Standards: General
4.4.1.2	There shall be a procedure for approval and monitoring of suppliers (internal and external), outsourced production or part of it.	• Does an approval procedure exist for new suppliers and co-packers? <supplier procedures> • How are supplies monitored? • Are suppliers graded? <supplier grading systems> • Have suppliers been barred? • How is a barred supplier identified? • How is the qualification of suppliers ensured? <product entry monitoring> <supplier audits> <lab tests> • Are there any co-packers? <co-packers list> • How are co-packers monitored? • Are co-packers IFS certified? <certificate>	When there are no approval procedures for suppliers and this ensues a safety risk	
4.4.1.3	The approval and monitoring procedure shall contain clear assessment criteria such as: audits, certificates of analysis, supplier reliability and complaints, as well as required performance standards.	• How often are external audits made? <external audit plan> • Which criteria are consulted for supplier assessment? • Which supplier has analysis certificates? <analysis certificates> • How was the risk analysis for supplier approval performed? <risk analysis>	No risk analysis was made	Risk analysis
4.4.1.4	The results of suppliers' assessments shall be reviewed regularly and this review shall be based on hazard analysis and assessment of associated risks. There shall be records of the reviews and of the actions taken as a consequence of assessment.	• Who reviews the results of supplier assessments? • How often are the results of supplier assessments reviewed? • What actions are taken after reviewal of the results for supplier assessments? <audit results>	When the results for supplier assessment are not taken into account and this ensues a safety or legality issue	
4.4.1.5	The purchased products shall be checked in accordance with the existing specifications and their authenticity. The schedule of these checks shall, as a minimum, take into account the following criteria; product requirements, supplier status (according to its assessment) and impact of the purchased products on the finished product. The origin shall be additionally checked, if mentioned in the specification.	• How are purchased products and their specifications reviewed? <incoming product check-list> <lab tests> • Does a test schedule exist? <test schedule>	When purchased products are never checked on compliance with specifications	Test schedule
4.4.1.6	The purchased services shall be checked in accordance with the existing specifications. The schedule of these checks shall at least take into account the following items: service requirements, supplier status (according to its assessment) and impact of the service on the finished product.			
4.4.2	**Trade of manufactured goods**	Mean purchased products, which have been already processed and which are bought and stored on-site of		

		the audited company. The suppliers of these products shall also be IFS certified.		
4.4.2.1	In case a company trades manufactured goods, it shall be ensured that a process for approving and monitoring suppliers exists and is implemented.	If the company trades manufactured goods as finished products, the suppliers of these purchased products shall itself be IFS Food certified and specific requirements of this audit check-list related to purchased products shall be audited. Trade products shall be clearly identified on the IFS certificate, precising the product scopes. If this is not the case, those products shall be excluded from the certificate. Mandatory field in the company profile: specify if the company has trade products.		FSMA Title II Sec 204
4.4.2.2	In case of traded manufactured goods, the process for approving and monitoring suppliers shall contain clear assessment criteria such as: audits, certificates of analysis, supplier reliability, complaints as well as required performance standards.			FSMA Title II Sec 204
4.4.2.3	In case of private labels, a supplier approval system in accordance with customer requirements shall exist for pre-suppliers of finished or semi-finished products.			FSMA Title II Sec 204
4.5	**Product packaging**			
4.5.1	Based on hazard analysis, assessment of associated risks and intended use, the company shall determine the key parameters for the packaging material.	• Does a risk assessment also exist for packaging material not in direct food contact, to prove the evidence of direct negative influence on the product?		
4.5.2	Detailed specifications shall exist for all packaging materials which comply with the current relevant legislation.	• How is it ensured that packaging material complies with current relevant legislation? • Who develops, reviews new packaging material? • Are specifications available for all packaging materials used? <packaging material specifications>	Packaging material that does not comply with legislation. Not all packaging materials have specifications	www.foodcontactmaterials.com VO 1935/2004 (General Packaging Directive) VO 10/2011 (Plastic Food contact materials) VO 2023/2006 (GMP for Food packaging)
4.5.3	For all packaging material which could have an influence on products, certificates of conformity shall exist which comply with current legal requirements. In the event that no specific legal requirements are applicable, evidence shall be available to demonstrate that packaging material is suitable for use. This applies for packaging material which could have an influence on raw materials, semi-processed and finished products.			
4.5.4	Based on hazard analysis and assessment of associated risks, the company shall verify the suitability of the packaging material for each relevant product (e.g. organoleptic tests, storage tests, chemical analysis, migration tests).	• How is it ensured that packaging materials have no negative effects on the product? • Has a risk analysis been performed in relation to suitability of packaging material? <risk analysis>	No risk analysis was made.	Risk analysis 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils

4.5.5	The company shall ensure that the packaging used corresponds to the product being packed. The use of correct packaging shall be regularly checked and checks shall be documented.			
4.5.6	Labelling information shall be legible indelible and shall comply with agreed customer product specifications. This shall be regularly checked and checks shall be documented.			
4.6.	**Factory location**			21 CFR Part: 101, 102, 104 (Color additive 21 CFR Part: 70, 71, 80, 81, 82) 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils
4.6.1.	The company shall investigate to what extent the factory environment (e.g. ground, air) may have an adverse impact on product safety and product quality. Where it is established product safety and quality could be compromised, appropriate measures shall be established. The effectiveness of the established measures shall be periodically reviewed (examples: extremely dusty air, strong smells).	• Does a location investigation exist? Can location have a negative influence on product quality? <location analysis> • What protective measures have been established if potentially damaging materials/substances are nearby? <protective measures> <corrective actions> • Is efficiency of protective measures regularly reviewed? • Who reviews the efficiency of the established protective measures? • How is efficiency of established protective measures reviewed?	When company surroundings have a negative influence on product (e.g. water treatment) and no protective measures have been established and therefore a safety problem exists. When established protective measures are unclear or with questionable efficiency and therefore a safety problem exists.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food (111 for dietary supplements) 110.20 Plant and grounds FSMA Title I Sec 418 o 3
4.7	**Factory Exterior**			
4.7.1	The factory exterior shall be maintained to be clean and tidy.	• Are factory exteriors tidy? • Are factory exteriors reviewed through internal audits? <audit results>		21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food (111 for dietary supplements) 110.20 Plant and grounds
4.7.2	All external areas of the factory shall be maintained in good condition. Where natural drainage is inadequate, a suitable drainage system shall be installed.	• Are grounds within the factory premises in good condition? • Is natural drainage sufficient? • If natural drainage is insufficient, has a suitable drainage system been installed?		21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food (111 for dietary supplements) 110.20 Plant and grounds 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.37 Sanitary facilities and controls
4.7.3	Outdoor storage shall be kept to a minimum. Where goods are stored outside, hazard analysis and assessment of associated risks shall be undertaken in order to ensure that there is no risk of contamination	• Are goods stored outdoors? • What is stored outdoors? • What rules exist for outdoor storage? • Is outdoor storage based on risk analysis?	No risk analysis exists for outdoor storage. Goods under outdoor storage are influenced in a	Risk analysis 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing,

	or adverse effect on quality and food safety.	<risk analysis>	way that a safety risk is given (e.g. unprotected primary packaging material is kept outdoors, becomes moldy and is not barred from use)	packaging or holding human food (111 for dietary supplements) 110.20 Plant and grounds
4.8	**Plant layout and process flows**			
4.8.1	Plans clearly describing internal flows of finished products, packaging materials, raw materials, waste, personnel, water, etc. shall be in place. A site map covering all buildings of the facility shall be available.	• How is it ensured that cross-contamination is avoided? <waste elimination plan> <personnel flow plan> <materials flow plan> <process flow plan> <hydraulic plan>	When there are no flow plans and internal flows do not respect the segregation of product processes (e.g. separation of "dirty" from "clean" processing areas but personnel cross boundaries without according protective clothing)	
4.8.2	The process flow, from receipt of goods to dispatch, shall be in place so that contamination of raw materials, packaging, semi-processed and finished products is avoided. The risk of cross-contamination shall be minimised through effective measures.	• How is cross-contamination avoided within factory premises? <process flow-diagram>	The process flow allows for a cross-contamination between raw materials, packaging material, half-finished products and finished products.	Regulation 852/2004 Annex2 chapter2 No1 Regulation 853/2004
4.8.3	In case of microbiologically sensitive production areas, these shall be operated and monitored to ensure product safety is not compromised.	• Are there high care areas? • Are high care areas ventilated? • How often are air borne micro-organism counts made? <micro-organism count results> • Who carries out the micro-organism measurements?	When ventilation is missing in high care areas and a safety problem is given	test plan 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food (111 for dietary supplements) 110.20 Plant and grounds
4.8.4	Laboratory facilities and in-process controls shall not affect the product safety.	• Is there a laboratory on site? • Has the lab a direct contact with production premises? • Do microbiology lab technicians change coats before entering production premises? • Can lab waste (e.g. lab waste water) dirty the production premises? <plant lay-out> <waste water drainage system>	When product safety is endangered through the laboratory (e.g. waste water, air circulation, waste disposal)	
4.9	**Constructional requirements for production and storage areas**			21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.35 Sanitary operations
4.9.1	**Constructional requirements**			
4.9.1.1	Rooms where food products are prepared, treated, processed and stored shall be designed and constructed so that food safety is ensured.	• Are there "dirty" and "clean" areas? • Are there appropriate storage rooms?	No separation of "dirty" and "clean" areas even though legally prescribed. When there is no	Regulation 852/2004 Annex 2 chapter I No 1+2; chapter II No 1 21 CFR 110 – Current Good manufacturing practice in manufacturing, packaging or

			compliance with legal requirements.	holding human food
4.9.2	**Walls**			
4.9.2.1	Walls shall be designed and constructed to prevent the accumulation of dirt, to reduce condensation and mould growth, and to facilitate cleaning.	• Are walls moldy?	Extreme mold build-up which ensues a contamination risk.	
4.9.2.2	The surfaces of walls shall be in a good condition and easy to clean; they shall be impervious and wear-resistant.	• How often are walls cleaned? <cleaning schedule> <cleaning evidence>		Regulation 852/2004 Annex 2 chapter II No 1 b 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.35 Sanitary operations
4.9.2.3	The junctions between walls, floors and ceilings shall be designed to facilitate cleaning.	• Are wall-floor junctions and corners rounded?		21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.35 Sanitary operations
4.9.3	**Floors**			
4.9.3.1	Floor covering shall be designed to meet production requirements and shall be in good condition and easy to clean. Surfaces shall be impervious and wear-resistant.	• Are floors cleanable? • How often are floors cleaned? <cleaning eschedule> <cleaning evidence>		Cleaning schedule Regulation 852/2004 Annex 2 chapter II No 1 a 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.35 Sanitary operations
4.9.3.2	The hygienic disposal of waste water shall be ensured. Drainage systems shall be easy to clean and designed to minimise the risk of product contamination (e.g. ingress of pests, etc.).	• How is waste water disposal ensured? • How often are gullies cleaned? <cleaning evidence> <drainage schedule>		Regulation 852/2004 Annex 2 chapter I No 8 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.37 Sanitary facilities and controls
4.9.3.3	Water or other liquids shall reach drainage without difficulties, using appropriate measures. Puddles shall be avoided.	• Are there water or other liquid puddles on the floors of production areas?		21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.37 Sanitary facilities and controls
4.9.3.4	In food handling areas, machinery and piping shall be arranged so that waste water, if possible, goes directly into a drain.	• Where is machinery which produces a large amount of waste water located? <machinery lay-out>		
4.9.4	**Ceilings/Overheads**			
4.9.4.1	Ceilings (or, where no ceilings exist, the inside of roofs) and overhead fixtures (incl. piping, cableway, lamps etc.) shall be constructed to minimise the accumulation of dirt and shall not pose any risk of physical and/ or microbiological contamination.	• How often are ceilings cleaned? <cleaning evidence> <cleaning evidence>	Ceilings are very dirty and dirt can fall on product	Regulation 852/2004 Annex 2 chapter II No 1 c 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.35 Sanitary operations
4.9.4.2	Where false ceilings are used, an access to the void shall be provided in order to facilitate cleaning,	• How often are false ceilings cleaned?		Cleaning schedule

	maintenance and inspections for pest control.	<cleaning evidence> <cleaning evidence>		
4.9.5	**Windows and other openings**			
4.9.5.1	Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in good condition.	• Can dirt accumulate on window sills?		Regulation 852/2004 Annex 2 chapter II No 1 d 21 CFR 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food
4.9.5.2	Where there is risk of contamination, windows and roof glazing shall remain closed and fixed during production.	• Are windows kept open?	Windows are open and no insect gratings are in place so that pests can enter production areas and a contamination risk exists. Pests are visible.	Regulation 852/2004 Annex 2 chapter II No 1 d
4.9.5.3	Where windows and roof glazing are designed to be opened for ventilation purposes, they shall be fitted with easily removable, good condition pest screens or other measures in order to avoid any contamination.	• Are windows sealed with insect gratings? <pest control schedule> • Is integrity of gratings regularly reviewed? <monitoring schedule>	Windows are open and no insect gratings are in place so that pests can enter production areas and a contamination risk exists	Regulation 852/2004 Annex 2 chapter II No 1 d
4.9.5.4	In areas where unpackaged product is handled, windows shall be protected against breakage.	• How are windows protected against breakage?	Windows with no breakage protection are in production areas where uncovered and broken and unpackaged products are handled which ensues a contamination risk.	
4.9.6	**Doors and gates**			
4.9.6.1	Doors and gates shall be in good condition (e.g. no splintering parts, flaking paints or corrosion) and easy to clean.	• Are doors damaged?	Doors are open or damaged so that pests can enter production areas and a contamination risk exists. Pests are visible.	Regulation 852/2004 Annex 2 chapter II No 1 e 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.37
4.9.6.2	External doors and gates shall be constructed to prevent the ingress of pests; if possible, they shall be self-closing.	• Do outer doors prevent pest entrance into production areas?		
4.9.7	**Lighting**			
4.9.7.1	All working areas shall have adequate lighting.	• What is the assurance that all working areas are adequately illuminated?		Regulation 852/2004 Annex2 chapter I No7 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.20 Plant and ground
4.9.7.2	All lighting equipment shall be protected by shatter proof covers and installed to minimise the risk of breakage.	• Where are fly killing units mandatory? <fly trap plan> • Are all fly killing units and lamps protected by splinter shields? <lighting protectors>	When fly traps and lighting devices constitute a contamination risk.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.20 Plant and ground

4.9.8	**Air conditioning/Ventilation**			
4.9.8.1	Adequate natural and/ or artificial ventilation shall exist in all areas.	• How is ventilation reviewed?		Regulation 852/2004 Annex2 chapter I No5 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.20 Plant and ground
4.9.8.2	If ventilation equipments are installed, filters and other components which require cleaning or replacement shall be easily accessible.	• How are air filters maintained and cleaned? <maintenance schedule> <maintenance documentation> <cleaning protocols>	Filters which are not cleaned as programmed constitute a product contamination risk	Regulation 852/2004 Annex2 chapter I No1 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.20 Plant and ground
4.9.8.3	Air conditioning equipment and artificially generated airflow shall not lead to any product safety or quality risks.	• Is the use of air during production based on risk analysis? <risk analysis> • Are there production areas with under- or over-pressurization?	When air supply causes a contamination which ensue a food safety risk.	Note: Certain references are generally applicable: Corrective actions; damaged products steerage; recall; crisis management 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils
4.9.8.4	Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated.	• Are there areas where large amounts of dust are formed? • Do dust extraction devices exist in these areas?		
4.9.9	**Water supply**			
4.9.9.1	Water which is used as ingredient in the production process, or for cleaning, shall be of potable quality and supplied in sufficient quantity; this also applies to steam and ice used within the production area. A supply of potable water shall be available at all times.	• Where does water supply come from? (City supply, well water, tanker..)? • is water demand always covered?		Resources 1998-83-EU (Drinking Water) 21 CFR Part: 130 – Food standards: General 130.12 General methods for water capacity and fill of containers 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.80 Production and preocess controls
4.9.9.2	Recycled water which is used in the process shall not pose a contamination risk. The water shall comply with applicable legal requirements for potable water; records of compliance testing shall be available.	• What for is water used in the company (social facilities, cleaning procedures, product ingredient, for washing fruits and vegetables)? • Is water treated on site (water hardness correction, chlorination, sterilization, filtration…)? • Are local legal requirements on hand? • Is water analysed according to legal requirements (own water supply, outside supply). Do results comply with standards? <several analysis results>	There is evidence that water does not comply with microbiological or chemical legal standards and is used for cleaning procedures of surfaces in direct contact with foodstuff or as ingredient, or company can not show that water complies with required standards. The checking interval for relevant water safety issues has been clearly	5.11.2 if identified deficits are not fixed within a reasonable time

			overdrawn. The company has no water analysis plan even though it is mandatory and water is used for cleaning procedures or as an ingredient.	
4.9.9.3	The quality of water, steam or ice shall be monitored following a risk based sampling plan.	• Is water, steam or ice used - is a station monitoring in place? <maintenance> ,analysis results> • What kind of piping system exists? Ring-pipes, water-tanks) • What is piping made from? • Is analysis and sampling plan based on risk analysis?	When contaminated water reaches the product due to bad conditions of piping or improper piping material	Maintenance Monitoring system, HACCP, risk analysis, filters Requirements for Germany: Drinking water Regulation 2001 + adaptions from 03.05.2011 Definition §3 (1b); Sampling were water is used §8 (4); Maximum values§5 (2) Microbiological standards - annex 1, part I, §6 (2); chemical standards - annex II, §7; [indicator parameters - annex 3]; exceptions §10; examination requirements §14; sampling frequency - annex 4 (2) II] <normally 4 routine analyses and 1 periodic analysis during the year> 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.37 Sanitary facilities and controls
4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall not be connected to the drinking water system, or allow the possibility of reflux to contaminate potable water sources or the factory environment.	• Is drinking water system completely separated from non potable water piping? <hydraulic system lay-out> • What other systems are there? (e.g. used water, cooling water, water used for fire fighting). • Are water systems properly marked and where they are? • Are reflux avoidance equipments installed wherever necessary?	All existing water systems are interconnected, no reflux avoidance equipments exist, therefor a contamination hazard is given.	Infrastructure
4.9.10	**Compressed air**			
4.9.10.1	The quality of compressed air that comes in direct contact with food or primary packaging material shall be monitored based on hazard analysis and assessment of associated risks.			
4.9.10.2	Compressed air shall not pose a risk of contamination.			
4.10	**Cleaning and disinfection**			
4.10.1	Based on hazard analysis and assessment of associated risks, cleaning and disinfection schedules	• Who is in charge of cleaning and disinfection? <cleaning schedule>	When a contamination of food products or tools	Monitoring system, HACCP

	shall be available and implemented. These shall specify: - objectives - responsibilities - the products used and their instructions for use - the areas to be cleaned and/ or disinfected - cleaning frequency - documentation requirements - hazard symbols (if necessary).	• What kind cleaning products and disinfectants are used? <up to date cleaning products and disinfectant list> • What must be observed when using different cleaning products and disinfectants? <product instructions> • What areas are cleaned and disinfected? <cleaning schedule> • How often are areas cleaned and disinfected? • Where are cleaning and disinfection procedures documented? <cleaning procedures documentation> • Do hazard symbols exist? • Does a contract exist for external service provider? <external services contract> • Cleaning schedules can include SSOP's	exists due to the use of inefficient or wrong kind of chemicals or inefficient cleaning procedures	
4.10.2	Cleaning and disinfection schedules shall be implemented and documented.			
4.10.3	Only qualified personnel shall be allowed to undertake cleaning and disinfection. The personnel shall be trained and retrained to carry out the cleaning schedules.	• Are cleaning personnel qualified? <training proof> • How often are they trained? • Who trains them? • Are these trainings documented?	When a product or tools contamination occurs due to untrained cleaning personnel or wrong use of cleaning products or when cleaning process is inefficient	3.1.1 when training deficits may become a safety issue
4.10.4	The effectiveness and safety of the cleaning and disinfection measures, based on hazard analysis and assessment of associated risks, shall be verified and documented according to a sampling schedule by using appropriate procedures. Resultant corrective actions shall be documented.	• How are cleaning and disinfection controls performed? <cleaning controls> • Who performs these controls? <cleaning controls> • How often are cleaning and disinfection controls performed? <cleaning controls> • Where are cleaning and disinfection controls documented? • When are corrective actions executed? <corrective actions> • Who executes corrective actions? • Who reviews effectiveness of corrective actions? • Where are corrective actions documented?	When cleaning is unsuccessful and this error is not corrected.	5.11.2 if identified deficits are not fixed within a reasonable time
4.10.5	Cleaning and disinfection schedules shall be reviewed and modified, if necessary, in the event of a change to product, process or cleaning equipment.	• When are cleaning and disinfection procedures validated? • Who adapts cleaning and disinfection procedures? • How often are cleaning and disinfection schedules changed?	When circumstances have been changed but no adaptations were made for cleaning and disinfection procedures and a contamination risk ensues.	Monitoring system, HACCP
4.10.6	The intended use of cleaning utensils shall be clearly identified. Cleaning utensils shall be used in a way to avoid contamination.			
4.10.7	Current material safety data sheets (MSDS) and instructions for use shall be available for chemicals	• Are material safety data sheets available for all cleaning chemicals?	When a safety risk occurs due to deficient material	Dangerous substances regulation

	and cleaning agents. Personnel responsible for cleaning shall be able to demonstrate their knowledge of such instructions, which shall be always available on site.	• Are these no older than two years? • Are cleaning chemicals instructions up to date? • How are instructions transmitted to personnel in charge of cleaning procedures? • Where and when can the instructions be inspected?	safety data sheets.	
4.10.8	Cleaning chemicals shall be clearly labelled, used and stored appropriately, to avoid contamination.	• How are cleaning utensils and chemicals recognizable? <chemicals list> • Where are cleaning utensils and chemicals stored? <chemicals storage list>	When cleaning utensils can be mixed up with other utensils and food contamination ensues. When improper storage can lead to food and other utensils contamination.	Dangerous substances regulation 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.35 Sanitary operations
4.10.9	Cleaning activities shall be carried out in periods of non-production. If this is not possible, these operations shall be controlled as to not affect the product.	• Where are containers cleaned? • When and where are tools cleaned? <cleaning evidence>	The tool cleaning process is a product contamination problem; e.g. wet cleaning of containers and pallets during production and near unprotected foodstuffs	Cleaning plan Regulation 852/2004 Annex 2 chapter II No 2
4.10.10	Where a company hires a third-party service provider for cleaning and disinfection activities, all requirements specified within section 4.10 shall be clearly defined in the respective contract.			
4.11	**Waste disposal**			
4.11.1	A waste management procedure shall exist and shall be implemented to avoid cross contamination.			
4.11.2	All current legal requirements for waste disposal shall be met.	• How is it ensured that current legal waste disposal requirements are met? • How is waste material disposed of?	When legal requirements regarding wastre disposal are not met.	Waste disposal legal requirements.
4.11.3	Food waste and other waste shall be removed as quickly as possible from areas where food is handled. The accumulation of waste shall be avoided.	• How often are food waste and other wastes removed from food handling areas? • Who is responsible for waste removal?	When wastes accumulate in food handling areas which ensues a food product contamination risk.	Regulation852/2004 Annex2 ChapterVINo1 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food (111 for dietary supplements) 110.20 Plant and grounds
4.11.4	Waste collection containers shall be clearly marked, suitably designed, in good state of repair, easy to clean, and where necessary disinfected.	• What kind of waste exists? What wastes are collected in separate containers? How are waste containers marked? Can waste containers easily be cleaned and disinfected? • How often are waste containers cleaned and disinfected? <cleaning protocol>	When waste containers can be mixed up with foodstuff containers which ensues a food contamination risk.	4.10.1 cleaning and disinfection Regulation 852/2004 Annex 2 Chapter VI No. 2
4.11.5	Waste collection rooms and containers (incl. compactors) shall be designed to be kept clean to minimise pest attraction.	• Are waste collection rooms kept clean? • Are waste collection rooms protected from pests? <integrated pest control>	When waste collection rooms are not protected from pest invasions and acontamination risk ensues.	4.10.1cleaning and disinfection Regulation 852/2004 Annex 2 Chapter VI No. 3
4.11.6	Waste shall be collected in separate containers in accordance with the intended means of disposal. Such waste shall be disposed by authorised third parties only. Records of waste disposal shall be kept	• What kinds of waste disposal records exist? • Who is responsible for waste disposal? <waste disposal registry>	When wastes are removed by unauthorized persons	Regulation concerning record keeping of waste disposal 852/2004 Annex 2 Chapter VI Nr. 4

	by the company.			
4.12	**Risk of foreign material, metal, broken glass and wood**			
4.12.1 KO	**KO N° 6 Based on hazard analysis and assessment of associated risks, procedures shall be in place to avoid contamination with foreign material. Contaminated products shall be treated as non-conforming products.**	• What kinds of foreign bodies may be found? • Where foreign body sources identified through risk analysis? <risk analysis> • Are staples used? • How are contaminated products handled? <segregation records> • What is done in case of glass breakage? <glass breakage prevention procedures> • What shall be considered when glass fixtures are replaced? <glass handling procedures>	When a foreign bodies contamination occurs due to lack of risk analysis or when foreign body sources are insufficiently considered	HACCP Risk analysis 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.20 Plant and grounds
4.12.2	In all areas, e.g. handling of raw materials, processing, packing and storage, where hazard analysis and assessment of associated risks have identified the potential for product contamination, the use of wood shall be excluded. Where the use of wood cannot be avoided, the risk shall be controlled and the wood shall be in good order and clean.	• Under what circumstances is the use of wood allowed? <risk analysis> • Is the wooden tool in use in good and clean conditions? • Who inspects and how often is the wooden tool condition inspected? <plant inspections>	When wood gets in contact with open product. When wood poses a contamination risk for food product. When wooden tool condition is not inspected and a contamination risk ensues.	4.8.2 Risk analysis Regulation 852/2004 Annex 2 Chapter IX No.2+3 Regulation 178/2002 Art. 14 para. 5 Regulation 852/2004 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.80 Processes and controls
4.12.3	Where metal- and/ or other foreign material detectors are required, they shall be installed to ensure maximum efficiency of detection, in order to avoid subsequent contamination. Detectors shall be subjected to regular maintenance to avoid malfunction.	• Where are the metal detector installed? <equipment lay-out>	When metal detectors are installed but later on a foreign bodies risk still persists which has not been taken into account.	
4.12.4	Potentially contaminated products shall be isolated. Access and actions for further handling or checking for these isolated products shall be carried out only by authorised personnel according to defined procedures. After this check, contaminated products shall be treated as non-conforming products.	• Are contaminated products automatically isolated? • Who may handle/has access to isolated products? • How are isolated products handled? <non-conforming products list> <isolation protocol>	When segregation does not work. When isolated products re-enter production line without previous inspection.	5.11.2 HACCP 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.80 Processes and controls
4.12.5	The appropriate accuracy of detectors shall be specified. Checks of proper function of detectors shall be carried out regularly. In case of malfunction or failure of a metal and/ or foreign material detector, corrective actions shall be defined, implemented and documented.	• How often are detector accuracies checked? • Who checks detector accuracy? <metal detector check-list> • What corrective actions exist when a detector is defective? • Are corrective actions verified? • Are operational defects documented? <defect/failure protocols>	When proper operation or measuring accuracy is not checked and a foreign body risk occurs.	Monitoring system 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils
4.12.6	In cases where special equipment or methods are used to detect foreign material, these shall be properly validated and maintained.	• Are filters and sieves or other technical or mechanical systems like strainers, magnets, vacuum cleaner, stone remover etc. being used? • How often are working conditions of filters or other technical or mechanical systems and sieves inspected? • Who inspects/maintains filters and sieves or other	When damage to sieves or filters passes without noticed and this leads to a foreign body contamination risk.	Housekeeping, maintenance

		technical or mechanical systems ? • What is the concern of inspection? <maintenance schedule> <monitoring system>		
4.12.7	In all areas, e.g. handling of raw materials, processing, packing and storage, where hazard analysis and assessment of associated risks have identified a potential product contamination, the presence of glass and brittle material shall be excluded. Where the presence of glass or brittle plastic cannot be avoided, appropriate measures shall be in place to protect against breakage.	• Does a risk analysis exist concerning contamination through glass? <risk analysis> • Where is glass used in the plant? • How is glass protected from breakage? <glass register>	When no risk analysis has been conducted. When there exists a contamination risk due to glass usage. When glass is unprotected and a contamination risk ensues.	Risk analysis 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.80 Processes and controls
4.12.8	All stationary objects made of or incorporating glass or brittle material present in areas of handling of raw materials, processing, packing and storage shall be listed in a specific register, including details of their exact location. An assessment of the condition of objects on the register shall be performed on a regular basis and recorded. Frequency of this check shall be justified by documents.	• Is there a glass fixtures register including location? <glass register> • How often and who inspects glass fixture conditions? • How often is glass fixtures register up dated? <inspection results> <glass register>	When glass breakage goes unnoticed and a contamination risk ensues.	HACCP
4.12.9	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.	• Is every glass breakage documented? <glass breakage registry> • Where is glass breakage documented? <glass register> • Are there exceptions to documentation? Are exceptions based on risk analysis? <risk analysis>	When no risk analysis has been made.	Risk analysis
4.12.10	Procedures shall be in place describing the measures to be taken in case of breakage of glass and/ or brittle material. Such measures shall include identifying the scope of goods to be isolated, specifying authorised personnel, cleaning the production environment and release of production line for continued production.	• What is done in case of glass breakage? • What should be taken into account? • Who cleans the production environment? • Who permits production continual? <glass breakage prevention procedures> <glass breakage documentation>	When a contamination risk exists due to glass breakage and because involved product has not been inspected.	
4.12.11	Based on hazard analysis and assessment of associated risks, preventive measures shall be in place for handling of glass packaging, glass containers or other kinds of containers in the production process (turn over, blow, rinse, etc.). After this process step there shall be no further risk of contamination.	• Has a risk analysis been performed due to glass packaging or glass container handling? <risk analysis> • What preventive measures are in place? <preventive measures>	When no risk analysis has been made. When there exists a contamination risk due to missing preventive measures.	Risk analysis
4.12.12	Where visual inspection is used to detect foreign material, the employees shall be trained and operative change shall be performed at an appropriate frequency to maximise effectiveness of process.			
4.13	**Pest monitoring /Pest control**			
4.13.1	The company shall have a pest control system in place which is in compliance with local legal	• How is pest control organized? <pest control procedures>	When no pest control is made.	Chemicals Regulation 852/2004 Annex 2 chapter IX

	requirements, taking into account, as a minimum: - the factory environment (potential pests) - site plan with area for application (bait map) - identification of the baits on site - responsibilities, in-house/ external - used products/ agents and their instructions for use and safety - the frequency of inspections. The pest control system shall be based on hazard analysis and assessment of associated risks.	• Which pests are controlled? • Which kinds of baits are used? <pest control chemicals list> • Is product contamination through baits being prevented? <bait map> • Who is responsible for pest control? • What is inspection schedule?	When a product contamination can occur due to unmapped baits. When a product safety occurs due to incorrect use of pest control chemicals or wrongly laid out baits.	No 4 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food Subpart B 110.20
4.13.2	The company shall have qualified and trained in-house staff and/ or employ the services of a qualified external provider. Where an external provider is used, the activities required on site shall be specified in a written contract.	• Is pest control executed by own staff members? • Who is responsible for pest control? • What kind of training has the responsible person? <training evidence> • Is pest control executed by external services provider? • Does a written contract exist between services provider and company? <written contract> • What is the content of the contract? • What kind of training has the external services provider? <training evidence>	When a product contamination occurs due to incorrect handling of bait material.	3.1.1
4.13.3	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded.	• Where are inspections and resulting corrective actions documented? <inspection results> • Are documents signed and dated by both parties? • Which corrective actions were executed lately?	When inspections are not documented.	5.11.2
4.13.4	Baits, traps and insect exterminators shall be functioning, shall be in sufficient numbers and shall be placed in an appropriate position. They shall be constructed and positioned as not to cause any contamination risk.	• Where are electrical fly killers installed? <fly killer map> • Are all fly killers correctly working and connected?	When fly killers are positioned in such a way that flies can fall directly on food products.	
4.13.5	Incoming deliveries shall be checked on arrival for the presence of pests. Any infestation shall be documented and control measures taken.	• Are incoming goods inspected for pest contamination? • Where is this documented? <incoming goods inspection> • Is pest presence documented? <incoming goods inspection> • What control measures are taken when pests are found? <corrective actions> • Where are these control measures documented? <corrective actions>	When incoming goods are not inspected for pest presence and an uncontrolled invasion ensues.	4.11.1
4.13.6	The effectiveness of the pest control shall be monitored with the help of regular trend analyses.			
4.14	**Receipt of goods and storage**			FSMA Title I Sec 111
4.14.1	All incoming goods, including packaging materials and labels, shall be checked for conformity against specifications and to a determined inspection plan. The inspection plan shall be risk based. Test results shall be documented.	• What goods (incl. semi-procedded products) are inspected when received? <receipt checks> • What is checked when received?	When no receipt checks are made. When checks do not guarantee legal requirements.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.20 Plant and grounds 110.93 Warehousing and distributions

		• Is receipt documented? • Who checks?	When receipt checks do not take into account specification requirements which prevent that products fulfil their given specifications.	
4.14.2	The storage conditions of raw materials, semi-processed and finished products as well as packaging shall in each case correspond to product requirements (e.g. refrigeration, protective covers) and shall not be detrimental to other products.	• Where are raw materials, half finished products and packaging materials stored? <storage plan> • How is cross-contamination avoided? <product flow plan>	When goods are improperly stored and a contamination risk ensues.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.80 Processes and controls
4.14.3	Raw materials, packaging, semi-processed and finished products shall be stored so as to minimise the risk of cross contamination.	• Where and how are packaging materials and equipments stored? <materials flow-diagram> • How is cross-contamination through packaging materials avoided? <materials flow-diagram> • How is return of packaging materials to the storeroom regulated? • What kind of storage regulations exist? • Are pests taken into account during storage? Are pallets located approximately 1 m from walls? <plant inspection protocol> • Are there baits laid out in storage rooms? <pest control schedule> • Are there sensitive products stored? • What kinds of preventive measures are in place for these goods? <preventive measures>	A product contamination risk is given due to storage of packaging materials and equipments (e.g. unprotected external storage of packaging material) When storage facilities are not inspected for pest presence.	Regulation 852/2004 Annex 2 chapter X Regulation 852/2004 Annex 2 Chapter IX No. 4 21 CFR Part: 101, 102, 104 (Color additive 21 CFR Part: 70, 71, 80, 81, 82) FSMA Title I Sec 111
4.14.4	Appropriate storage facilities shall be available for the management and storage of working materials, process aids, and additives. The personnel responsible for the management of storage facilities shall be trained.	• How are chemicals stored? • Who uses chemicals and takes them out of storage? <responsibility list> • Are the chemicals users trained? • Is training documented? <training documentation>	When a food or utensils contamination occurs due to inappropriate storage conditions. When a food or utensils contamination occurs due to insufficient knowledge.	3.1.1 when training deficits may become a safety issue 21 CFR Part: 101, 102, 104 (Color additive 21 CFR Part: 70, 71, 80, 81, 82) 21 CFR Part: 130 – Food standards: General 130.11 Label designations of ingredients for standardized foods
4.14.5	All products shall be clearly identified. Use of products shall be undertaken in accordance with the principles of First In/ First Out and/ or First Expired/ First Out.	• How is “FIFO” ensured?	When goods are taken out of storage without control and a product safety risk ensues.	Regulation 178/2002 Art. 18 Traceability Directive 89/396 (on indications or marks identifying the lot to which a foodstuff belongs)
4.14.6	Where a company hires a third-party storage service provider, the service provider shall be subject to IFS Logistics requirements. If the third party service	• Is storage leased to storage service provider? • Does a contract exist? <service provider contract>		

	provider is not certified to IFS Logistics, all relevant requirements equivalent to the company's own warehousing practices shall be fulfilled and this shall be clearly defined in the respective contract.	• What is specified in the contract? • Has storage service provider an IFS Logistics certification? <certificate copy>		
4.15	**Transport**			
4.15.1	Before loading transport vehicles, their condition (e.g. absence of strange smells, high dust load, adverse humidity, pests, mould) shall be checked and action taken, if necessary.	• What is checked before loading? <expedition inspection> • Where is inspection documented? • What corrective actions are taken?		
4.15.2	Where goods must be transported at certain temperatures, before loading, the temperature inside the vehicle shall be checked and documented.	• May goods be transported alongside with non food products? • How is cross-contamination prevented?	When a contamination can occur during transport.	Regulation 852/2004 Annex 2 Chapter IV No. 3, 5 and 6
4.15.3	Procedures to prevent contamination during transport shall be implemented (food/ non-food/ different categories of goods).	• Are products which require a certain temperature being loaded? • Is vehicle temperature checked and documented before loading? <expedition inspection> • What are the procedures when vehicle temperature is not according to specifications? <expedition inspection> • How the company ensure the compliance of temperatures during transport? <"temperature indicator" occasionally placed in Products>	When there are certain temperature specifications for outgoing product but they are not checked before loading and a health issue for the consumer occurs.	
4.15.4	Where goods must be transported at certain temperatures, maintaining the adequate range of temperatures during transport shall be ensured and documented.	• Are vehicles equipped with thermostats and registering devices? <registering devices> • How is it ensured that products reach destination under good conditions?	When there are temperature specifications for the product and temperature control is not ensured during transport so that a health issue for the consumer may occur.	5.3.2 Regulation 852/2004 Regulation 37/2005 (on the monitoring of temperatures in the means of transport, warehousing and storage of quickfrozen foodstuffs intended for human consumption)
4.15.5	Adequate hygienic requirements for all transport vehicles and equipment used for loading/ unloading (e.g. hoses of silo installations) shall exist. There shall be records of the measures taken.	• Are transport vehicles cleaned? • Where are cleaning procedures documented? <cleaning protocol>	When absence of cleaning procedures ensue a product contamination problem.	Regulation 852/2004 Annex 2 Chapter IV No. 1
4.15.6	Loading and unloading areas shall have equipment in place to protect transported products from external influences.	• How is goods reception organized? • How is loading organized? External influences: e.g. pollen, climate, etc.		
4.15.7	Where a company hires a third-party transport service provider, all the requirements specified within section 4.15 shall be clearly defined in the respective contract or the service provider shall be subject to IFS Logistics requirements.	• Are there internal or external transportation regulations? • Does a contract exist with a transportation services provider? <service provider contract> • Has storage service provider an IFS Logistics certification? <certificate copy>		
4.15.8	Security of transport vehicles shall be appropriately maintained.			
4.16	**Maintenance and repair**			

4.16.1	An adequate system of maintenance shall be in place, maintained and documented, covering all critical equipment (incl. transport) for compliance with product requirements. This applies both for internal and external maintenance activities.	• How is maintenance organized? <maintenance plan> • Where are maintenance procedures documented? • Which equipments are subject to external maintenance?	No maintenance system exists	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food (111 for dietary supplements) 110.40 Equipment and utensils
4.16.2	Product requirements and prevention of contamination shall be ensured during and after maintenance and repair work. Records of maintenance and repair work and of corrective actions taken shall be kept.	• How is it ensured that maintenance and repair works do not affect product safety? • How are lighting fixtures repaired? • Where are repair works documented? • Are corrective actions necessary after repair works? • What rules are in place for re-activating equipment when maintenance is completed? <examples for repair works and maintenance>	When a contamination risk for the product occurs due to maintenance and product is not segregated.	
4.16.3	All materials used for maintenance and repair shall be fit for the intended use.	• How is it ensured that materials used in maintenance or repair work are fit for intended use? • What kinds of greases are used? <grease list>	When materials used in maintenance or repair works are not food grade and a safety risk for the consumer ensues.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils 120.6 Sanitation SOP 21 CFR 170 Food additives e.g. 170.30
4.16.4	Failures of plant and equipment (incl. transport) covered by the maintenance system shall be documented and reviewed with a view to adapting the maintenance system.	• Are processing interruptions documented? <processing interruptions> • Are processing interruptions considered in maintenance planning?		
4.16.5	Temporary repairs shall be carried out so that product requirements are not affected. Such work shall be documented and a short-term deadline set for eliminating the fault.	• Are temporary repairs allowed? • Where are these documented? • How fast must temporary repairs be definitely mended? • Who verifies this?		
4.16.6	Where a company hires a third-party maintenance and repair service provider, all the company specified requirements regarding material and equipment shall be clearly defined, documented and maintained.			
4.17	**Equipment**			www.foodcontactmaterials.com Regulation 1935/2004 Regulation 10/2011
4.17.1	Equipment shall be suitably designed and specified for the intended use. Before commissioning, it shall be verified that the product requirements are complied with.	• Are equipments suitably designed and were they checked before start up? <start up protocol>	When equipment construction can lead to a foodstuff contamination.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.20 Plant and grounds
4.17.2	For all equipment and tools with direct food contact, certificates of conformity shall exist which confirm compliance with current legal requirements. In case no specific legal requirements are applicable, evidence shall be available to demonstrate that all equipment and tools are suitable for use. This applies for all equipment and tools in direct contact with raw materials, semi-processed and finished products.	• Are conformity certificates or other certificates available for all packaging materials which come into direct contact with food products? <conformity certificates> • Are conformity certificates available for packaging materials which come into direct contact with raw materials, half-finished or finished products? <conformity certificates> • Are conformity certificates available for containers and conveyor belts?	Packages and packaging materials which come into direct contact with foods are not suitable for intended use and therefore a safety risk exists for the consumer.	Migration 1935/2004 (General Packaging Directive) Regulation 10/2011 (plastic food contact materials) Articles and utensils in contact with oodstuffs Articles, utensils and feedstuffs legislation 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing,

		<conformity certificates>		packaging or holding human food 110.20 Plant and grounds
4.17.3	Equipment shall be designed and located so that cleaning and maintenance operations can be effectively performed.	• Are equipments suitably designed and were they checked before start up? <start up protocol> • What rules exist for start up of new equipments? • Were new equipments immediatly considered in maintenance plan? • Does an equipment installation plan exist? <machinery installation plan>	When equipment is installed in a way that cleaning procedures are hindered and thus constitute a contamination source.	Regulation 852/2004 Annex 2 Chapter IV No. 1
4.17.4	The company shall ensure that all product equipment is in good condition without any negative influence on food safety.			
4.17.5	The company shall ensure that in the event of changes to processing methods and equipment, process characteristics are reviewed in order to assure that product requirements are complied with.	• What happens in case of equipment failures? <equipment stops>	When equipment stops lead to a product safety issue and these are not segregated.	21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.20 Plant and grounds
4.18	**Traceability (including GMOs and allergens)**			21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food Subpart B Production and Process control
4.18.1 KO	**KO N° 7: A traceability system shall be in place which enables the identification of product lots and their relation to batches of raw materials, packaging in direct contact with food, packaging intended or expected to be in direct contact with food. The traceability system shall incorporate all relevant receiving processing and distribution records. Traceability shall be ensured and documented until delivery to the customer.**	• How is traceability ensured? <traceability procedures> • What products come from which supplier? • Is there a list available with all current suppliers? <supplier list>	When no traceability system exists and the system does not include raw and packaging materials. When traceability is not complete up to the supplier	Regulation 178/2002 Art. 18 Directive 1830/2003
4.18.2	Downstream traceability records (from production sites to the customers) shall be available. The timeframe for producing these records for review shall be compliant with customer's requirements.			
4.18.3	Traceability shall be in place to identify the relationship between batches of final products and their labels.			FSMA Title II Sec 204
4.18.4	The traceability system shall be tested on a periodic basis - at least annually and each time traceability system changes. The test shall verify upstream and downstream traceability (from delivered products to raw materials, and vice versa), including quantity checking. Test results shall be recorded.	• When was the last traceability test in both directions done? <traceability test results> • What percentage of total amount was traced? • How big is a lot?	When traceability system is not tested in both directions so that no assurance is given as to its effectiveness. When test results are negative and no corrective actions are taken.	
4.18.5	Traceability shall be ensured at all stages, including work in progress, post treatment and rework.	• Can rework be completely traced? <results from rework traceability test>	When rework traceability is not ensured.	Regulation 178/2002 Art. 18

		• How is rework documented/		
4.18.6	Labelling of semi-finished or finished product lots shall be made at the time when the goods are directly packed to ensure a clear traceability of goods. Where goods are labelled at a later time, the temporarily stored goods shall have been provided with a specific lot labelling. The shelf life (e.g. best before date) of the labelled goods shall be calculated from the original production batch.	• When is lot labelling done? • What is the lot labelling code? <lot labelling example> • When are labels applied to product units? • How is shelf-life calculated? <shelf-life example>	When lot labelling is done at a step where mix ups occur which unable correct traceability.	Labelling regulation Regulation 89/396 21 CFR Part: 101, 102, 104 (Color additive 21 CFR Part: 70, 71, 80, 81, 82) A Food labeling Guide see: http.//www.cfsan.fda.gov/guidance.html Additional requirements in product specific 21 CFR parts
4.18.7	If required by customer, identified samples representative for the manufacturing lot shall be stored appropriately and kept until expiration of the "Use by" or "Best before date" of the finished product and if necessary for a determined period beyond this date.	• is a sample bank implemented?		
4.19	**Genetically modified organisms (GMOs)**			
4.19.1	For products being delivered to customers and/ or countries with GMO requirements, the company shall have in place systems and procedures to allow the identification of products consisting of GMOs, containing GMOs or produced from GMOs, including food ingredients, additives and flavouring(s).	• How is traceability of GMO's ensured? • How is identification of GMO's organized?	GMO's are not identified	Regulation 1830/2003 Regulation 1829/2003
4.19.2	Raw material specifications and delivery documents identifying products consisting of, being made from, or containing GMOs shall be available. The assurances concerning the GMO status of the raw materials shall be agreed by contract with the supplier or the relevant technical documents shall specify the GMO status. The company shall maintain a continuously updated listing of all GMO raw materials used at its premises, which also identifies all blends and formulas to which such GMO raw materials are added.	• Is GMO status documented in specifications? <raw materials specifications> <finished product specifications> • What rules concerning GMO's are established with suppliers? <evidence for GMO's absence>	GMO's are not namend. No compliance as to GMO status exists.	
4.19.3	There shall be adequate procedures to ensure that where products consisting of or containing GMOs are manufactured, contamination of non-GMO products is avoided. Adequate control measures shall be in place to avoid GMO cross contamination. The effectiveness of these procedures shall be monitored by testing.	• Is a procedure in place to avoid contamination of GMO free products? • How often is effectiveness of these procedures reviewed? • Where are these proofs documented? <examples>		
4.19.4	Finished products containing GMOs or labelled as not containing GMOs shall be declared in accordance with current legal requirements. Delivery documents shall include the corresponding reference to GMOs.	• Is GMO status documented in specifications? <finished product specifications>	GMO's are not declared	Regulation 1829/2003 Regulation 2000/13
4.19.5	Customer requirements concerning the GMO status of products shall be clearly implemented by the company.	• Do customers demand GMO free products? • When yes how is this managed within QA?	Customer demands are not kept.	
4.20	**Allergens and specific conditions of production**			Directive 68/2007/EC to Annex 3 of

				Directive 2000/13/EC FSMA Title I Sec 112
4.20.1	Raw material specifications identifying allergens requiring declaration that are relevant to the country of sale of the finished product shall be available. The company shall maintain a continuously up to date listing of all raw materials containing allergens used at its premises, which also identifies all blends and formulas to which such raw materials containing allergens are added.	• Are allergens identified in specifications? • Does a list exist that covers allergens in use? <allergen list>	Allergens are not identified and a customer safety issue ensues.	Regulation 2003/83 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs Food Allergen Labeling and Consumer Protection Act of 2004 (Title II of Public Law 108-282) Different Allergens in US and EU 21 CFR Part: 130 – Food standards: General 130.8 Conformity to definitions ans standards identity 130.9 Sulfites in standardized food 130.10 Requirements for foods named by use of nutrient content claim and a standardized term 21 CFR 179 Irradiation in the production, processing and handling of food.
4.20.2	The manufacturing of products which contain allergens requiring declaration shall be carried out as to ensure cross contamination is minimised as far as possible.	• Is a procedure in place to avoid contamination of allergen free products? • How often is effectiveness of these procedures reviewed? • Where are these proofs documented? <examples>		
4.20.3	Finished products containing allergens requiring declaration shall be declared in accordance with current legal requirements. For the adventitious or unintentional presence, the labelling of legally declared allergens and traces shall be based on hazard analysis and assessment of associated risks.	• Has allergen status been documented in specifications? <finished product specifications>	Allergens are not declered and a safety risk for the consumer occurs.	Regulation 2003/89 Regulation 2000/13 Risk analysis 21 CFR Part: 101, 102, 104 (Color additive 21 CFR Part: 70, 71, 80, 81, 82) Food Allergen Labeling and Consumer Protection Act of 2004 (Title II of Public Law 108-282) Different Allergens in US and EU
4.20.4	Where customers specifically require that products are “free from” certain substances or ingredients (e.g. gluten, pork, etc), or that certain methods of treatment or production are excluded, verifiable procedures shall be in place.	• Do customers demand that certain substances are not included in the product? • When yes, how is it managed by QA?	Consumer demands are not kept.	
5.	**Measurements, Analysis, Improvements**			
5.1	**Internal audits**			
5.1.1 KO	**KO N° 8: Effective internal audits shall be conducted according to a defined agreed audit program and shall cover at least all requirements of the IFS Standard. Scope and frequency of internal audits shall be determined by hazard analysis and assessment of associated risks. This**	• Does an up to date internal audit plan exist? <audit plan> • Is audit plan based on risk analysis? <risk analysis>	No internal audits are performed	Risk analysis FSMA Title I Sec 103

	is also applicable for off site storage locations owned or rented by the company.			
5.1.2	Internal audits of activities which are critical to food safety and product specifications shall be carried out at least once a year.	• How often are internal audits performed? <audit plan> • The following issues can be taken into consideration for internal audits: - all production steps (packaging area,labeling,GMP's, GHP's, CP's) - traceability, - control plan (analysis, calibration) - documentation management (updates) - management of non-conformities (complaints, internal non-conformities, withdrawal, recall)		
5.1.3	The auditors shall be competent and independent from the audited department.	• Who are the auditors? <auditors list> • How are auditors qualified for this job? <continued education evidence> • Have auditors any connection with audit area?		
5.1.4	Audit results shall be communicated to the senior management and to responsible persons of concerned department. Necessary corrective actions and a schedule for implementation shall be determined and documented and communicated to every relevant person.	• How are audit results communicated to the persons in charge? <audit report distribution> • Is the communication immediate and in time to take mesaures? • Are corrective actions documented? <audit report> • Is a time schedule in place for corrective actions? <audit report> • From which audits were corrective actions derived? <audit report containing corrective actions> • How are audit results forwarded to senior management? <audit report distribution> • How are audit results evaluated?	No documented audit results	
5.1.5	It shall be documented how and when the corrective actions resulting from the internal audits shall be verified.	• How corrective action verification regulated? <verification evidence> • Who verifies and when?	No corrective actions taken although necessary.	5.11.2
5.2	**Site factory inspections**			FSMA Title I Sec 101, Title III Sec 306
5.2.1	Factory inspections shall be planned and carried out (e.g. product control, hygiene, foreign material hazards, personnel hygiene and housekeeping). The frequency of inspections in every area (including outdoor areas) and every single activity shall be based on hazard analysis and assessment of associated risks and on the history of previous experience.	• How often and who makes site inspections? <site inspections protocol> • What is reviewed during site inspections? • For which areas do site inspections exist?	No site inspections are performed	Cross reference in product specific regulations (e.g. 21 CFR 108)
5.3	**Process validation and control**			
5.3.1	The criteria for process validation and control shall be clearly defined.			
5.3.2	In circumstances where the control of process and working environment parameters (temperature, time,	• How are temperatures monitored? • Where are temperatures recorded?	In case a legality issue occurs due to missing	Regulation 37/2005 (on the monitoring of temperatures in the means of transport,

	pressure, chemical properties etc.) is essential to ensure the product requirements, such parameters shall be monitored and recorded continuously and/ or at appropriate intervals.	<printed measurement data>	records. 4.12.4	warehousing and storage of quickfrozen foodstuffs intended for human consumption) 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.80 Processes and controls
5.3.3	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.	• How is it assured that reworks comply to specifications? • Where is rework documented? <model documentation for rework> • Who reviews rework results? • Who decides rework liberation? • How is it ensured that rework fulfils legal requirements?		4.18.5 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.80 Processes and controls
5.3.4	There shall be appropriate procedures for prompt notification, recording and monitoring of equipment malfunction and process deviations.	• What happens when a failure occurs? • What happens when cold chain is interrupted? <machinery stand still protocol>	In case failures are not noticed and result in a safety or legal problem	FSMA Title II Sec 204
5.3.5	Process validation shall be performed using the collected data that is relevant for product safety and the processes. If substantial modifications occur, a revalidation shall be carried out.			
5.4	**Calibration, adjustment and checking of measuring and monitoring devices**			
5.4.1	The company shall identify the measuring and monitoring devices required to ensure compliance with product requirements. These devices shall be recorded on a document and clearly identified.	• What kinds of monitoring devices exist? <monitoring devices list> • What is demanded of monitoring devices? • What monitoring device is adequate for which kind of measurement? • How are monitoring devices identified? <identification stickers on monitoring devices> • Do calibrated devices exist? <monitoring devices list>	The company has no measuring and monitoring devices	Inspection plan 21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils
5.4.2	All measuring devices shall be checked, adjusted and calibrated, under a monitoring system, at specified intervals and in accordance with defined recognised standard/ methods. The results of the checks, adjustments and calibrations shall be documented. Where necessary, corrective actions on devices and, if necessary, on process and products shall be carried out.	• How is measuring devices check organized? <calibration procedures> • Are measuring devices regularly calibrated? <calibration protocol> • Who is resposible for calibration? • How is calibration done? Where is it documented? <calibration records> • What corrective actions are taken when a tolerance deviation is found? <corrective actions> <calibration protocol> • Is calibration up to date? <calibration certificate>	No calibration is performed	
5.4.3	All measuring devices shall be used exclusively for	• What actions are taken when measurement results are	When defetive measuring	21 CFR Part: 110 – Current Good

	their defined purpose. Where the results of measurements indicate a malfunction, the device in question shall be immediately repaired or replaced.	uncertain? • How are embargoed measuring devices identified? <identification stickers>	devices are not exchanged and a safety issue ensues. (e.g. defective thermometers)	manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils
5.4.4	The calibration status of the measuring devices shall be clearly identified (labelling at the machine or on a list of test devices).	• How is calibration status of measuring device identified? <measuring devices list>		21 CFR Part: 110 – Current Good manufacturing practice in manufacturing, packaging or holding human food 110.40 Equipment and utensils
5.5	**Quantity checking (quantity control/ filling quantities)**			
5.5.1	The frequency and methodology of quantity checking shall be determined so that the legal requirements and customer specifications, or if appropriate, guidelines for nominal quantity are met.	• How is it ensured that legal requirements for amount control are met?	Legal requirements are not met due to lack of or insufficient amount measurements being made.	Regulation 2000/13 Cross reference in product specific regulations´ 21 CFR 101.9; 101.105
5.5.2	A procedure shall exist to define compliance criteria for lot quantity checking. This procedure shall also, among others, take into consideration the tare, the density and other critical attributes.			
5.5.3	Checks shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing lot.			
5.5.4	Results of these checks shall be compliant with defined criteria for all products ready to be delivered.			
5.5.5	For purchased, already pre-packed products from third parties, there shall be evidence about the compliance with the legal requirements for nominal quantity.	• How is it ensured that purchased, pre-packed products from third parties contain the correct product amount (applicable for retail branded products and other labels)? <inspection plan> <dealer evidence>	No evidence exists that purchased products comply with legal requirements.	
5.5.6	If applicable, all equipment used for final checking shall be legally approved.	• Are measuring devices in use regularly calibrated? • Where is calibration recorded? <calibration protocol> • Are there calibrated measuring devices? <calibration certificate>	Not even one calibrated device exists to inspect packed products	Regulation 2000/13
5.6	**Product analysis**			
5.6.1	There shall be procedures ensuring that all specified product requirements are met, including legal requirements and specifications. Microbiological, physical and chemical analysis required for that purpose shall be performed internally and/ or subcontracted.	• Which physical, chemical or microbiological analyses are made or subcontracted? <analyses results>	No reasults of analyses are available	Regulation 1881/2006 (contaminants) Regulation 1441/2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs Regulation 2073/2005 Regulation 37/2010 Cross reference in product specific regulations
5.6.2	Analyses, which are relevant for food safety, shall preferably be performed by laboratories having appropriate accredited programs/ methods (ISO 17025). If the analyses are performed by a factory internal or a laboratory not having appropriate accredited programs/ methods, the results shall be	• Is there an analytical laboratory on site? Is it accredited under ISO 17025? <accreditation evidence> • Are internal lab results verified by an accredited lab? • Which external laboratories are used? Are these accredited under ISO 17025?		120.25 Process verification for certain processors 21 CFR 120 Subpart B Pathogen Reduction FSMA Title II Sec 202

	verified on a regular basis by laboratories accredited on these programs/ methods (ISO 17025).	<accreditation evidence>		
5.6.3	Procedures shall exist which ensure the reliability of the internal analysis results on the basis of official recognised analysis methods. This shall be demonstrated by ring tests or other proficiency tests.	• How is it ensured that internal analytical methods are appropriate? • Are ring tests performed? <ring test performance evidence>		Regulation 96/23
5.6.4	A test plan shall be drawn up for internal and external analysis, based on hazard analysis and assessment of associated risks, which covers raw materials, semi-processed and finished products as well as processing equipments and packaging materials, and where necessary environmental tests. The test results shall be documented.	• Does an inspection plan exist? <inspection plan> • Who organizes inspection plan? Which products are encompassed by inspection plan? (raw materials, half-finished and finished products, packaging materials, environmental tests?) <inspection plan> • Is inspection plan based on risk analysis? <risk analysis> • Where are test results documented? <test results>	No inspection plan exists	Risk analysis
5.6.5	Results of analysis shall be evaluated promptly. Appropriate corrective measures shall be introduced for any unsatisfactory results. The analytical results shall be reviewed regularly in order to identify trends. Trends indicating potential unsatisfactory results shall be taken into consideration.	• Who reviews analytical results? • How are analytical results verified? • Are trends investigated? • Are corrective actions introduced when results are unsatisfactory? <corrective actions>	When test results exist that do not comply with legal requirements and no corrective actions were taken.	Regulation 1881/2006 (contaminants) Regulation 1441/2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs Regulation 2073/2005 Regulation 37/2010
5.6.6	Where internal analysis is undertaken, qualified and trained personnel shall be in place, as well as appropriate equipment and premises.	• Which tests are performed internally? • What qualifications have lab technicians? <qualification evidence> • Is an internal lab available? • Is an incubator, sterylization equipment available? • How is product contamination by internal lab prevented?		
5.6.7	For verification of finished product quality, internal organoleptic tests shall be carried out regularly. These tests shall be in accordance with specifications and related to the impact on respective parameters of product characteristic. The results of these tests shall be documented.	• When and how are organoleptic tests performed? <inspection plan> <documentation of organoleptic test results>		
5.6.8	Based on any internal or external information on product risks which may have an impact on food safety and / or quality (incl. adulteration and fraud), the company shall update its control plan and/ or take any appropriate measure to control impact on finished products.	For example, if an Alert System informs that a raw material sourced from a specific country regularly has specific rate of dangerous substance, and if the company is used to buying this specific raw material, the company shall increase the frequency of analysis of this raw material, to improve monitoring. On the other hand, if results of analysis always show good results, and if the raw material is considered as a low risk one, the company can decide to decrease the frequency of analysis.		
5.7	**Product quarantine (blocking/hold) and product release**			

5.7.1	A procedure shall be in place, based on hazard analysis and assessment of associated risks, for the quarantine (blocking/hold) and release of all raw materials, semi-processed and finished products and packaging materials. The procedure shall ensure that only products and materials conforming to product requirements are processed and dispatched.	• Who quarantines or releases products? <job description> • How are quarantined products identified?	When no procedures exist for product quarantine or release. When quarantined products go unchecked into further use and a safety issue occurs.	Risk analysis Regulation 178/2002 Process authority and/or product release required in product specific regulations (e.g. 21 CFR 106, 21 CFR 113) FSMA Title II Sec 207
5.8	**Management of complaints from authorities and customers**			
5.8.1	A system shall be in place for the management of product complaints.	• How are complaints handled? <complaint handling procedure>	If there is no procedure for complaint handling	Regulation 178/2002 21 CFR Part: 7– Enforcement Policy 7.40 Recall policy FSMA Title II Sec 206 7.41 Health hazard evaluation and recall classification 7.42 Recall strategy 7.45 FDA requested Recall 7.46 Firm-initiated recall 7.49 Recall communications 7.50 Public notification of recall 7.51 Recall status reports 7.55 Termination of a recall 7.59 General Industry guidance
5.8.2	All complaints shall be assessed by competent staff. Where it is justified appropriate actions shall be taken immediately, if necessary.	• Who ponders about complaint significance? • Who defines the actions to be taken? • Within what time frame must actions be taken?		
5.8.3	Complaints shall be analysed with a view to implementing preventive actions which avoid the recurrence of the non-conformity.	• Who manages complaint statistics? <complaint statistics> • How often are complaint statistics compiled? • What actions are taken to avoid recurrence?	No corrective actions were taken although a failure comes up more frequently or is considered as serious.	
5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons and to the senior management.	• To whom are complaint statistics data presented? <retailer complaint statistics data>		
5.9	**Management of incidents, product withdrawal, product recall**			
5.9.1	A documented procedure shall be defined for management of incidents and of potential emergency situations that impact food safety, legality and quality. This procedure shall be implemented and maintained. This includes as a minimum: the nomination and training of a crisis team, an alert contact list, sources of legal advice (if necessary), contacts availability, customer information, and a communication plan, including information to consumers.	• Who belongs to incident management staff? <phone list> • Who is informed when an incident occurs? • How are incidents managed? <crisis management procedures> • What is an incident? <incident management procedures>	If there is no incident management system implemented	Regulation 178/2002 21 CFR Part: 7– Enforcement Policy 7.40 Recall policy FSMA Title II Sec 206 7.41 Health hazard evaluation and recall classification 7.42 Recall strategy 7.45 FDA requested Recall 7.46 Firm-initiated recall 7.49 Recall communications 7.50 Public notification of recall 7.51 Recall status reports

				7.55 Termination of a recall 7.59 General Industry guidance
5.9.2	**KO N° 9: There shall be an effective procedure for the withdrawal and recall of all products, which ensures that involved customers are informed, as soon as possible. This procedure shall include a clear assignment of responsibilities.**	• How much is distribution involved with incident management? • When and who informs customer? <alarm plan> <phone list> A withdrawal / recall management procedure is not enough to define an incident management procedure.	If there is no procedure for recall and withdrawl in place.	Regulation 2001/95/EC about product safety
5.9.3	Updated emergency contact details (such as names and phone numbers of suppliers, customers and competent authorities) shall be available. A person of the company, who has the authority to initiate the incident management process, shall be permanently available.	• What kind of incident management is implemented? • Who is responsible for communication with customers, press/media and authorities? • Is a list of important telephone numbers available? <phone list>, <emergency plan> • Who is informed when a crisis occurs? <alarm plan> <phone list> • When are media involved? <incident management procedures>	No incident management is available in the company.	FSMA Title 3 Sec 301
5.9.4	The feasibility, effectiveness and timeliness of implementation of the withdrawal procedure shall be subject to regular internal testing, based on hazard analysis and assessment of associated risks but carried out at least once a year. This shall be carried out in a manner to ensure the effective implementation and operation of the procedure.	• How is effectiveness of withdrawal tested? • How often is effectiveness of withdrawal tested? <withdrawal test results>	When withdrawal procedures are not tested or when test results have shown that the procedures are ineffective but no corrective actions were implemented.	Risk analysis
5.10	**Management of non-conformities and non conforming products**			
5.10.1	A procedure shall exist for the management of all non-conforming raw materials, semi-finished and finished products, processing equipment and packaging materials. This shall include, as a minimum: - isolation/ quarantine procedures - hazard analysis and assessment of associated risks - identification (e.g. labelling) - decision about the further use (e.g. release, rework/ post treatment, blocking, quarantine, rejection/ disposal).	• What procedures exist for non-conforming products management? • How are non-conforming products identified? • What rules exist for product quarantine procedures? <quarantine tickets>	When no procedures exist for non-conforming products management.	Regulation 178/2002 21 CFR 189 Substances prohibited from use in human food. 21 CFR 182 Substances generally recognized as safe 21 CFR 185 Direct food substances affirmed as generally recognized as safe (GRAS) 21 CFR 186 Indirect food substances affirmed as generally recognized as safe
5.10.2	The responsibilities for the management of non-conforming products shall be clearly identified. The procedure for the management of non-conforming products shall be understood by all relevant employees.	• Who is responsible for putting non-conforming products into quarantine? <quarantine tickets> • Who may release quarantined products? <quarantine tickets> • How is it ensured that only authorized persons release quanrantined products? <quarantine tickets>	When employees do not know who is authorized to release quarantined products or when the products are in conditions to be released or when products are quarantined and a safety issue occurs.	
5.10.3	Where non-conformities are present, immediate corrections shall be taken to ensure that product	• What procedures are implemented with non-conforming products?		

	requirements are complied with.	<quarantine tickets> • Who devcides about non-conforming products? <quarantine tickets>		
5.10.4	Out of specification, final packaged products or packaging materials, both related to private labels, shall not be placed in the market under the label concerned. Exceptions shall be agreed in writing with the contract partners.	For example, evidences can be provided to show that products have not been placed on the market (e.g.contracts with external waste destroying service providers). Exceptions can be checked with examples (situations which already occured), by checking the content of the contract.		
5.11	**Corrective actions**	• in case of a renewal audit: were the corrective actions of the previous IFS audit applied?		
5.11.1	A procedure shall be in place for the recording and analysis of the non-conformities with the objective to avoid recurrences by preventive actions and/ or corrective actions.	• What are corrective actions procedures? <corrective actions procedures>	No corrective actions procedures exist.	21 CFR 120 HACCP 120.8 HACCP plan 120.10 Corrective actions 120.11 verification and validation
5.11.2 KO	**KO N° 10: Corrective actions shall be clearly formulated, documented and undertaken, as soon as possible to avoid further occurrence of non-conformity. The responsibilities and the timescales for corrective action shall be clearly defined. The documentation shall be securely stored, and easily accessible.**	• Which corrective actions were implemented? <model corrective action procedures> • Where are corrective actions documented? <model corrective action procedures> • Who is responsible for corrective actions? <model corrective action procedures > • How long may it take to implement corrective actions? <model corrective action procedures >	No corrective actions are taken. Corrective actions are not implemented within a short time span. Corrective actions are not documented No responsiblties are assigned to implement corrective actions.	FSMA Title I Sec 418 g
5.11.3	The performance of the implemented corrective actions shall be documented and the effectiveness shall be checked.	• Where are corrective actions documented? <model corrective action procedures> • How are corrective actions verified? <model with verified corrective action procedures>	Corrective actions are not documented and/r verified.	
6.	**Food defense and external inspections**	See specific Food defense Guidelines		FSMA Title I Sec 108
6.1	**Defense assessment**			
6.1.1	Responsibilities for food defense shall be clearly defined. Those responsible shall be key staff or shall have access to the top management team. Sufficient knowledge in this area shall be demonstrated.	• Who has the accountability for the food defense program? • What are the competence and qualifications demonstrated for the person(s) responsible for the food defense program? • What is the position of the person(s) responsible for the food defense program with respect to the management team? • How do management teams support the person(s) responsible for the food defense program? • Where are the responsibilities clearly defined? • Was this communicated to the members of the company? How?		
6.1.2	A food defense hazard analysis and assessment of associated risks shall have been performed and	• What are the legal / customer food defense requirements applicable to the company?		FSMA Title I Sec 108

	documented. Based on this assessment, and based on the legal requirements, areas critical to security shall be identified. Food defense hazard analysis and assessment of associated risks shall be conducted annually or upon changes that affect food integrity. An appropriate alert system shall be defined and periodically tested for effectiveness.	• How can the company demonstrate compliance with such requirements? • What is the process / procedure used to perform the hazard analyisis and assessment of associated risks? • Is the hazard analysis in line with legal and/or customer needs and/or expectations? • How do the systems assist the company to identify critical or high risk areas? • How often is a review of the food defense program performed? • What criteria does the company consider in order to determine the frequency to perform the hazard analysis, if is not done annually? • How is the company alerted of any food defense breach? • How does the company evaluate the effectiveness of the food defense program?		
6.1.3	If legislation makes registration or onsite inspections necessary, evidence shall be provided.	• What are the legal / customer food defense requirements applicable to the company? • Based on legal requirements in the country where the plant is located or by the country where the product is consumed, is it required to apply for formal registration? • If registration is required, who has this information? Could the company demonstrate compliance? • Is there any requirement for periodic inspection? If yes, then: - Who performs it? - Against what standard? - When was the last inspection? - What was the result of the inspection? - Is it required to provide evidence that deviations have been solved? (Corrective Actions) - What are the implications if a major breach is identified?		
6.2	**Site Security**			
6.2.1	Based on a hazard analysis and assessment of associated risks, identified areas critical to security shall be adequately protected to prevent unauthorized access. Access points shall be controlled.	• Based on the hazard analysis and assessment of associated risks, what areas have been identified as critical? • What control measures are in place in order to control the entrance to those areas? • How does the company maintain control over who enters to the premises and critical areas? • What are the access controls applicable to the following people? - Temporary employees - Contractors - Visitors - Employees - Carrier drivers	Unauthorized persons freely enter production or storage areas so that a safety risk occurs	21 CFR Part 108 Emergency Permit Control The Bioterrorism Act of 2002

6.2.2	Procedures shall be in place to prevent tampering and/ or allow identification of signs of tampering.	• Does the company define procedures to identify tampering of raw materials, Works in Process (WIP) and final goods? • Are there means to verify if products have been tampered? • Are employees trained in the identification of tampered products? • Does the design of packaging material include the identification of tamper evident measures? Is it required by law in the country of origin or destination? • Are there tests to verify that measures against tampering are properly applied and working properly?		
6.3	**Personnel & Visitor Security**			
6.3.1	Visitor policy shall contain aspects of food defense plan. Delivery and loading staff in contact with the product shall be identified and shall respect the access rules of the company. Visitors and external service providers shall be identified in areas with product storage and shall be registered at the time of access. They should be informed about the site policies and their access controlled accordingly.	• Do visitor / contractor access policies include controls to avoid that no members of the company are able to move freely without escorts inside the premises? • Are visitors and contractors informed of the food defense rules and their scope while inside company premises? • Does the company have defined means to ensure that contractors who will spend a long time inside the plants are properly identified, supervised and escorted inside critical areas? • Are there controls to ensure that the access for truck drivers who load or unload products/materials is restricted to defined areas inside and outside the building and company premises? Are there means to watch the movements of non-employees once they enter company premises? (E.g. cameras or guards at defined areas? Other procedures?) • If contractors and visitors are provided with access keys, are those keys programmed to limit the access to specified and selected areas? • If escorts are required to guide visitors and contractors at all times, are there arrangements to have defined guides at all shifts? • Are security/guards aware of how to deal in cases where there are no escorts available at any particular moment?		
6.3.2	All employees shall be trained in food defense on an annual basis or when significant program changes occur. The training sessions shall be documented. Employee hiring and employment termination practices shall consider security aspects as permitted by law.	• Does the annual training program include food defense? • How is food defense and associated controls explained to new employees? • Are there records that demonstrate that employees received food defense training? • Is training updated according to changes in the Food Defense program? • How are employees informed of major changes in the food defense program?		

		• Does the system evaluate training effectiveness? • Does training include controls of knowledge acquired from the last version of the food defense training? • What controls are implemented at the time of hire/termination of an employee or creation/termination of a service by a contractor? • Are access controls updated at the time of termination of an employee or when the work is finished on the part of a contractor?		
6.4	**External Inspections**			
6.4.1	A documented procedure shall exist for managing external inspections and regulatory visits. Relevant personnel shall be trained to execute the procedure.	• Is there a documented procedure that defines the criteria to follow in case an external organization requires access to the company's premises? • Are there clearly defined levels of authority to provide access to external organizations at all times? • Does the procedure define the means to proceed if or when a regulatory body requests access to the premises? • Are relevant functions aware of their responsibilities under such conditions? • Are levels of authority defined with respect to the kind of information that is allowed to be provided? • Are there means to ensure a complete record of activities done and details of the visit?		FSMA Title III Sec 306