IFS Food

IFS Food Version 7

Guideline for the IFS Food Assessment

Typical auditor questions, examples for KO/Major and cross references for European and United States legislation

VERSION 1

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ENGLISH

PREFACE

Aim

The implementation of IFS requirements often depends on the situation and risk assessment of the respective company. The objective of this guideline is to provide examples to support companies when preparing for the assessment and it may also be used by auditors to perform assessments in compliance with IFS requirements.

Focussing on products and processes

IFS offers a product certification standard, therefore the respective assessment is focussed on products / processes. Thus, any objective evidence is closely related to products and processes. The products that the auditor chooses as "the assessment trail" for questioning during the assessment are important. If the auditee can prove with objective evidence that these products – selected by the auditor in an appropriate quantity – are produced in a safe manner according to the agreed specification, it provides a reliable assessment of the auditee. The typical questions listed in the guideline are closely linked to checks on products. Sometimes it makes sense to ask these questions in order to get maximum information about a representative sample of products (retailer and own branded products) and about the auditee.

Incompleteness

The listed questions are just examples and cannot provide a fully comprehensive overview. The auditor shall adapt his assessment to the specific situation of the company case by case. The assessment is not automatically complete if the auditor asks every question from the list.

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 The list shows the current legal situation and will be out of date once new regulations apply.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

Improvements

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

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
1	**Governance and commitment**			
1.1	**Policy**			

1.1.1	The senior management shall develop, implement and maintain a corporate policy, which shall include, at a minimum:
	• food safety and product quality
	• customer focus
	• food safety culture.
	This corporate policy shall be communicated to all employees and shall be broken down into specific objectives for the relevant departments.
		• How and where is corporate policy documented?
		• What are the contents of the corporate policy?
		• Is food safety culture addressed in the corporate policy?
		  ◦ Was corporate policy, including food safety culture, communicated to all employees?
		  ◦ How were elements of food safety culture implemented within the company?
		  ◦ Are there specific objectives related to food safety culture? And are they communicated to relevant departments?
		• How was corporate policy communicated to all employees?
		• 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 the fulfilment of objectives?
		• What actions are taken by specific departments, e.g. purchasing, to attain the objectives?
		• What quality objectives are defined?
		• Are these objectives known by the employees concerned?
		• What tools are used to measure whether the objectives have been fulfilled?
		• When is the fulfilment of objectives reviewed?
		• How often is this review performed?
		<corporate policy>, <documented evidence of corporate policy communication>, <written review meeting minutes>, <list of attendees at review meeting>, <mailing list of review meeting minutes>, <overview of quality objectives>,<posters showing the different department objectives>, <internal audit report>
		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 processes of awareness of both topics in companies.
			• There is basically no review / other rating of objectives available.	• US
				• This cross reference should be seen as introduction. Please keep in mind that you have additional state regulations.
				• There are a lot of product specific cross references.

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
1.1.2	All relevant information related to food safety, product quality and authenticity shall be communicated effectively and in a timely manner to the relevant personnel.	• How is relevant information transmitted to the 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 KO	**KO n° 1:** **The senior management shall ensure that employees are aware of their responsibilities related to food safety and product 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 the Auditor has evidence during the assessment that key employees are not aware of their responsibilities and this leads to a Food Safety and/or Legality issue.	
1.2.2	The senior management shall provide sufficient and relevant resources to meet the product and process requirements.	• How were the necessary resources defined? <budget plan>	• When senior management does not provide enough resources and this leads to a Food Safety and/or Legality issue.	
1.2.3	The department responsible for food safety and quality management shall have a direct reporting relationship to the senior management. An organisational chart shall be available, showing the structure of the company.	• Who is the designated person responsible for FS / QM? • To whom does the QMD manager report? • Is an organisation chart available? • How is the organisation structured? <job description>, <Organisation chart>		
1.2.4	The senior management 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)? • Interview of at least: QAM, person responsible for labelling, person responsible for product development, person responsible for production, person responsible for monitoring CCP´s Processes can be understood as ISO processes (see also chapter 2.3, Part 1 of the standard)	• When relevant employees have no process knowledge and this leads to a Food Safety and/or Legality issue and/or severe quality issues not connected to a specific contractually agreed customer requirement.	

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1.2.5	The senior management shall have a system in place to ensure that the company is kept informed of all relevant legislation, scientific and technical developments, industry codes of practice, food safety and product quality issues, and that they are aware of factors that can influence food defence and food fraud risks.	• How does management ensure that all relevant food safety laws are in place and known? • 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 an absence of legal knowledge and information on relevant laws leads to a Food Safety and/or Legality issue.	**Regulations (EC)** • 178/2002 (General principles of food law) • 852/2004(General Food Hygiene) • 853/2004(food of animal origin) • 854/2004 (Official controls) • 2073-2005 (microbiological criteria) • 1441/2007 (microbiological criteria f) • 1935/2004 (materials […] contact with food) • 10/2011 (plastic materials […] contact with food) • 2023/2006 (GMP for materials […] contact with food) • 1169/2011 (provision of food information to consumers) • 1924/2006 (nutrition and health claims) • 1829/2003 (GMO) • 1830/2003 (traceability and labelling of GMO) • 37/2005 (monitoring of temperatures i[…] quick frozen foodstuffs • 1881/2006 (contaminants) 37/2010 (pharmacologically active substances) • 1925/2006 (addition of vitamins and minerals) • 1331/2008 (authorization procedure for foods additives, enzymes and flavourings) • 1332/2008 (food enzymes) • 1333/2008 (food additives) • 1334/2008 (food flavourings) • 834/2007 (organic production and labelling) • 1924/2006 (health claims) **Directives** • 2001/95/EC (General Product Safety) 1998/83/EC (Quality of water) • 1999/2/EC (ionising radiation) • 21 Code of Federal Regulations (CFR) • Food Allergen Labeling and Consumer Protection Act of 2004 • 21 CFR 189 Substances prohibited from use in human food.

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1.2.6	The senior management shall ensure that the certification body is informed of any changes that may affect the company's ability to conform to the certification requirements. This shall include, at a minimum: • any legal entity name change • any production site location change. For the following specific situations: • any product recall • any product recall and / or withdrawal by official order for food safety and / or food fraud reasons • any visit from health authorities which results in notifications and / or penalties issued by authorities The certification body shall be informed within three (3) working days.	• Have there been any important changes? • Have there been any regulatory actions against the company • If yes, has the CB been notified? • What is the name of the authorities and when was the last visit? <CB notifications>, <RASFF>, <FDA/USDA recall notification database>, <company webpage>	In case the CB has not been informed about e.g. • an important change • legal actions against the company • recall.	
1.3	**Customer focus**			
1.3.1	A process shall be in place to identify fundamental needs and expectations of customers. The feedback from this process shall be used as input for the company's continuous improvement.	• How are customer needs and expectations identified? • How often are these identified? • What were the results of the last customer survey • How were these results evaluated regarding quality objectives? • Do identified needs influence the production process? <questionnaire/survey regarding customers' needs and expectations>, <analysis of customer surveys>, <quality objectives>, <survey analyses>		

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1.4	**Management review**			
1.4.1	The senior management shall ensure that the food safety and quality management system is reviewed at least annually, or more frequently if significant changes occur. Such reviews shall include, at a minimum: • a review of objectives and policies including elements of food safety culture • results of audits and site inspections • positive and negative customer feedback • process compliance • authenticity and conformity issues • status of corrections and corrective actions • notifications from authorities.	• When is the quality management system reviewed and evaluated? • How often was the system reviewed last year? • What was the result of the review? • Does the management review assess a minimum 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 withdraws/recalls, ◦ incidents, corrective actions, results out of specification and non-conforming materials, ◦ process performance and product compliance, ◦ review of the HACCP system and changes which may affect the quality and food safety system, ◦ developments in scientific information related to products, ◦ improvement of quality system efficiency and production process, ◦ improvement of product, related to customer requirements, ◦ needs in resources (including investments)? • Are the food safety culture objectives reviewed during the annual management review? <review report>	• When the quality management system is not reviewed regularly and there is no assurance that it works properly.	• 21 CFR 117.170 (b) Reanalysis
1.4.2	Actions from the management review shall be clearly aimed at supporting improvement. The management review shall assess follow-up actions from previous management reviews and any change that could affect the food safety and quality management system. The management review shall be fully documented.	• Based on the review result, have any actions for improvement been taken? <improvement actions>	• No actions are taken following identified weaknesses.	

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1.4.3	The senior management shall identify and regularly review (e.g. by internal audits or on-site verification) the infrastructure and work environment needed to conform to product requirements. This shall include, at a minimum: • buildings • supply systems • machines and equipment • transport • 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 risks, for investment planning.	• How often is this review performed? • 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 the work environment evaluation? • Who evaluated the work environment? • What were the results of the work environment assessment? • Were the results used for further work environment planning? • What risks were identified according to the results of the work environment assessment? • What are the work environment related investments for the near future? • When is the objective achievement reviewed? <review>, <review minutes>,<internal audit report>, <investment plan>, <corrective actions>, <risk assessment>	• When infrastructure is not evaluated and therefore a safety, quality and legal risk of products occur. • When work environment is not evaluated and therefore a safety, quality and legal risk of products occur.	
2	**Food safety and quality management system**			**Reg. (EC) 852/2004 (on the hygiene of foodstuffs)**
2.1	**Quality management**			
2.1.1	**Document management**			• **21 CFR Part: 117, § 117.126 (a)**
2.1.1.1	The food safety and quality management system shall be documented and implemented, and shall be kept 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.	• Reg. (EC) No. 852/2004 Art. 5 (1), (2) (f) • 21 CFR 117.126 Food Safety Plan. • 21 CFR 117.315 (c) Requirements for record retention"
2.1.1.2	All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to the relevant personnel at all times.	• 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 117.305 General requirements applying to records

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
2.1.1.3	A documented procedure shall exist for the control of documents and their amendments. All documents which are necessary for compliance with the product requirements shall be available in their latest version. The reason for any amendments to documents, critical to the product requirements, shall be recorded.	• 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? • How is document validity identified? • How is it ensured that only valid documents are in circulation? • Are the reasons for any amendments to documents, critical for the product requirements recorded? <procedure>, <distribution lists>, <review of examples>	• When documents are unavailable and this endangers legality, safety or quality of the product. • When void / obsolete or out-of date documents are not identified as such and thus endanger legality, safety or quality.	• Reg. (EC) 852/2004 Art. 5, (4) (b)
2.1.2	**Records and documented information**			• **21 CFR Part: 117, § 117.305, § 117.310, § 117.315**
2.1.2.1	Records and documented information shall be legible and genuine. They shall be maintained in a way that subsequent revision or amendment is prohibited. If records are documented electronically, a system shall be in place to ensure that only authorised personnel have access to create or amend those records (e.g. password protection).	• What records/information exist? • Are the records/information complete? • Are the records/information available? • Are records/information plausible? • Are records/information legible? • What kind of assurance is given that records/ information cannot be subsequently manipulated? • Are the records/information reviewed by a supervisor? • How are amendments to records/information carried out? • Who is authorized to make amendments? • How are amendments authorised? <review of examples>	• When insufficient or no records are made and thus endanger legality, safety or quality. • When records are illegible and therefore no evidence exists for legally required checks/ inspections. • When a general problem exists regarding record changes/ amendments in the company.	• Reg. (EC) 852/2004 Art. 5, (4) • 21 CFR 117.305 General requirements applying to records

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2.1.2.2	All records and documented information shall be kept in accordance with legal and customer requirements. If no such requirements exist, records and documented information shall be kept for a minimum of one year after the specified shelf life. For products which have no shelf life, the duration of record and documented information keeping shall be justified and this justification shall be documented.	• Where are records/information stored? • Who stores records/information? • How long are records/information kept? • On what basis were records/information storage times defined? • For products with a short shelf life, was record/ information storage time definition based on risk analysis? <procedure documents>, <risk assessment>	• When records are not stored in accordance to legal requirements.	• Art. 5 (4) Reg. (EC) No. 852/2004 • 21 CFR 120.12 (d) Records • 21 CFR 117.315 (c) Requirements for record retention
2.1.2.3	Records and documented information shall be securely stored and easily accessible.	During the course of the assessment, the auditor evaluates if all required evidence has been provided to the auditor in time and without difficulties.	• In case records can´t be found.	• Art. 5 (4) Reg. (EC) No. 852/2004
2.2	**Food safety Management**			• **21 CFR Part: 117, § 117.126 Food safety plan**
2.2.1	**HACCP system**			• **Reg. (EC) 852/2004 Art. 5 21 CFR Part: 117, § 117.30 Hazard Analysis.** • **21 CFR Part: 117 Subpart C Hazard Analysis and Risk-Based Preventive Controls** • **21 CFR 120 Hazard Analysis and Critical Control Point (HACCP) Systems"**
2.2.1.1	The basis of the company's food safety management system shall be a fully implemented, systematic and comprehensive HACCP based plan, following the Codex Alimentarius principles and any legal requirements of the production and destination countries which may go beyond such principles. The HACCP plan shall be specific and implemented at the production site.	• What principles is the company's HACCP plan based on? • Does every site/plant have a separate HACCP plan? • Which specific regulations are taken care of in the HACCP plan? • Are the legal requirements of the destination country known, especially the labelling regulations? <HACCP plan>	• If there is no HACCP plan. • If legal requirements are not included in the HACCP plan. • If there is no HACCP plan for each individual site /plant.	• Art. 5 (1) Reg. (EC) No. 852/2004 • 21 CFR 117.126 (a) (1) Food Safety Plan. • 21 USC 350g (a) Hazard analysis and risk-based preventive controls • 21 CFR 120.8 (a) HACCP plan
2.2.1.2	The HACCP plan shall cover all raw materials, packaging materials, products or product groups, as well as every process from incoming goods up to the dispatch of finished products, including product development.	• Does the HACCP plan cover all product groups, processes incl. product development, and product packaging? Which processes are performed? • Are processes for DEL-Products available? <product group overview>, <flow chart>	• When the HACCP plan does not cover all product groups and processes.	• Art. 1 (1) (b), 3, 5 Reg. (EC) No. 852/2004 • 21 CFR 117.130 (a) (1) Hazard analysis. • 21 USC 350g (a) Hazard analysis and risk-based preventive controls • 21 CFR 120.7 Hazard analysis • 21 CFR 120.8 (a) HACCP plan

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
2.2.1.3	The company shall ensure that the HACCP plan is based upon scientific literature or expert advice obtained from other sources, which may include: trade and industry associations, independent experts and regulatory authorities. This information shall be maintained in line with any 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? • 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 supersede requirements of the standard. Related to Canadian and US law, certain forms and formats are required.) <references of used literature, etc.>	• When the HACCP plan is not based on scientific literature or technically verified data about products and processes and therefore causes a food safety or legal risk.	• Art. 5 (2) Reg. (EC) No. 852/2004 • 21 CFR 117.130 (a) (1) Hazard analysis. • 21 CFR 120.7 (a) (2) Hazard analysis
2.2.1.4	The company shall ensure that in the event of changes to raw materials, packaging materials, processing methods, infrastructure and/or equipment, the HACCP plan is reviewed to assure that product safety requirements are complied with.		• In case the generally changes are not addressed in the HACCP system at an appropriate time.	• Art. 5 (2) 2 Reg. (EC) No. 852/2004 • 21 CFR 117.170 Reanalysis. • 21 USC 350g (i) Hazard analysis and risk-based preventive controls • 21 CFR 120.7 (a) (4) Hazard analysis
2.2.2	**HACCP team**			• **21 CFR Part: 117, § 117.126 Food safety plan**
2.2.2.1	**Assemble HACCP Team:** The HACCP team shall have the appropriate specific knowledge and expertise and be a multidisciplinary team which includes operational staff.	• Who are the members of the HACCP team? • Which departments/functions are included in the HACCP team? • How was qualification for HACCP team membership verified? • What hazards are connected to the product? • Does a contract exist with an external expert? <service contract>, <evidences for education, advanced training>	• Although there is a lack of product knowledge, no external expert has been consulted and this results in food safety and legal risk.	• Art. 4 (2) Annex II Chapt. XII No. 2 Reg. (EC) No. 852/2004 • 21 CFR 117.180 (c) Requirements applicable to a preventive controls qualified individual and a qualified auditor. • 21 CFR 120.8 (a) HACCP plan • 21 CFR 120.13 Training
2.2.2.2	Those responsible for the development and maintenance of the HACCP plan shall have an internal team leader and shall have received adequate training in the application of the HACCP principles and specific knowledge of the product and processes.	• What is the content of a HACCP training course? • When was the last HACCP training course held? • Who participated in the HACCP training course? <HACCP training proofs>, <training proofs>		• Art. 4 (2) Annex II Chapt. XII No. 2 Reg. (EC) No. 852/2004 • 21 CFR 117.180 (c) Requirements applicable to a preventive controls qualified individual and a qualified auditor. • 21 CFR 120.8 (a) HACCP plan • 21 CFR 120.13 Training

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2.2.3	**HACCP analysis**			**Reg. (EC) 852/2004 Art. 5 21 CFR Part: 117, § 117.130**
2.2.3.1	**Describe product:** A full description of the product including all relevant information on product safety shall exist, such as: • composition • physical, organoleptic, chemical and microbiological characteristics • 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).	• Art. 5 (2) Reg. (EC) No. 852/2004 • 21 CFR 117.130 (c) (2) (i) Hazard analysis • 21 CFR 120.7 (d) Hazard analysis
2.2.3.2	**Identify intended use:** The intended use of the product shall be described in relation to the expected use of the product by the end consumer, taking vulnerable groups of consumers into account.	• What is the intended use of the product? • For which consumer group is the product unsuitable? • 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 detailing for whom the product is suitable/unsuitable.	• Art. 5 (2) Reg. (EC) No. 852/2004 • 21 CFR 117.130 (c) (2) (viii) Hazard analysis • 21 CFR 120.7 (d) Hazard analysis
2.2.3.3	**Construct flow diagram:** A flow diagram shall exist for each product, or product group, and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall be dated, and after the determination of control measures, clearly identify each CCP and other control measures. In the event of any changes, the flow diagram shall be updated.	• Are flow charts available for all products? • Are the flow charts dated? • Are all CCPs identified in the flow chart? • Are all CCPs numbered? • Are all flow charts with CCPs up-to date? <flow charts for all products>	• Flow charts are unavailable for any of the products or charts are not conform to the specifications.	
2.2.3.4	**On-site confirmation of the flow diagram:** Representatives of the HACCP team shall verify the flow diagram, by on-site verifications, at all operation stages and shifts. Where appropriate, amendments to the diagram shall be made.	• Was the flow chart confirmed during a HACCP meeting? <meeting minutes>	• When flow charts are not validated.	

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2.2.3.5	**Conduct a hazard analysis for each step:**
	A hazard analysis shall be conducted for all possible and reasonably expected physical, chemical (including radiological and allergens) and biological hazards. The analysis shall also include hazards linked to materials in contact with food, packaging materials and hazards related to the work environment. The hazard analysis shall consider the likely occurrence of hazards and the severity of their adverse health effects. Consideration shall be given to the specific control measures that shall be applied to control each hazard.
		• Does a hazard analysis exist for each step?
		• Does it include every hazard?
		• Which biological, physical and chemical hazards can be expected?
		• Does a risk analysis for all product groups including harm and likelihood exist?
		• Compare information from the plant tour with the hazard analysis,
		  ◦ are all observed hazards addressed?
		  ◦ are the assigned risk levels appropriate?
		<hazard analysis>, <risk assessment>
			• 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.
			• When, due to lack of a risk analysis, a safety risk exists.
				• Art. 14 Reg. (EC) No. 178/2002 (Basic-Reg.)
				• Art. 5 (2) (a) Reg. (EC) No. 852/2004
				• 21 CFR 117.130 (b) (c) Hazard analysis
				• 21 USC 350g (b) Hazard analysis and risk-based preventive controls
				• 21 CFR 120.7 Hazard analysis

2.2.3.6	**Determine critical control points and other control measures:** The determination of relevant CCPs and other control measures 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? • Of the defined CCPs, can the process be influenced in order to prevent, eliminate or reduce a food safety hazard? • Which other control measures are identified? • Which prerequisite measures were taken regarding CCPs? • Which prerequisite measures are documented? • How are the measures documented? <hazard analysis>, <flow chart>, <HACCP plan>, <decision tree>, <prerequisite measures>	• When CCPs were not identified as such and/or they are not under permanent control so that a safety risk exists. • When, due to missing prerequisite measures, not all other control measures are covered and this leads to a safety risk.	• Art. 5 (2) (b) Reg. (EC) No. 852/2004 • 21 CFR 117.135 Hazard analysis • 21 USC 350g (c) Hazard analysis and risk-based preventive controls • 21 CFR 120.7 (a) (5) Hazard analysis
2.2.3.7	**Establish critical limits for each CCP:** For each CCP, the appropriate critical limits shall be defined and validated 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>, <Overview of CCPs with limits>	• When there are no critical limits for each CCP or they are insufficient and this causes a safety risk.	• Art. 5 (2) (c) Reg. (EC) No. 852/2004 • 21 CFR 120.8 (b) (3) HACCP plan
2.2.3.8	**Establish a monitoring system for each CCP**			• Art. 5 (2) (d) Reg. (EC) No. 852/2004 • 21 CFR Part: 117, § 117.145

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2.2.3.8.1 KO	**KO N° 2:** **Specific monitoring procedures in terms of method, frequency of measurement or observation and recording of results, shall be established for each CCP to detect any loss of control at that CCP. Each defined CCP shall be under control. Monitoring and control of each CCP shall be demonstrated by records.**	• How are CCPs monitored? • Are the CCPs under control? • How is the monitoring of each CCP documented? • Who is responsible for documenting? • 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 a company is unaware of the loss of control at a CCP. • If records don't clarify who, when and where a measure is taken or with what results. • If records are not stored for an adequate time period. • If legal requirements in connection with the CCP records are not met.	• Art. 5 (2) (d) (g) Reg. (EC) No. 852/2004 • 21 CFR 117.135 Hazard analysis • 21 CFR 117.145 Monitoring • 21 USC 350g (c) Hazard analysis and risk-based preventive controls • 21 CFR 120.8 (b) (4) HACCP plan
2.2.3.8.2	Records of CCP monitoring shall be verified by a responsible person within the company and maintained for a relevant period.	• Who is responsible for verifying the records of CCP monitoring? • For how long are records of CCP monitoring kept?	• If records of CCP monitoring are not verified by a responsible person within the company and/ or if they are not maintained for a relevant period.	• Art. 5 (2) (f), (4) (c) Reg. (EC) No. 852/2004 • 21 CFR 117.180 (a) Requirements applicable to a preventive controls qualified individual and a qualified auditor
2.2.3.8.3	The operative personnel in charge of the monitoring of CCPs and other control measures shall have received specific training / instruction.	• What training has been performed? <Review of training records>		• Art. 4 (2) Annex II Chapt. XII No. 2 Reg. (EC) No. 852/2004 • 21 CFR 117.180 (c) Requirements applicable to a preventive controls qualified individual and a qualified auditor • 21 CFR 120.13 Training
2.2.3.8.4	Control measures, other than CCPs, shall be monitored, recorded and controlled by measurable or observable criteria.	• Who is responsible for monitoring other records of control measures? <Review of other records of control measures >		• 21 CFR 117.145 Monitoring
2.2.3.9	**Establish corrective actions:** In the event that the monitoring indicates that a particular CCP or control measure other than CCP is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any action taken relating to non-conforming products and identify the root cause for the loss of control of CCPs.	• 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 other control measures as well in IFS.	• When there are no corrective actions defined or no corrective actions are taken. • When corrective actions are not documented.	• Art. 5 (2) (e) Reg. (EC) No. 852/2004 • 21 CFR 117.150 Corrective actions and corrections. • 21 USC 350g (e) Hazard analysis and risk-based preventive controls • 21 CFR 120.8 (b) (5) HACCP plan • 21 CFR 120.10 Corrective actions

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
2.2.3.10	**Establish verification procedures:** Procedures of verification shall be established to confirm that the HACCP plan is working correctly. Verification of the HACCP plan shall be performed at least once a year. Examples of verification activities include: • internal audits, • analyses, • sampling, • deviations, • complaints. The results of this verification shall be incorporated into the HACCP plan.	• 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? • On what date was the HACCP plan last changed? <audit reports or other reports for verification>	• When no verification was carried out and this leads to a safety risk.	• Art. 5 (2) (f) Reg. (EC) No. 852/2004 • 21 CFR (a) 117.155 Verification • 21 CFR 117.160 Validation • 21 CFR 117.165 Verification of implementation and effectiveness • 21 USC 350g (f) Hazard analysis and risk-based preventive controls • 21 CFR 120.8 (b) (6) HACCP plan • 21 CFR 120.11 Verification and validation
2.2.3.11	**Establish documentation and record keeping:** Documentation related to the HACCP plan shall be in place. Examples of documentation include: • hazard analysis • determination of CCPs and other control measures • determination of critical limits • processes, procedures • Examples of records include: • outcome of CCPs and other control measure monitoring activities • observed deviations and implemented corrective actions.	• What HACCP plan related documents exist? • Do these documents include processes, procedures and results? <inspection plans>, <records>, <product descriptions>, <hazard analysis>, <risk assessment>	• When the HACCP plan is not sufficiently documented and this leads to a legality issue.	• Art. 5 (2) (g) Reg. (EC) No. 852/2004 • 21 CFR 117.155 (b) Verification • 21 CFR 117.190 Implementation records required for this subpart • 21 USC 350g (g) (h) Hazard analysis and risk-based preventive controls • 21 CFR 120.8 (b) (7) HACCP plan • 21 CFR 120.12 Records
3.	**Resource Management**			
3.1	**Human resources**			
3.1.1	All personnel performing work that affects product safety, quality and legality shall have the required competence, appropriate to their role, as a result of education, work experience and / or training.	• 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.	• Art. 4 (2), Annex II Chap. XII No. 1, 2 Reg. (EC) No. 852/2004 • 21 CFR 110.10 (c) Personnel • 117.4 Qualifications of individuals who manufacture, process, pack, or hold food

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
3.1.2	The responsibilities, competencies and job descriptions for all job titles with an impact on food safety and product quality shall be clearly defined, documented and in place. Assignment of key roles shall be defined.	• For which positions do written job descriptions exist? • What is regulated in the job descriptions? • Who, for example, substitutes the QA manager during their absence? • What is the content of the job descriptions? • For which positions do job descriptions exist? <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 110.10 (d) Personnel • 117.4 Qualifications of individuals who manufacture, process, pack, or hold food
3.2	**Personal hygiene**			• **Art. 4 (2), Annex II Chap. VIII Reg. (EC) No. 852/2004**
3.2.1	Documented requirements relating to personal hygiene shall be in place and shall include, at a minimum, the following areas: • hair and beards • protective clothing (including their conditions of use in staff facilities) • hand washing, disinfection and hygiene • eating, drinking and smoking • actions to be taken in case of cuts or skin abrasions • fingernails, jewellery and personal belongings (including medicines) • notification of infectious diseases and conditions impacting food safety via a medical screening procedure. The requirements shall be based on hazard analysis and assessment of associated risks.	• What is the policy regarding personal hygiene? • Are the rules based on a risk analysis? • The rules regarding personnel hygiene include hand cleaning, food and beverages, smoking, handling of injuries, fingernails and jewelry, hair and beards? • Where is smoking permitted? • How should lesions be treated/covered? • What kinds of hair restraints are required 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. <hygiene rules for employees>, <risk assessment>	• When insufficient rules for personal hygiene cause a safety risk. • When no correspondent risk analysis exists.	• Art. 4 (2), Annex II Chap. VIII Reg. (EC) No. 852/2004 • 21 CFR 110.10 Personnel • 21 CFR 117.10 Personnel
3.2.2 KO	**KO N° 3:** **The requirements for personal hygiene shall be in place and applied by all relevant personnel, contractors and visitors.**	• How is the hygiene policy communicated? • Are personnel hygiene rules also followed by external service providers/workmen and visitors? • How is it assured that external persons know the relevant hygiene rules? • How are employees monitored during work? Is employee compliance to hygiene rules checked on a regular basis? <hygiene rules for employees>, <hygiene rules for visitors>, <observation on the shop floor.>, etc.	• When, during the assessment major violations of the rules are identified that lead to a safety risk.	• Art. 4 (2), Annex II Chap. VIII Reg. (EC) No. 852/2004 • 21 CFR 110.10 Personnel • 21 CFR 117.10 Personnel

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
3.2.3	Compliance with personal hygiene requirements shall be checked regularly.	<hand swab tests, etc.>, <minutes site inspection>, <list of identified failures>, etc.		• Art. 4 (2), Annex II Chap. VIII Reg. (EC) No. 852/2004 • 21 CFR 110.10 (d) Personnel
3.2.4	Visible jewellery (including piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated by hazard analysis and assessment of associated risks and shall be effectively managed.	• Is it permitted to wear jewelry and watches in production areas? • Is authorisation based on risk hazard analysis? <risk assessment>, <personnel hygiene rules>	• When wearing jewellery or a watch causes a food or employee safety risk.	• 21 CFR 110.10 (b) (4) Personnel • 21 CFR 117.10 (b) (4) Personnel
3.2.5	Cuts and skin abrasions shall be covered with a coloured plaster/bandage different from the product colour. Where appropriate: • plasters / bandages shall contain a metal strip • single use gloves shall be worn.	• What colour is the plaster and where is it used? • Does the plaster contain a metal strip? • What is an employee required to observe in case of a hand injury? <personnel hygiene rules>	• When hand injuries result in a product safety risk (e.g. an uncovered purulent wound that comes into contact with the product).	• 21 CFR 110.10 (b) (5) (9) Personnel • 21 CFR 117.10 (b) (5) (9) Personnel
3.2.6	In work areas where wearing headgear and/or beard snood (coverings) is required, the hair shall be covered completely to prevent product contamination.	• In which production areas is wearing protective headgear and/or beard snood mandatory? • What kind of headgear is used? • How shall headgear be used? <personnel hygiene rules> <observation during plant tour>	• When incorrect wear or absence of headgear and/or bear snood ensues a product safety risk.	• 21 CFR 110.10 (b) (6) Personnel • 21 CFR 117.10 (b) (6) Personnel
3.2.7	Clearly defined usage rules shall exist for work areas / activities where it is required to wear gloves (coloured differently from the product colour).	• In which production areas is it mandatory to wear gloves? • What kinds of gloves are used? • When must gloves be changed? • How is compliance with these rules checked? <glove swab test results >, <on-site inspections>, <observation during plant tour>, <personal hygiene rules>	• When missing or unclean gloves ensue a product safety risk.	• 21 CFR 110.10 (b) (5) Personnel
3.2.8	Suitable protective clothing shall be available and 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.	

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
3.2.9	All protective clothing shall be thoroughly and regularly laundered in-house, by approved contractors or by employees. This decision shall be justified by risk assessment. Defined requirements shall ensure, at a minimum: • sufficient segregation between dirty and clean clothing at all times • defined laundering conditions on water temperature and detergent dosage • avoidance of contamination until use. The effectiveness of the laundering shall be appropriately monitored.	• How is protective clothing laundered? • Are there any employees who launder their protective clothing at home? • Is protective clothes laundering based on a risk analysis? • What are the rules regarding protective clothing? • Are protective clothing rules based on risk analysis? • When must protective clothing be changed? • How is the laundering procedure checked for effectiveness? • What guidelines exist regarding the laundering of protective clothing? <risk assessment>, <personal hygiene rules>, <protective clothes swab test results>, examples of areas to observe: catering, changing rooms, smoking area, toilets, high risk areas, etc.	• When insufficient laundering ensues a product contamination risk. • When the lack of protective clothing ensues a product safety risk.	
3.2.10	In case of any health issue or infectious disease that may have an impact on food safety, actions shall be taken to minimise contamination risks.	• How shall personnel and visitors behave in case of the presence or suspicion of an infectious disease? • How is it ensured that personnel and visitors know the guidelines? <personal hygiene rules>, <visitors hygiene rules>	• When due to the infectious disease of an employee, a product safety risk is given and no preventive steps are taken by the company.	• Art. 4 (2), Annex II Chap. VIII Reg. (EC) No. 852/2004 • 21 CFR 110.10 (a) Personnel • 21 CFR 117.10 (a) Personnel
3.3	**Training and instruction**			• **Art. 4 (2), Annex II Chap. XII Reg. (EC) No. 852/2004** • **21 CFR 110.10 (c) Personnel A lot of training references are made in the product specific regulations. (e.g. 113.10; 123.10)** • **21 CFR 120.13 Training**
3.3.1	The company shall implement documented training and/or instruction programs with respect to the product and process 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.	• Who is responsible for training? • What evidences is there of the trainer's qualification? • What was the content of the last training session? • 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 program>, <training schedule>, <training proof>	• When, due to lack or insufficient training, a product safety or legality risk exists. • When legally required food safety instructions are not undertaken.	• Art. 4 (2), Annex II Chap. XII No. 1 Reg. (EC) No. 852/2004 • 21 CFR 117.4 Qualifications of individuals who manufacture, process, pack, or hold food • 21 CFR 117.180 (c) Requirements applicable to a preventive controls qualified individual and a qualified auditor. • 21 CFR 120.13 Training

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
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/instructed 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? <trainings proofs>		• 21 CFR 117.4 (b) Qualifications of individuals who manufacture, process, pack, or hold food
3.3.3	Records of all training/instruction events shall be available, stating: • list of participants (including their signature) • date • duration • contents of training • name of trainer/tutor. A procedure or program shall be 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 proof of training? • 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.	• 21 CFR 117.4 (d) Qualifications of individuals who manufacture, process, pack, or hold food • 21 CFR 117.180 (d) Requirements applicable to a preventive controls qualified individual and a qualified auditor
3.3.4	The contents of training and/or instruction shall be regularly reviewed and updated when necessary. Special consideration shall be given, at a minimum, to these specific issues: • food safety • food fraud • product quality • food defence • food related legal requirements • product/process modifications • feedback from the previous documented training/instruction programs.	• How are training contents reviewed? • When are training contents reviewed? • When did the latest training content update take place? • What was the content of the latest update? <assessment results>, <reviews>, < tests> specific issues: non-conformitites, failure, complaints, etc.	• During the on-site evaluation, evidence was given that employees did not act according to knowledge transmitted in the training sessions and this lead to a product safety risk.	• Art. 4 (2), Annex II Chap. XII No. 2, 3 Reg. (EC) No. 852/2004
3.4	**Staff facilities**			• **Art. 4 (2), Annex II Chap. I Reg. (EC) No. 852/2004**
3.4.1	The company shall provide suitable staff facilities, which shall be proportional in size, equipped for the number of personnel, designed and controlled so to minimise food safety risks. Such facilities shall be kept in a clean and good condition.	Staff facilities = e.g. changing room, smoking area, dining room, etc. • 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>	• When social facilities are underequipped or are out of proportion to the number of employees so that a safety issue arises.	• Art. 4 (2), Annex II Chap. I No. 9 Reg. (EC) No. 852/2004 • 21 CFR 110.35 (a) Sanitary operations • 21 CFR 117.35 (a) Sanitary operations

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
3.4.2	Product contamination risks by food and drink and/or foreign materials shall be minimised. Consideration shall be given to food and drink from vending machines, canteen and/or brought to work by personnel.	• May employees bring food from home? • May employees take medicine along to their work place? • Does a risk analysis exist regarding foreign bodies from social facilities? <risk assessment>, <personal hygiene rules>		• 21 CFR 110.10 (b) (7) Personnel
3.4.3	Changing rooms shall be located to allow direct access to the areas where food products are handled. If this is not possible, preventive measures shall be in place to minimise product contamination risks. 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? • Are there cleaning facilities for boots and protective aprons? • Locker rooms give direct access to processing areas? • How is protective clothing handled during breaks/intervals? • Does a risk analysis exist for locker rooms with no direct access to processing areas? <risk assessment>, <personal hygiene rules>	• When no locker-rooms exist or there is no separation between outdoor and protective clothing although high risk products are being processed. • When a contamination occurs due to locker-room location which leads to food product safety problem.	• Art. 4 (2), Annex II Chap. I No. 9 Reg. (EC) No. 852/2004
3.4.4	Toilets shall neither have direct access nor pose contamination risks to an area where food products are handled. 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.	• Where are toilets located? • How is the ventilation system for toilets working? • Do toilets pose any risk to production? • Do toilets open directly into production areas?	• When toilet refuse poses a contamination risk.	• Art. 4 (2), Annex II Chap. I No. 3, 5, 6 Reg. (EC) No. 852/2004 • 21 CFR 110.37 (d) (4) Sanitary facilities and controls • 21 CFR 117.37 (d) Sanitary facilities and controls
3.4.5	Hand hygiene facilities shall be provided and shall address, at a minimum: • adequate number of wash basins • suitably located at access points to and/or within production areas • sole use for cleaning hands only. The necessity of similar equipment in further areas (e.g. packing area) shall be based on hazard analysis and assessment of associated risks.	• 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.	• Art. 4 (2), Annex II Chap. I No. 4 Reg. (EC) No. 852/2004 • 21 CFR 110.37 (e) (1) Sanitary facilities and controls
3.4.6	Hand hygiene facilities shall provide: • running potable water at an appropriate temperature • appropriate cleaning and disinfection equipment • appropriate means 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?		• Art. 4 (2), Annex II Chap. I No. 4 Reg. (EC) No. 852/2004 • 21 CFR 110.37 (e) (2) (3) Sanitary facilities and controls • 21 CFR 117.37 (e) Sanitary facilities and controls

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
3.4.7	Where the processes require a higher standard of hygiene, the hand washing equipment shall provide in addition: • hand contact-free fittings • hand disinfection • 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.	
3.4.8	Based on hazard analysis and assessment of associated risks, a program shall be in place to control effectiveness of hand hygiene.			• 21 CFR 117.135 (3) (6) Preventive controls • 21 CFR 120.6 (a) (4) Sanitation standard operating procedures • 21 CFR 120.8 (c) Hazard Analysis and Critical Control Point (HACCP) plan
3.4.9	Where it is justified by risk assessment, cleaning and disinfection facilities shall be available and used for boots, shoes and further protective clothing.	• Is there any equipment for shoe or other protective equipment cleaning? <risk assessment>, <observation during site tour>		
4.	**Operational processes**			
4.1	**Contract agreement**			
4.1.1	All requirements related to food safety and product quality, within the defined agreement with customers, and any revision of these clauses, shall be communicated to and implemented by 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? • How is it ensured that customers are informed about product changes? • Who checks and approves specifications?	• When there are no approved specifications and no clarity exists if the required product can be delivered.	

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.1.2	In accordance with customer requirements, the senior management shall inform their affected customers, as soon as possible, of any issue related to product safety or legality, including non-conformity/ies identified by competent authorities.			• 21 CFR 7.49 (a) (3) Recall communications • 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.
4.2	**Specifications and Formulas**			• **21 CFR Part: 117, § 117.30 (c)(2)(i)**
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 in compliance with legal and customer requirements.	<specifications>		**Compliance with legal requirements: e. g. labelling requirements:** • **Horizontal requirements** ◦ Reg. (EC) No. 853/2004 (hygiene rules for food of animal origin) ◦ Reg. (EC) No. 1924/2006 (health claims) ◦ Reg. (EC) No. 1925/2006 (addition of vitamins and minerals) ◦ Reg. (EC) No. 834/2007 (on organic products) ◦ Reg. (EC) No. 889/2008 (imp. reg. on organic products) ◦ Reg. (EU) No. 1332/2008 (food enzymes) ◦ Reg. (EU) No. 1333/2008 (food additives) ◦ Reg. (EU) No. 1334/2008 (flavourings) ◦ Reg. (EU) No. 1169/2011 (food information) ◦ Reg. (EU) No. 231/2012 (specifications on food additives)

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
cont. 4.2.1.1				• Reg. (EU) No. 432/2012 (list of permitted health claims made on foods) • Reg. (EU) No. 1151/2012 (quality schemes for agricultural products) • Del. Reg. (EU) No. 665/2014 (mountain products) • Imp. Reg. (EU) No. 828/2014 (absence or reduced presence of gluten in food) • Reg. (EU) 2018 / 848 (on organic products) • Dir. 76/211/ECC (making-up by weight or by volume of certain prepackaged products) • **Vertical requirements** • Art. 1a, 3 5, 7, 7a Reg. (EEC) No. 2136/89 (sardines) • Art. 2 5 Reg. (EEC) No. 1536/92 (tuna and bonito) • Art. 13 15, 17 Reg. (EC) No. 1760/2000 (bovine animals, beef and beef products) • Art. 3 Reg. (EC) No. 1825/2000 (beef and beef products) • Art. 8 12, 14, Annex II Reg. (EC) No. 110/2008 (spirit drinks) • Art. 1, 3 5, 9 11, Annex III, V Reg. (EC) • No. 543/2008 (poultrymeat) • Art. 12 ff. Reg. (EC) No. 589/2008 (eggs) • Art. 3 6, Annex I Imp. Reg. (EU) No. 543/2011 (fruit and vegetables and processed fruit and vegetables sectors) • Art. 1, 3 6 Imp. Reg. (EU) No. 29/2012 (olive oil) • from 20/07/2016: Art. 10 Reg. (EU) No. 609/2013 (food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control)

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
cont. 4.2.1.1				• Art. 74 ff., 78, 92, 100, 119 121, Annex III, VII Reg. (EU) No. 1308/2013 (agricultural products) • Art. 5, 7 Reg. (EU) No. 1337/2013 (fresh, chilled and frozen meat of swine, sheep, goats and poultry) • Art. 35 ff., Annex I, III Reg. (EU) No. 1379/2013 (fishery and aquaculture products) • Art. 5 8, Annex II Reg. (EU) No. 251/2014 (aromatised wine products) • Art. 2, 3 Reg. (EU) 2016/128 (dietary foods for special medical purposes) • Art. 4, 22, 23, 44-47, 49 ff. Reg. (EU) 2019/33 (certain wine sector products) • up to 19/07/2016: Art. 5 Dir. 96/8/EC (foods intended for use in energy-restricted diets for weight reduction) • Art. 2, Annex Dir. 1999/4/EC (coffee extracts and chicory extracts) • Art. 2, 3, Annex I, II Dir. 2000/36/EC (cocoa and chocolate products) • Art. 2, 3 Dir. 2001/110/EC (honey) • Art. 2, Annex Dir. 2001/111/EC (certain sugars) • Art. 3, Annex I Dir. 2001/112/EC (fruit juices and certain similar products) • Art. 2, Annex I Dir. 2001/113/EC (fruit jams, jellies and marmalades and sweetened chestnut purée) • Art. 6, 8, 9 Dir. 2002/46/EC (food supplements) • Art. 4, 6, 7 Dir. 2003/40/EC (natural mineral waters and ozone-enriched air used for the treatment of natural mineral waters and spring waters) • Art. 8 Dir. 2006/125/EC (processed cereal-based foods and baby foods for infants and young children) (until remittal of a delegated Reg. according to Art. 11, Art. 20 (4) Reg. (EU) No. 609/2013)

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
cont. 4.2.1.1				• Art. 11 13 Dir. 2006/141/EC (infant formulae and follow-on formulae) (until remittal of a delegated Reg. according to Art. 11, Art. 20 (4) Reg. (EU) No. 609/2013) • Art. 3, 7 9, Annex I, II, III Dir. 2009/54/EC (natural mineral waters) **e. g. compositional requirements:** • Reg. (EEC) No. 2136/89 (sardines) • Reg. (EEC) No. 1536/92 (tuna and bonito) • Reg. (EC) No. 853/2004 (hygiene rules for food of animal origin) • Reg. (EC) No. 110/2008 (spirit drinks) • Reg. (EC) No. 543/2008 (poultrymeat) • Reg. (EC) No. 589/2008 (eggs) • Imp. Reg. (EU) No. 543/2011 (fruit and vegetables and processed fruit and vegetables sectors) • Imp. Reg. (EU) No. 29/2012 (olive oil) • Reg. (EU) No. 231/2012 (food additives) • Reg. (EU) No. 609/2013 (food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control) • Reg. (EU) No. 1308/2013 (agricultural products) • Reg. (EU) No. 1379/2013 (fishery and aquaculture products) • Reg. (EU) No. 251/2014 (aromatised wine products) • Reg. (EU) 2016/128 (dietary foods for special medical purposes) • Dir. 96/8/EC (foods intended for use in energy-restricted diets for weight reduction) • Dir. 1999/4/EC (coffee extracts and chicory extracts) • Dir. 2000/36/EC (cocoa and chocolate products)

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
cont. 4.2.1.1				• Dir. 2001/110/EC (honey) • Dir. 2001/111/EC (certain sugars) • Dir. 2001/112/EC (fruit juices and certain similar products) • Dir. 2001/113/EC (fruit jams, jellies and marmalades and sweetened chestnut purée) • Dir. 2002/46/EC (food supplements) • Dir. 2003/40/EC (natural mineral waters and ozone-enriched air used for the treatment of natural mineral waters and spring waters) • Dir. 2006/125/EC (processed cereal-based foods and baby foods for infants and young children) (until remittal of a delegated Reg. according to Art. 11, Art. 20 (4) Reg. (EU) No. 609/2013) • Dir. 2006/141/EC (infant formulae and follow-on formulae) (until remittal of a delegated Reg. according to Art. 11, Art. 20 (4) Reg. (EU) No. 609/2013) • Dir. 2009/54/EC (natural mineral waters) • 21 CFR 189 Substances prohibited from use in human food. • 21 CFR 182 Substances generally recognized as safe • 21 CFR 184 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

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.2.1.2	A procedure to control the creation, approval and amendment of specifications shall be in place and shall include, where required, the acceptance of the customer(s). Where required by customers, product specifications shall be formally agreed. This procedure shall include the update of finished product specifications in case of any modification related to: • raw materials • formulas/recipes • processes which impact the finished products • packaging materials which impact the finished products.	• How are specifications compiled, checked and approved? • Are there specifications for all final products? • How are up to date specifications recognizable? <specifications>	• When not all specifications for final products are up to date and in conformance with legal requirements.	
4.2.1.3 KO	**KO N° 4:** **Specifications shall be available and in place for all 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? • What assurance is given that specifications are in conformance with legal requirements? • Who writes, checks and approves specifications? <proof of specification compliance, e.g. lab results>	• When not all raw materials, ingredients, additives, packaging materials and rework have specifications. • When specifications do not comply with legal requirements.	**Compliance with legal requirements:** e.g. • Reg. (EC) No. 396/2005 (MRL pesticides) • Reg. (EC) No. 2073/2005 (microbiological criteria) • Reg. (EC) No. 1881/2006 (maximum levels on contaminants) **Legal requirements in product specific regulations:** e.g. • 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, 170
4.2.1.4	Specifications and/or their contents shall be available on site for 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.	
4.2.1.5	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 (e.g. GMOs), verifiable procedures shall be in place.	• Who writes, amends, checks and approves specifications? Are there products / raw materials consisting of GMOs, containing GMOs or produced from GMOs?	• When specifications are used but have not been properly approved and it is not clear if they can be complied with.	• Art. 21, 36 (2), (3) (d) Reg. (EU) No. 1169/2011 Reg. (EU) No. 828/2014 • 21 CFR 101.91 (c) Gluten-free labeling of food.

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.2.2	**Formulas/Recipes**			
4.2.2.1 KO	**KO N° 5:** **Where there are customer agreements related to:** • **product recipe (including raw materials characteristics)** • **process** • **technological requirements** • **packaging** • **labelling** **these shall be complied with.**	• What assurance is given that specified recipe, process, technological requirement, packaging, labelling is followed? • How is recipe compliance checked? • If no specific technological requirements and / or 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 there is evidence that recipe and finished product specifications do not fit together. • When during a traceability test there is evidence that the 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	For each new development or modification of products, a hazard analysis and assessment of associated risks shall be conducted.	• 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.	• Art. 5 (2) Reg. (EC) No. 852/2004 • 21 CFR 117.170 Reanalysis • 21 USC 350g (i) Hazard analysis and risk-based preventive controls
4.3.2	The product development/modification process shall result in specifications about formulation, packaging requirements, manufacturing processes and process parameters related to the fulfilment of product requirements. This includes factory trials and product testing. The progress and results of product development/ modification shall be recorded.	• What do product development procedures look like? • 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? • What tests are made while a product is developed? • Are all steps and test results for product development properly recorded? • Is the developed product submitted to trial runs? <product development documentation>, <trial run documentation>, <test results>, <organoleptic test results evaluation>, <product development procedures>	• 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.	

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.3.3	Shelf-life tests or adequate validation through microbiological, chemical and organoleptic evaluation shall be carried out and consideration shall be given to product formulation, packaging, manufacturing and declared conditions. In accordance with this evaluation, the shelf life shall be established.	• How are shelf lives determined? • Are organoleptic test results considered for shelf life determinations? • Are products submitted to shelf-life tests? <shelf-life test results>, <microbiological tests>	• When no proof for defined shelf-life exists and a safety issue can occur.	
4.3.4	A procedure shall be in place to ensure that labelling complies with current legislation of the destination country/ies 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.	**Compliance with legal EC-labelling requirements:** e. g. • Dir. 76/211/ECC (making-up by weight or by volume of certain pre-packaged products) • Reg. (EU) No. 1169/2011, Reg. (EU) No. 1337/2013, Reg. (EU) No. 828/2014 • Reg. (EC) No. 1924/2006 • Reg. (EC) No. 1925/2006 • Reg. (EC) No. 834/2007, Reg, (EC) No. 889/2008 • Reg. (EU) No. 1151/2012 • Reg. (EU) No. 1308/2013 • Reg. (EU) No. 1332/2008 • Reg. (EC) No. 1333/2008 • Reg. (EC) No. 1334/2008 Please also see requirement 4.2.1.1 **Compliance with legal labeling requirements:** e.g. • 21 CFR 101 Food Labeling • 21 CFR 107.10 Nutrient information • 21 CFR 107.20 Directions for use
4.3.5	Recommendations for preparation and / or use of food product instructions shall be established, where appropriate.	• 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).	• Art. 27 Reg. (EU) No. 1169/2011 • Color additive: 21 CFR Part: 70 • 21 CFR 107.20 Directions for use

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.3.6	The company shall demonstrate through studies and/or perform relevant tests to validate nutritional information or claims which are declared on labelling, throughout the shelf life of the products.			• Art. 31 (4) Reg. (EU) No. 1169/2011 • 21 CFR 101.9 (g) Nutrition labeling of food
4.3.7	In the event of changes to process characteristics or product formulation, including rework and/or packaging materials, the company shall ensure that the food safety and product quality requirements are complied with. Labelling shall be reviewed and adapted when necessary.	• Who reviews and ensures that specifications are met in the event of changes to the recipe or processes?	• When it is not sure if a safety or legality issue occurs due to applied changes.	
4.4	**Purchasing**			
4.4.1	The company shall control purchasing processes to ensure that all externally sourced raw materials, semi-finished products, packaging materials and services, which have an impact on food safety and product quality, conform to defined requirements.	• 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.	• Art. 10 Reg. (EC) No. 852/2004 21 CFR 110.80 Processes and controls • 21 CFR 117.405 Requirement to establish and implement a supply-chain program **Legal requirements:** • 21 CFR 189 Substances prohibited from use in human food. • 21 CFR 182 Substances generally recognized as safe • 21 CFR 184 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

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.4.2	A procedure for the approval and monitoring of suppliers (internal and external) shall be in place. The approval and monitoring procedure shall contain clear assessment criteria, such as: • audits performed by an experienced and competent person • certificates of analyses • supplier reliability • complaints • required performance standards.	• Does an approval procedure exist for new suppliers and co-packers and services? • How are supplies monitored? • Are suppliers graded? • Have suppliers been barred? • How is a barred supplier identified? • How often are external audits made? • Which criteria are consulted for supplier assessment? • Which supplier has analysis certificates? • How was the risk analysis for supplier approval performed? <risk assessment>, <supplier procedures>, <analysis certificates>, <external audit plan>, <supplier audits>, <supplier grading systems>, <product entry monitoring>, <lab tests>, <co-packers list>, <certificate for co-packer>	• When there are no approval procedures for suppliers and this ensues a safety risk. • No risk analysis was made.	• 21 CFR 117.415 Responsibilities of the receiving facility • 21 CFR 117.435 Onsite audit
4.4.3	The results from the supplier assessments shall be reviewed regularly and this review shall be justified by risk assessment. Records of the reviews and the consequential actions of the assessment shall be documented.	• Who reviews the results of supplier assessments? • How often are the results of supplier assessments reviewed? • What actions are taken after review of the results for supplier assessments? <assessment results>	• When the results for supplier assessment are not taken into account and this ensues a safety or legality issue.	• 21 CFR 117.475 Records documenting the supply-chain program
4.4.4	The purchased raw materials, semi-finished products and packaging materials shall be checked in accordance with the existing specifications and justified by risk assessment for their authenticity. The schedule of these checks shall take into account, at a minimum, defined food safety and product quality risks. The frequency and/or scope of sampling shall be based on: • the impact of the raw materials, semi-finished products and packaging materials on the finished product • the supplier's status.	• How are purchased products and their specifications reviewed? • Does a test schedule exist? <incoming product check-list>, <lab tests>, <test schedule>	• When purchased products are never checked for compliance with specifications.	• 21 CFR 117.405 Requirement to establish and implement a supply-chain program

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.4.5	The purchased services shall be checked in accordance with the existing specifications. The schedule of these checks shall take into account, at a minimum: • the defined service requirements • the supplier's status (according to its assessment) • the impact of the service on the finished product.	• How are services monitored? • Are suppliers graded? • Have suppliers been barred? • How is a barred supplier identified? • How is the qualification of suppliers ensured? • How often are external audits made? • Which criteria are consulted for supplier assessment? • Which supplier has analysis certificates? • How was the risk analysis for supplier approval performed? <risk assessment>, <supplier procedures>, <analysis certificates>, <external audit plan>, <supplier audits>, <supplier grading systems>, <product entry monitoring>, <lab tests>, <co-packers list>, <certificate for co-packer>		
4.4.6	Where a company outsources a part of the product processing and/or primary packaging and/or labelling, the company shall have it documented in the food safety and quality management system and ensure control over such processes to guarantee that food safety and product quality are not compromised. Control of such outsourced processes shall be identified and documented. When required by the customer, there shall be evidence that he has been informed and has agreed to such outsourced process.	• How is the qualification of suppliers ensured? • Are there any co-packers? / suppliers of the outsourced processes? • How are they monitored? <lab tests>, <suppliers of outsourced processes list>, <certificate for suppliers>, external audit plan>, <supplier audits>,		
4.4.7	A written agreement shall be in place, covering the outsourced processes and describing any arrangements made in connection with it, including in-process controls, sampling and analyses.	• Are contracts with outsourcing companies available? <contracts>		
4.4.8	The company shall approve the supplier of the outsourced processes through: • certification against IFS Food or other GFSI recognised food safety certification standard or • documented supplier audit, performed by an experienced and competent person, which shall include, at a minimum, requirements for food safety, product quality, legality and authenticity.	• Are the suppliers of the outsourced processes IFS certified? Or certified to other GFSI recognised food safety certification standard? • If not, was a documented supplier audit performed? By whom? <lab tests>, <suppliers of outsourced processes list>, <certificate for suppliers>, <external audit plan>, <supplier audits>		

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.5	Product packaging			**Regulations (EC)** • Art. 4 (2), Annex II Chap. X No. 1 Reg. (EC) No. 852/2004 + • Reg. (EU) No. 1935/2004 (materials and articles intended to come into contact with food) • Reg. (EC) No. 1895/2005 (certain epoxy derivatives in materials and articles intended to come into contact with food) • Reg. (EC) No. 2023/2006 (materials and articles intended to come into contact with food) • Reg. (EC) No. 282/2008 (recycled plastic materials and articles intended to come into contact with food) • Reg. (EC) No. 450/2009 (active and intelligent materials and articles intended to come into contact with food) • Reg. (EU) No. 10/2011 (plastic materials and articles intended to come into contact with food) **Directives** • Dir. 84/500/ECC (ceramic articles intended to come into contact with foodstuffs) • Dir. 93/11/ECC (N-nitrosamines and N- nitrosatable substances from elastomer or rubber teats and soothers) • Dir. 2007/42/ECC (materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs)

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.5.1	Based on hazard analysis, assessment of associated risks and intended use, the company shall define the key parameters for the packaging materials in detailed specifications complying with the current relevant legislation and other relevant hazards or risks. The company shall check and verify the suitability and existence of functional barrier(s) of the consumer unit packaging material for each relevant product tests/analysis, such as: • organoleptic tests • storage tests • chemical analyses • migration test results.	• Does a risk assessment also exist for packaging material without direct contact to food, to prove the evidence of direct negative influence on the product? • 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 in use? • 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 assessment>, <packaging material specifications>	• Packaging material that does not comply with legislation. Not all packaging materials have specifications. • No risk analysis was made.	**www.foodcontactmaterials.com** **Directives** • Dir. 84/500/ECC • Dir. 93/11/ECC • Dir. 2007/42/ECC **Regulations (EC)** • Art. 4 (2), Annex II Chap. X No. 1 Reg. (EC) No. 852/2004 + • Reg. (EU) No. 1935/2004 • Reg. (EC) No. 1895/2005 • Reg. (EC) No. 2023/2006 • Reg. (EC) No. 282/2008 • Reg. (EC) No. 450/2009 • Reg. (EU) No. 10/2011 • Reg. (EC) 1169/2011, Art. 12, 13 • 21 CFR 109 Unavoidable contaminants in food for human consumption and packaging material • 21 CFR 170 Food additives • 21 CFR 171 Food additive petitions • 21 CFR 172 Food additives permitted for direct addition to food for human consumption • 21 CFR 173 Secondary direct food additives permitted in food for human consumption • 21 CFR 178 Indirect food additives: Adjuvants, production aids, and sanitizers • 21 CFR 180 Food additives permitted in food or in contact with food on an interim basis pending additional study • 21 CFR 110.80 Processes and controls

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.5.2	For all packaging materials which could have an impact on products, certificates of conformity shall exist which attest compliance with legal requirements. In the event that no specific legal requirements are applicable, evidence shall be available to demonstrate that packaging materials are suitable for use. This applies for packaging materials which could have an influence on raw materials, semi-finished and finished products	<certificates of conformity>, <migration tests>		**Regulations (EU)** • Art. 16 Reg. (EU) No. 1935/2004 • Reg. (EC) No. 1895/2005 • Reg. (EC) No. 282/2008 • Reg. (EC) No. 450/2009 • Reg. (EU) No. 10/2011 **Directives** • Dir. 84/500/ECC • Dir. 2007/42/ECC
4.5.3	The company shall ensure that the used packaging and labelling used correspond to the product being packaged and comply with agreed customer product specifications. This shall be regularly checked and documented.	• Which process is in place to ensure conformity?		• Art. 12, 13 Reg. (EU) No. 1169/2011 • 21 CFR 101 Food Labelling
4.6	**Factory location**			
4.6.1.	The company shall investigate the extent to which the factory environment (e.g. ground, air) may have an adverse impact on food safety and product quality. Where it is established that product safety and/or quality is at risk of being compromised, appropriate control measures shall be implemented. The effectiveness of the implemented measures shall be periodically reviewed (e.g. extremely dusty air, strong smells).	• Does a location investigation exist? Can a location have a negative influence on product quality? • What protective measures have been established if potentially damaging materials/substances are nearby? • Is the efficiency of protective measures regularly reviewed? • Who reviews the efficiency of the established protective measures? • How is efficiency of established protective measures reviewed? <location analysis>, <protective measures>, <corrective actions>	• 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.	• Art. 4 (2), Annex II Chap. I No. 2 Reg. (EC) No. 852/2004 • 21 CFR 110.20 Plant and grounds • 21 CFR 117.20 Plant and grounds
4.7	**Factory exterior**			
4.7.1	All external areas of the factory shall be clean, tidy and maintained in good condition. Where natural drainage is inadequate, a suitable drainage system shall be installed.	• Are factory exteriors tidy? • Are factory exteriors reviewed through internal audits? • 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? <audit results>		• Art. 4 (2), Annex II Chap. I No. 8 Reg. (EC) No. 852/2004 • 21 CFR 110.20 (a) (3) Plant and grounds • 21 CFR 110.37 Sanitary facilities and controls

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.7.2	Outdoor storage shall be kept to a minimum. Where goods are stored outside, it shall be justified by risk assessment to ensure that there are no contamination risks or adverse effects on food safety and quality.	• Are goods stored outdoors? • What is stored outdoors? • What rules exist for outdoor storage? • Is outdoor storage based on risk analysis? <risk assessment>	• No risk analysis exists for outdoor storage. • Goods under outdoor storage are influenced in a way that a safety risk is given (e.g. unprotected primary packaging material is kept outdoors, becomes mouldy and is not barred from use).	
4.8	**Plant layout and process flows**			• **21 CFR Part: 117, § 117.20**
4.8.1	A site map covering all buildings of the facility shall be available. Plans shall be in place that clearly describe the process flow of : • finished products • packaging materials • raw materials • personnel • waste • water	• 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 established, reviewed and where necessary, modified to ensure that the microbiological, chemical and physical contamination risks of raw materials, packaging material, semi-finished and finished products are avoided. The cross-contamination risks 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.	• Art. 4 (2), Annex II Chap. I No. 2, Chap. IX No. 3 Reg. (EC) No. 852/2004 • Reg. (EC) No. 853/2004
4.8.3	In the case of areas sensitive to microbiological, chemical and physical risk(s) which is/are justified by risk assessment, they shall be designed and operated to ensure product safety is not compromised.	• Are there high care areas? • Are high care areas ventilated? • How often are air born micro-organism counts made? • Who carries out the micro-organism measurements? <micro-organism count results>	• When ventilation is missing in high care areas and a safety problem is given.	• Art. 4 (2), Annex II Chap. II No. 1 Reg. (EC) No. 852/2004 • 21 CFR 110.20 Plant and grounds

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.8.4	Laboratory facilities and in-process controls shall not affect 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).	• Art. 4 (2), Annex II Chap. V Reg. (EC) No. 852/2004
4.9	**Production and storage premises**			
4.9.1	**Constructional requirements**			
4.9.1.1	Premises where food products are prepared, treated, processed and stored shall be designed and constructed to ensure food safety.	• 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 compliance with legal requirements.	• Art. 4 (2), Annex II Chap. I, Chap. II No. 1 Reg. (EC) No. 852/2004 • 21 CFR 110.20 Plant and grounds
4.9.2	**Walls**			• **21 CFR Part: 117, § 117.20 (b) (4)**
4.9.2.1	Walls shall be designed and constructed to prevent the accumulation of dirt, reduce condensation and mould growth and facilitate cleaning.	• Are walls mouldy?	• Extreme mould build-up which ensues a contamination risk.	• Art. 4 (2), Annex II Chapt. II No. 1 (b) (f) Reg. (EC) No. 852/2004 • 21 CFR 110.20 (b) (4) Plant and grounds
4.9.2.2	The surfaces of walls shall be in good condition and easy to clean; they shall be impervious and wear-resistant to minimise product contamination risks.	• How often are walls cleaned? <cleaning schedule>, <cleaning evidence>		• Art. 4 (2), Annex II Chapt. II No. 1 (b) (f) Reg. (EC) No. 852/2004 • 21 CFR 110.20 (b) (4) Plant and grounds • 21 CFR 110.35 (a) Sanitary operations
4.9.2.3	The junctions between walls, floors and ceilings shall be designed to facilitate cleaning.	• Are wall to floor junctions and corners rounded?		• 1 CFR 110.20 (b) (4) Plant and grounds • CFR 110.35 (a) Sanitary operations
4.9.3	**Floors**			• **21 CFR Part: 117, § 117.20 (b) (4)**
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>		• Art. 4 (2), Annex II Chap. II No. 1 (a) (f) Reg. (EU) No. 852/2004 • 21 CFR 110.20 (b) (4) Plant and grounds • 21 CFR 110.35 (a) Sanitary operations

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.9.3.2	The hygienic disposal of water and other liquids shall be ensured. Drainage systems shall be easy to clean and designed to minimise product contamination risks (e.g. entry of pests, areas sensitive to transmission of odour or contaminants).	• How is waste water disposal ensured? • How often are gullies cleaned? <cleaning evidence>, <drainage schedule>		• Art. 4 (2), Annex II Chap. I No. 8 Reg. (EC) No. 852/2004 • 21 CFR 110.37 (b) (2) (3) Sanitary facilities and controls
4.9.3.3	Water or other liquids shall reach drainage using appropriate measures without difficulty. Puddles shall be avoided.	• Are there water or other liquid puddles on the floors of production areas?		• Art. 4 (2), Annex II Chap. I No. 8 Reg. (EC) No. 852/2004 • 21 CFR 110.37 (b) (5) Sanitary facilities and controls
4.9.3.4	In food handling areas, machinery and piping shall be arranged to allow waste water, if possible, to flow directly into a drain.	• Where is machinery which produces a large amount of waste water located? <machinery lay-out>		• Art. 4 (2), Annex II Chap. I No. 8 Reg. (EC) No. 852/2004 • 21 CFR 110.37 (b) (5) Sanitary facilities and controls
4.9.4	**Ceilings/Overheads**			• **21 CFR Part: 117, § 117.20 (b) (4)**
4.9.4.1	Ceilings (or, where no ceilings exist, the inside of roofs) and overhead fixtures (including piping, cableway, lamps, etc.) shall be constructed to minimise the accumulation of dirt and condensation and shall not pose any physical and/or microbiological contamination risks.	• How often are ceilings cleaned? <cleaning evidence>, <cleaning evidence>	• Ceilings are very dirty and dirt can fall on the product.	• Art. 4 (2), Annex II Chap. II No. 1 (c) Reg. (EC) No. 852/2004 • 21 CFR 110.20 (b) (4) Plant and grounds • 21 CFR 110.35 (a) Sanitary operations
4.9.4.2	Where false ceilings are used, access to the vacant area shall be provided to facilitate cleaning, maintenance and inspection for pest control.	• How often are false ceilings cleaned? <cleaning evidence>, <cleaning evidence>		
4.9.5	**Windows and other openings**			• **21 CFR Part: 117, § 117.20 (b) (4)**
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?		• Art. 4 (2), Annex II Chap. II No. 1 (d) Reg. (EC) No. 852/2004 • 21 CFR 110.20 (a) Plant and grounds
4.9.5.2	Where there are contamination risks, 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.	• Art. 4 (2), Annex II Chap. II No. 1 (d) Reg. (EC) No. 852/2004
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 to avoid any contamination.	• Are windows sealed with insect gratings? • Is the integrity of gratings regularly reviewed? <monitoring schedule>, <pest control schedule>	• Windows are open and no insect gratings are in place so that pests can enter production areas and a contamination risk exists.	• Art. 4 (2), Annex II Chap. II No. 1 (d) Reg. (EC) No. 852/2004 • 21 CFR 110.20 (b) (7) Plant and grounds

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.9.5.4	In areas where unpackaged products are 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.	• Art. 4 (2), Annex II Chap. I No. 2 (c) Reg. (EC) No. 852/2004
4.9.6	**Doors and gates**			• **21 CFR Part: 117, § 117.20 (b) (4)**
4.9.6.1	Doors and gates shall be in good condition and easy to clean. They shall be constructed of non-absorbent materials to avoid: • splintering parts • flaking paint • corrosion.	• Are doors damaged?	• Doors are open or damaged so that pests can enter production areas and a contamination risk exists. Pests are visible.	• Art. 4 (2), Annex II Chap. II No. 1 (e) Reg. (EC) No. 852/2004 • 21 CFR 110.20 (a) Plant and grounds
4.9.6.2	External doors and gates shall be constructed to prevent the access of pests; they shall be self-closing, unless non-essentiality is justified by risk assessment.	• Do outer doors prevent pest entrance into production areas?		• Art. 4 (2), Annex II Chap. I No. 2 (c) Reg. (EC) No. 852/2004 • 21 CFR 110.35 (c) Sanitary operations
4.9.6.3	Plastic strip curtains separating the internal areas shall be in good condition and easy to clean.	• Are curtains damaged?		
4.9.7	**Lighting**			• **21 CFR Part: 117, § 117.20 (b) (4)**
4.9.7.1	All production, storage, receipt and dispatch areas shall have adequate levels of light.	• What is the assurance that all working areas are adequately illuminated?		• Art. 4 (2), Annex II Chap. I No. 7 Reg. (EC) No. 852/2004 • 21 CFR 110.20 (b) (5) Plant and ground
4.9.8	**Air conditioning/Ventilation**			• **21 CFR Part: 117, § 117.20 (b) (4)**
4.9.8.1	Adequate natural and/or artificial ventilation shall be in place in all areas.	• How is the ventilation reviewed?		• Art. 4 (2), Annex II Chap. I No. 5, 6 Reg. (EC) No. 852/2004 • 21 CFR 110.20 (b) (6) Plant and ground
4.9.8.2	If ventilation equipment is installed, filters and other components shall be easily accessible and checked, cleaned or replaced as necessary.	• 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.	• Art. 4 (2), Annex II Chap. I No. 5 Reg. (EC) No. 852/2004 • 21 CFR 110.35 (a) Sanitary operations
4.9.8.3	Air conditioning equipment and artificially generated airflow shall not compromise product safety and quality.	• Is the use of air during production based on risk analysis? • Are there production areas with under- or over-pressurization? <risk assessment>	• When air supply causes contamination, which ensues a food safety risk.	• Art. 4 (2), Annex II Chap. I No. 2 (c) Reg. (EC) No. 852/2004 • 21 CFR 110.40 (a) Equipment and utensils

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
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?		• Art. 4 (2), Annex II Chap. I No. 2 (b), (c) Reg. (EC) No. 852/2004
4.9.9	**Water**			• **21 CFR Part: 117, § 117.20 (b) (4)**
4.9.9.1	Water which is used as an ingredient in the production process or for cleaning shall be of potable quality at the point of use and supplied in sufficient quantity; this also applies to steam and ice used within the production area	• Where does water supply come from? (City supply, well water, tanker.)? • Is water demand always covered?		• Art. 4 (2), Annex II Chap. VII No. 1 (a), 4, 5 Reg. (EC) No. 852/2004 • Dir. 98/83/EC (quality of water for human consumption) • 21 CFR 110.37 (a) Sanitary facilities and controls • 21 CFR 110.80 (a) (1), (b) (16) Processes and controls
4.9.9.2	Recycled water, which is used in the process, shall not pose contamination risks.	• What is water used for in the company (social facilities, cleaning procedures, product ingredient, for washing fruit 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 surfaces in direct contact with foodstuff or as an ingredient, or the company cannot show that water complies with required standards. • The checking interval for relevant water safety issues has been clearly overdrawn. • The company has no water analysis plan even though it is mandatory and water is used for the cleaning procedures or as an ingredient.	• Art. 4 (2), Annex II Chap. VII No. 3 Reg. (EC) No. 852/2004 • 21 CFR 110.80 (a) (1) Processes and controls
4.9.9.3	The quality of water (including recycled water), steam or ice shall be monitored following a sampling plan on hazard analysis and assessment of associated risks.	• Is water, steam or ice used - is a station monitoring in place? • What kind of piping system exists? Ring-pipes, water-tanks) • What is piping made from? • Is there an analysis and sampling plan based on risk analysis? <maintenance>, <analysis results>	• When contaminated water reaches the product due to bad conditions of piping or improper piping material.	

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall neither be connected to the drinking water system nor allow the possibility of reflux, to avoid contamination of potable water sources or factory environment.	• Is drinking water system completely separated from non-potable water piping? • What other systems are there? (e.g. used water, cooling water, water used for firefighting). • Are water systems properly marked and where are they? • Is reflux avoidance equipment installed wherever necessary? <hydraulic system lay-out>	• All existing water systems are interconnected, no reflux avoidance equipment exists, therefore a contamination hazard is given.	• Art. 4 (2), Annex II Chap. VII No. 2 Reg. (EC) No. 852/2004
4.9.10	**Compressed air and gases**			
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. If gases are used, they shall demonstrate adequate safety and quality through a declaration of compliance and shall be suitable for the intended use.	• What kind of oil is used in the compressor? • What kind of filter is in use? • How often are filters changed? • Are microbiological tests performed? • Are chemical tests performed? <maintenance reports>, <lab results>, <risk assessment>	• Non-Food grade lubricant used in the compressor with no appropriate filter system and lab results in place.	• 21 CFR 110.40 (g) Equipment and utensils
4.9.10.2	Compressed air shall not pose contamination risks.			• Art. 4 (2), Annex II Chap. I No. 2 (c) Reg. (EC) No. 852/2004 • 21 CFR 110.40 (g) Equipment and utensils
4.10	**Cleaning and disinfection**			• **21 CFR Part: 117, § 117.35 (d)**
4.10.1	Based on hazard analysis and assessment of associated risks, cleaning and disinfection schedules shall be available and implemented. These shall specify: • objectives • responsibilities • the products used and their instructions for use • dosage of cleaning and disinfection chemicals • the areas to be cleaned and/or disinfected • cleaning and disinfection frequency • documentation requirements • hazard symbols (if necessary).	• Who is in charge of cleaning and disinfection? • What kind of cleaning products and disinfectants are used? • What must be observed when using different cleaning products and disinfectants? • What are areas cleaned and disinfected? • How often are areas cleaned and disinfected? • Where are cleaning and disinfection procedures documented? • Do hazard symbols exist? • Does a contract exist for external service providers? • Cleaning schedules can include SSOP's <cleaning schedule>, <up to date cleaning products and disinfectant list>, <product instructions>, <cleaning schedule>, <cleaning procedures documentation>, <external services contract>	• When a contamination of food products or tools exists due to the use of inefficient or wrong kind of chemicals or inefficient cleaning procedures.	• 21 CFR 110.35 Sanitary operations

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.10.2	Cleaning and disinfection shall result in effectively cleaned premises, facilities and equipment. Defined methods shall be adequately implemented, documented and monitored.	<Observation>		• Art. 4 (2), Annex II Chap. I, II, V Reg. (EC) No. 852/2004 • 21 CFR 110.35 Sanitary operations
4.10.3	Monitoring records for cleaning and disinfection shall be available.	• How is cleaning monitored? <monitoring records>		
4.10.4	Only qualified personnel shall be allowed to undertake cleaning and disinfection. The personnel shall be trained and retrained to carry out the cleaning and disinfection schedules.	• Are cleaning personnel qualified? • How often are they trained? • Who trains them? Are these trainings documented? <training proof>	• When a product or tools contamination occurs due to untrained cleaning personnel or wrong use of cleaning products or when cleaning process is inefficient when training deficits may become a safety issue.	
4.10.5	The effectiveness of the cleaning and disinfection measures shall be verified and justified by risk assessment. The verification shall be based on an appropriate sampling schedule and shall consider: • visual inspection • rapid testing • analytical testing methods. Resultant corrective actions shall be documented.	• How are cleaning and disinfection controls performed • Who performs these controls? • How often are cleaning and disinfection controls performed? • Where are cleaning and disinfection controls documented? • When are corrective actions executed? • Who executes corrective actions? • Who reviews effectiveness of corrective actions? • Where are corrective actions documented? <cleaning controls>, <cleaning controls>, <corrective actions>	• When cleaning is unsuccessful and this error is not corrected • If identified deficits are not fixed within a reasonable time.	
4.10.6	Cleaning and disinfection schedules shall be reviewed and modified, in the event that changes occur to products, processes or cleaning and disinfection equipment, if necessary.	• 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.	
4.10.7	The intended use of cleaning and disinfection utensils shall be clearly identified. Cleaning and disinfection utensils shall be used in a way that avoids contamination.			• Art. 4 (2), Annex II Chap. II No. 2, Chap. I No. 10 Reg. (EC) No. 852/2004 • 21 CFR 110.35 Sanitary operations

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.10.8	Safety Data Sheets and instructions for use shall be available for chemicals and cleaning and disinfection agents. Personnel responsible for cleaning and disinfection shall be able to demonstrate their knowledge of such instructions, which shall always be available on site.	• Are safety data sheets available for all cleaning chemicals? • Are these no older than two years? • Are cleaning chemical instructions up to date? • How are instructions transmitted to personnel in charge of cleaning procedures? • Where and when can the instructions be inspected?	• When a safety risk occurs due to deficient material safety data sheets.	
4.10.9	Cleaning and disinfection chemicals shall be clearly labelled, used and stored appropriately, to avoid contamination.	• How are cleaning utensils and chemicals recognizable? • 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 contamination of food and other utensils.	• Art. 4 (2), Annex II Chap. I No. 10 Reg. (EC) No. 852/2004 • 21 CFR 110.35 (b) (e) Sanitary operations
4.10.10	Cleaning and disinfection activities shall be carried out in periods of non-production. If this is not possible, these operations shall be controlled in order not to affect the products.	• Where are containers cleaned? • When and where are tools cleaned? <chemicals list>, <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.	
4.10.11	Where a company hires a third-party service provider for cleaning and disinfection activities, all requirements specified above shall be clearly defined in the service contract.	• Which areas are cleaned and disinfected by a third-party service provider?		
4.11	**Waste management**			• **21 CFR Part: 117, § 117.20; § 117.37**
4.11.1	A waste management procedure shall be in place to avoid cross contamination.	<waste management procedure>		• Art. 4 (2), Annex II Chap. I No. 2 (c), Chap. VI Reg. (EC) No. 852/2004 • 21 CFR 110.20 (a) (4) Plant and grounds
4.11.2	All local 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 waste disposal are not met.	• Art. 4 (2), Annex II Chap. VI Reg. (EC) No. 852/2004
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 is food waste and other waste removed from food handling areas? • Who is responsible for waste removal?	• When waste accumulate in food handling areas which ensues a food product contamination risk.	• Art. 4 (2), Annex II Chap. VI No. 1 Reg. (EC) No. 852/2004 • 21 CFR 110.20 (a) (1) Plant and grounds

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.11.4	Waste collection containers shall be clearly marked, suitably designed, in a good state of repair, easy to clean, and where necessary, disinfected.	• What kind of waste exists? • What waste is collected in separate containers? • How are waste containers marked? • Can waste containers be easily 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.	• Art. 4 (2), Annex II Chap. VI No. 2 Reg. (EC) No. 852/2004 • 21 CFR 110.20 Plant and grounds
4.11.5	If a company decides to separate food waste and to reintroduce them into the feed supply chain, adequate measures or procedures shall be implemented to prevent a contamination or deterioration of this material.	• 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 a contamination risk ensues.	
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 by the company.	• What kinds of waste disposal records exist? • Who is responsible for waste disposal? <waste disposal registry>, <waste disposal licencey>	• When waste is removed by unauthorized persons.	• Art. 4 (2), Annex II Chap. VI No. 4 Reg. (EC) No. 852/2004
4.12	**Foreign material risk mitigation**			• **See IFS Foreign Body Management Guideline** • **21 CFR Part: 117, § 117.80; § 117.130**
4.12.1	The products being processed shall be protected against physical contamination, which includes but is not limited to: • environmental contaminants • oils or dripping liquids from machinery • dust spills. Special consideration shall also be given to product contamination risks caused by : • equipment and utensils • pipes • walkways • platforms • ladders. If, for technological characteristics and/or needs, it is not possible to protect the products, appropriate control measures shall be defined and applied.	<site inspection>		• Art. 4 (2), Annex II Chap. IX No. 3 Reg. (EC) No. 852/2004 • 21 CFR 110.20 Plant and grounds • 21 CFR 110.35 (a) (d) Sanitary operations • 21CFR 110.40 Equipment and utensils • 21 CFR 110.80 Processes and controls

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.12.2 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 are identified through risk analysis? • Are staples used? • How are contaminated products handled? • What measures are taken in case of glass breakage? • What shall be considered when glass fixtures are replaced? <risk assessment>, <glass handling procedures>, <segregation records>, <glass breakage prevention procedures>	• When a foreign bodies contamination occurs due to lack of risk analysis or when foreign body sources are insufficiently considered.	• Art. 4 (2), Annex II Chap. I No. 2 (c) Reg. (EC) No. 852/2004 • 21 CFR 110.20 Plant and grounds • 21 CFR 110.80 Processes and controls • 21 CFR 117.135 (c) (3) Preventive controls • 21 CFR 120.6 Sanitation standard operating procedures
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 detectors installed? <equipment lay-out>	• When metal detectors are installed but later on a risk of foreign bodies still persists which has not been taken into account.	• 21 CFR 110.80 (b) (8) Processes and controls
4.12.4	The adequate accuracy of all equipment and methods designed to detect and/or eliminate foreign materials shall be specified. Functionality checks of such equipment and methods shall be carried out regularly. In case of malfunction or failure, corrective actions shall be defined, implemented and documented.	• How often is detector accuracy checked? • Who checks detector accuracy? • What corrective actions exist when a detector is defective? • Are corrective actions verified? • Are operational defects documented? <defect/failure protocols>, <metal detector check-list>	• When proper operation or accuracy of measurement is not checked and a foreign body risk occurs.	• 21 CFR 110.40 Equipment and utensils • 21 CFR 110.80 (b) Processes and controls
4.12.5	Potentially contaminated products shall be isolated. Access and actions for the further handling or checking of these isolated products shall only be carried out 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 the production line without previous inspection.	• 21 CFR 110.80 Processes and controls • 21 CFR 7 Enforcement Policy
4.12.6	In areas where raw materials, semi-finished and finished products are handled, the use of glass and/or brittle materials shall be excluded; however where the presence of glass and/or brittle materials cannot be avoided, the risks shall be controlled and the glass and/or brittle materials shall be clean and pose no risks to product safety.	• Does a risk analysis exist concerning contamination from glass? • Where is glass used in the plant? • How is glass protected from breakage? <risk assessment>, <glass register>,	• When no risk analysis has been conducted. • When a contamination risk exists due to glass usage. When glass is unprotected and a contamination risk ensues.	• 21 CFR 110.80 (b) (8) Processes and controls

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.12.7	Based on hazard analysis and assessment of associated risks, preventive measures shall be in place for the 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 contamination risks.	• What measures are taken 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 the involved product has not been inspected.	• Art. 4 (2), Annex II Chap. X No. 1, 2, 3 Reg. (EC) No. 852/2004
4.12.8	Procedures shall be in place describing the measures to be taken in case of glass breakage and/or brittle material. Such measures shall include identifying the scope of goods to be isolated, specifying authorised personnel, cleaning the production environment and releasing the production line for continued production.	• Is every glass breakage documented? • Where is glass breakage documented? • Are there exceptions to documentation? • Are exceptions based on risk analysis? <glass breakage registry>, <glass register>, <risk assessment>	• When no risk analysis has been made.	
4.12.9	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.	<breakage records>		
4.12.10	Where visual inspection is used to detect foreign materials, the employees shall be trained and operative changes shall be performed at an appropriate frequency to maximise the effectiveness of the process.	• Description of visual detection method, changing frequency for personnel and last training for personnel.		• Art. 4 (2), Annex II Chap. XII No. 1 Reg. (EC) No. 852/2004
4.12.11	In areas where raw materials, semi-finished and finished products are handled, the use of wood shall be excluded; however, where the presence of wood cannot be avoided, the risks shall be controlled and the wood shall be clean and pose no risks to product safety.	• Does a risk analysis exist concerning contamination from wood? • Where is wood used in the plant? <risk assessment>	• When no risk analysis has been conducted. • When there a contamination risk due to wood usage exists. When wood is used and a contamination risk ensues.	• Art. 4 (2), Annex II Chap. IX No. 2, 3 Reg. (EC) No. 852/2004 • 21 CFR 110.80 Processes and controls
4.13	**Pest monitoring and control**			• **See IFS Pest Control Guideline**
4.13.1	Site infrastructure and operations shall be designed and built to prevent pest infestation.	<site inspection>		• Art. 4 (2), Annex II Chap. I No. 2 (c) Reg. (EC) No. 852/2004 • 21 CFR 110.20 (a) Plant and grounds

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.13.2	The company shall have adequate pest control measures in place which shall be in compliance with local legal requirements and shall take into account, at a minimum: • factory environment (potential pests) • type of raw material/finished products • site plan with area for application (bait map) • constructional designs susceptible for pest activity, such as ceilings, cellars, pipes, corners • identification of the baits on site • responsibilities, in-house / external • agents used and their instructions for use and safety • frequency of inspections • rented storage if applicable. The pest control measures shall be based on hazard analysis and assessment of associated risks.	• How is pest control organised? • Which pests are controlled? • Which kinds of baits are used? • Is product contamination being prevented through the use of baits? • Who is responsible for pest control? • What is the inspection schedule? • In case of the identification of pest activity, what were the corrective actions? <pest control procedures>, <pest control chemicals list>, <bait map>	• When no pest control is made. • When a product contamination can occur due to unmapped baits. • When a product safety risk occurs due to incorrect use of pest control chemicals or wrongly laid out baits.	• Art. 4 (2), Annex II Chap. I No. 2 (c), Chapt. IX No. 4 Reg. (EC) No. 852/2004 • 21 CFR 110.20 Plant and grounds • 21 CFR 110.35 (c) Sanitary operations
4.13.3	Where a company hires a third-party service provider for pest control, all requirements specified above shall be clearly defined in the service contract. A person at the company shall be appointed and trained to monitor the pest control measures. Even if the pest control service is outsourced, responsibilities for the necessary actions (including ongoing supervision of pest control activities) shall remain within the company.	• Is pest control executed by own staff members? • Who is responsible for pest control? • What kind of training does the responsible person have? • Is pest control executed by an external service provider? • Does a written contract exist between the service provider and the company? • What is the content of the contract? • What kind of training does the external service provider have? <training evidence>, <written contract>	• When a product contamination occurs due to incorrect handling of bait material.	
4.13.4	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded. Any infestation shall be documented and control measures taken.	Where are inspections and resulting corrective actions documented? • Are documents signed and dated by both parties? • Which corrective actions were executed lately? <inspection results>	• When inspections are not documented.	

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.13.5	Baits, traps and insect exterminators shall be fully functioning, sufficient in number, designed for purpose, placed in appropriate positions and used in a way that avoids any contamination risks.	• Where are electrical fly killers installed? • Are all fly killers connected and properly functioning? <fly killer map>	• When fly killers are positioned in such a way that flies can fall directly on food products.	• 21 CFR 110.35 (c) Sanitary operations
4.13.6	Incoming deliveries shall be inspected on arrival for the presence of pests. Any findings shall be recorded.	• Are incoming goods inspected for pest contamination? • Where is this documented? • Is pest presence documented? • What control measures are taken when pests are found? • Where are these control measures documented? <corrective actions>, <incoming goods inspection>	• When incoming goods are not inspected for pest presence and an uncontrolled invasion ensues.	• Art. 4 (2), Annex II Chap. IX No. 1, 4 Chap. IX No. 3 Reg. (EC) No. 852/2004 • 21 CFR 110.80 Processes and controls • 21 CFR 117.410 General requirements applicable to a supply-chain program
4.13.7	The effectiveness of the pest control measures shall be monitored, including trend analysis, to allow timely appropriate actions. Records of this monitoring shall be available.			
4.14	**Receipt and storage of goods**			• **See IFS Pest Control Guideline**
4.14.1	All incoming goods, including packaging materials and labels, shall be checked for conformity against specifications and a determined inspection plan. The inspection plan shall be justified by risk assessment. Records of those inspections shall be available.	• What goods (incl. semi-proceeded products) are inspected when received? • What is checked when received? • Is receipt documented? • Who checks? <receipt checks>	• When no receipt checks are made. • When checks do not guarantee legal requirements. • When receipt checks do not take into account specification requirements which prevent products fulfilling their given specifications.	
4.14.2	The storage conditions of raw materials, semi-finished, finished products and packaging materials shall correspond to product specification and shall not have any negative impact on other products. This shall be defined in an implemented and maintained system.	• Where are raw materials, half finished products and packaging materials stored? • How is cross-contamination avoided? <product flow plan>, <storage plan>	• When goods are improperly stored and a contamination risk ensues.	• Art. 4 (2), Annex II Chap. IX No. 2, 3, 4, 5, 6, 7, 8 Chap. X No. 2 Reg. (EC) No. 852/2004 • 21 CFR 110.40 (e) Equipment and utensils • 21 CFR 110.80 (b) (2) (7) Processes and controls • 21 CFR 110.93 Warehousing and distributions

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.14.3	Raw materials, packaging materials, semi-finished and finished products shall be stored to minimise contamination risks or other negative impact.	• Where and how is packaging material and equipment stored? • How is cross-contamination through packaging materials avoided? • 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 1m from walls? • Are there baits laid out in storage rooms? • Are sensitive products stored there? • What kinds of preventive measures are in place for these goods? <preventive measures>, <pest control schedule>, <plant inspection protocol>, <materials flow-diagram>	• A product contamination risk is given due to storage of packaging materials and equipment (e.g. unprotected external storage of packaging material) • When storage facilities are not inspected for pest presence.	• Art. 4 (2), Annex II Chap. IX No. 2, 3, 4, 5, 6, 7, 8 Reg. (EC) No. 852/2004 • 21 CFR 110.80 (b) (2) (7) Processes and controls • 21 CFR 110.93 Warehousing and distributions
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? • Are chemical users fully trained? • Is training documented? <responsibility list>, <training documentation>	• When a food or utensil contamination occurs due to inappropriate storage conditions. • When a food or utensil contamination occurs due to insufficient knowledge.	• 21 CFR 110.20 (b) (1) Plant and grounds
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.	
4.14.6	Where a company hires a third-party storage service provider, the service provider shall be certified for IFS Logistics or any other GFSI recognised certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own storage practices shall be fulfilled and this shall be clearly defined in the respective contract.	• Is storage leased to a storage service provider? • Does a contract exist? • What is specified in the contract? • Does the storage service provider have an IFS Logistics certification? <certificate copy>, <service provider contract>		

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.15	**Transport**			• **21 CFR Part: 117, § 117.93; § 117.130 (c) (3) (iv)**
4.15.1	The conditions inside the vehicles, such as: • absence of strange smells • high dust load • adverse humidity • pests • mould shall be checked before loading and documented to ensure compliance with the specified conditions.	• What is checked before loading? • Where is inspection documented? • What corrective actions are taken? <expedition inspection>		• 21 CFR 1.908 (a) (3) What requirements apply to transportation operations? • 21 CFR 1.908 (c) (1) What requirements apply to transportation operations? • 21 CFR 110.93 Warehousing and distribution
4.15.2	Where goods are transported at certain temperatures, the temperature inside the vehicles shall be checked and documented before loading.	• Are products which require a certain temperature being loaded? • Is vehicle temperature checked and documented before loading? • What is the procedure when vehicle temperature is not according to specifications? • How does the company ensure the compliance of temperatures during transport? <"temperature indicator" occasionally placed in Products>, <expedition inspection>, <expedition inspection>	• When there are certain temperature specifications for outgoing products but they are not checked before loading and a health issue for the consumer occurs.	• 21 CFR 1.906 (c) What requirements apply to vehicles and transportation equipment? • 21 CFR 1.908 (c) (2) What requirements apply to transportation operations?
4.15.3	Procedures to prevent contamination during transport, including loading and unloading, shall be in place. Different categories of goods (food / non-food) shall be taken into consideration, if applicable.	• May goods be transported alongside non-food products? • How is cross-contamination prevented?	• When contamination can occur during transport.	• Art. 4 (2), Annex II Chap. IV No. 1, 2, 3, 4, 5, 6 Reg. (EC) No. 852/2004 • 21 CFR 1.908 (a) (3) (i) What requirements apply to transportation operations? • 21 CFR 1.908 (a) (4) What requirements apply to transportation operations? • 21 CFR 1.908 (b) (3) What requirements apply to transportation operations? • 21 CFR 110.80 Processes and controls
4.15.4	Where goods are 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? • How is it ensured that products reach their destination in good condition? <registering devices>	• 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.	• Art. 4 (2), Annex II Chap. IV No. 7 Reg. (EC) No. 852/2004; • Art. 2 Reg. (EC) No. 37/2005 (monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuff) • 21 CFR 1.908 (a) (3) (iii) What requirements apply to transportation operations?

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.15.5	Adequate hygiene requirements for all transport vehicles and equipment used for loading/ unloading (e.g. hoses of silo installations) shall exist. Measures taken shall be recorded.	• Are transport vehicles cleaned? • Where are cleaning procedures documented? <cleaning protocol>	• When absence of cleaning procedures ensues a product contamination problem.	• Art. 4 (2), Annex II Chap. IV No. 1, 2, 3, 4, 5, 6 Reg. (EC) No. 852/2004 • 21 CFR 1.906 (b) What requirements apply to vehicles and transportation equipment? • 21 CFR 1.908 (c) (1) What requirements apply to transportation operations? • 21 CFR 110.80 Processes and controls
4.15.6	The loading/unloading area shall be appropriate for their intended use. They shall be constructed in a way that: • the risks of pest intake are mitigated • products are protected from adverse weather conditions • accumulation of waste is avoided • condensation and growth of mould are prevented • cleaning can be easily undertaken.	• How is goods reception organised? • How is loading organised? External influences: e.g. pollen, climate, etc.		• Art. 4 (2), Annex II Chap. I No. 2 (c) Reg. (EC) No. 852/2004
4.15.7	Where a company hires a third-party transport service provider, the service provider shall be certified for IFS Logistics or any other GFSI recognised certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own transport practices shall be fulfilled and this shall be clearly defined in the respective contract.	• Are there internal or external transportation regulations? • Does a contract exist with a transportation service provider? • Does the storage service provider have an IFS Logistics certification? <service provider contract>, <certificate copy>		
4.16	**Maintenance and repair**			• **21 CFR Part: 117, § 117.35 (a) General maintenance**
4.16.1	An adequate maintenance plan shall be in place, maintained and documented, that covers all critical equipment (including transport) for compliance with product requirements. This applies both to internal maintenance activities and service providers. The plan shall include responsibilities, priorities and due dates.	• How is maintenance organised? • Where are maintenance procedures documented? • Which equipment is subject to external maintenance? <maintenance plan>	• No maintenance system exists.	• 21 CFR 110.40 Equipment and utensils • 21 CFR 110.80 (b) Processes and controls • 21 CFR 1.906 (b), (c) What requirements apply to vehicles and transportation equipment?

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
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 shall be kept.	• How is it ensured that maintenance and repair work 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 the product is not segregated.	
4.16.3	All materials used for maintenance and repair shall be fit for the intended use and shall not pose contamination risks.	• How is it ensured that materials used in maintenance or repair work are fit for intended use? • What kinds of grease are used? <grease list>	• When materials used in maintenance or repair works are not food grade and a safety risk for the consumer ensues.	
4.16.4	Failures and malfunctions of plant and equipment (including transport) that are essential for food safety and quality, shall be identified, documented and reviewed to enable prompt actions and to improve the maintenance plan.	• Are processing interruptions documented? • Are processing interruptions considered in maintenance planning? <processing interruptions>		
4.16.5	Temporary repairs shall be carried out not to compromise food safety and product quality. Such work shall be documented and a short-term deadline set for eliminating the issue.	• Are temporary repairs allowed? • Where are these documented? • How fast must temporary repairs be 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, equipment and operational rules shall be clearly defined, documented and maintained in the service contract, to prevent any product contamination.			

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.17	**Equipment**			• **www.foodcontactmaterials.com** • **Regulation 1935/2004** • **Reg. 2023/2006** • **Regulation 10/2011** • **Art. 4 (2), Annex II Chap. V Reg. (EC) No. 852/2004** • **21 CFR Part: 117, § 117.40**
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.	• Is equipment suitably designed and were they checked before start up? <start up protocol>	• When equipment construction can lead to a foodstuff contamination.	**Regulations (EC)** • Art. 4 (2), Annex II Chap. V Reg. (EC) No. 852/2004 • Reg. (EC) No. 2023/2006 • Reg. (EU) No. 1935/2004 **Directives** • Reg. (EC) No. 1895/2005 • Reg. (EC) No. 282/2008 • Reg. (EC) No. 450/2009 • Reg. (EU) No. 10/2011 • 84/500/EEC, 2007/42/EC • 21 CFR 110.40 Equipment and utensils
4.17.2	For all equipment and utensils with direct food contact, a certificate of conformity shall be in place, which confirms compliance with legal requirements. In case no specific legal requirements are in place, evidence shall be available, such as: • certificate of conformity • technical specifications • manufacturer's self-declaration to demonstrate that they are suitable for the intended use.	• Are conformity certificates or other certificates available for all packaging materials which come into direct contact with food products? • Are conformity certificates available for packaging materials which come into direct contact with raw materials, half-finished or finished products? • Are conformity certificates available for containers and conveyor belts? <conformity certificates>	• 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.	**Regulations (EU)** • Art. 16 (1) Reg. (EU) No. 1935/2004 • Reg. (EC) No. 1895/2005 • Reg. (EC) No. 282/2008 • Reg. (EC) No. 450/2009 • Reg. (EU) No. 10/2011 • 1935/2004, Art. 16 (1) **Directives** • Dir. 84/500/EEC • Dir. 2007/42/EC
4.17.3	Equipment shall be located to allow effective cleaning and maintenance operations.	• Is equipment suitably designed and were they checked before start up? • What rules exist for starting up new equipment? • Were new equipment immediately considered in maintenance plan? • Does an equipment installation plan exist? <start up protocol>, <machinery installation plan>	• When equipment is installed in a way that cleaning procedures are hindered and thus constitute a contamination source.	• Art. 4 (2), Annex II Chap. V No. 1 (b) Reg. (EC) No. 852/2004 • 21 CFR Part: 117, § 117.40 (c), (d)

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.17.4	The company shall ensure that all product equipment is in a condition that does not compromise food safety and product quality.			• Reg. (EC) 852/2004, Art. 4 (2), Annex II Chap. V, (1) (a) • 21 CFR 110.35 (a) (d) Sanitary operations. • 21 CFR 110.40 Equipment and utensils
4.17.5	The company shall ensure that in the event of changes to equipment, the process characteristics are reviewed to assure that the product requirements, as agreed with customers, 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.	
4.18	**Traceability**			• **Regulations (EC)** • **Art. 18 Reg. (EG) No. 178/2002** • **Reg. (EU) No. 931/2011 (traceability requirements)** • **Art. 4 ff. Reg. 1830/2003 (GMO)** • **Art. 58 Reg. (EC) No. 1224/2009 (Fish)** • **Reg. (EC) No. 1760/2000 (Beef)** • **Reg. (EC) No. 1825/2000 (Beef)"**
4.18.1 KO	**KO N° 7:** **A traceability system shall be in place that enables the identification of product lots and their relation to batches of raw materials and primary packaging materials. The traceability system shall incorporate all relevant records of:** • **receipt** • **processing** • **use of rework** • **distribution.** **Traceability shall be ensured and documented until delivery to the customer.**	• How is traceability ensured? • What products come from which supplier? • Is there a list available with all current suppliers? <traceability procedures>, <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	• **Regulations (EC)** ◦ Art. 18 Reg. (EC) No. 178/2002 ◦ Art. 1 ff. Reg. (EU) No. 931/2011 ◦ Art. 58 Reg. (EC) No. 1224/2009 ◦ Art. 4 ff. Reg. (EC) No. 1760/2000 ◦ Art. 1 ff. Reg. (EC) No. 1825/2000 • 21 USC 2223: Enhancing tracking and tracing of food and recordkeeping (FSMA Title II Sec. 204) • 21 USC 350c: Maintenance and inspection of records • 21 CFR part 1, subpart J: Establishment, Maintenance, and Availability of Records • Proposed Rule by the Food and Drug Administration on 09/23/2020: Requirements for Additional Traceability Records for Certain Foods (85 FR 59984)

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.18.2	The traceability system shall be tested on a periodic basis, at least annually and each time the traceability system changes. The test samples shall represent the complexity of the company´s product range. The test records shall verify upstream and downstream traceability (from delivered products to raw materials, and vice versa). The traceability of the finished product shall be performed within four (4) hours maximum.	• Which traceability exercises have been performed? • Are records from those exercises available? • What has been the result from the review of the traceability exercises? • When was the last traceability test in both directions done? • What percentage of total amount was traced? • How big is a Lot? <records of traceability exercises>	• When the 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.	• Art. 18 Reg. (EC) No. 178/2002 • Art. 1 ff. Reg. (EU) No. 931/2011 • Art. 58 Reg. (EC) No. 1224/2009 • Art. 4 ff. Reg. (EC) No. 760/2000 • Art. 1 ff. Reg. (EC) No. 1825/2000
4.18.3	Test results, including the timeframe for obtaining the information, shall be recorded and where necessary appropriate action shall be taken. Timeframe objectives shall be defined and be in compliance with customer requirements.	• Are there customer requirements for the timeframe? • Have timeframes been respected during own traceability exercises? • How big is a Lot? <records of traceability exercises>, <contracts>	• Timeframe not in compliance with customer requirements.	
4.18.4	The Traceability system shall identify the relationship between batches of final products and their labels.			• Art. 4 ff. Reg. 1830/2003 • Art. 58 Reg. (EC) No. 1224/2009 • Art. 4 ff. Reg. (EC) No. 760/2000 • Art. 1 ff. Reg. (EC) No. 1825/2000
4.18.5	Traceability shall be ensured at all stages, including work in progress, post treatment and rework.	• Can rework be completely traced? • How is rework documented/ <results from rework traceability test>	• When rework traceability is not ensured.	• Art. 18 Reg. (EC) No. 178/2002 • Art. 4 ff. Reg. 1830/2003 • Art. 58 Reg. (EC) No. 1224/2009 • Art. 4 ff. Reg. (EC) No. 760/2000 • Art. 1 ff. Reg. (EC) No. 1825/2000"
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 clear traceability of goods. Where goods are labelled at a later time, the temporarily stored goods shall have a specific lot labelling. Shelf life (e.g. best before date) of labelled goods shall be established using the original production batch.	• When is lot labelling done? • What is the lot labelling code? • When are labels applied to product units? • How is shelf-life calculated? <lot labelling example>, <shelf-life example>	• When lot labelling is done at a step where mix-ups occur which are unable to correct traceability.	
4.18.7	If required by the customer, identified representative samples of the manufacturing lot or batch number shall be stored appropriately and kept until expiration of the "Use by" or "Best before" date of the finished products and, if necessary, for a determined period beyond this date.	• Are there customer requirements for samples? • Are samples taken? • Are samples stored in accordance with product requirements?		

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.19	**Allergen risk mitigation**			• **Art. 21 Reg. (EC) No. 1169/2011.**
4.19.1	Raw material specifications that identify allergens requiring declarations relevant to the country of sale of the finished products shall be available. The company shall maintain a continuously up to date listing of all raw materials containing allergens used on the premises. This shall also identify all blends and formulas to which such raw materials containing allergens are added.	• Are allergens identified in specifications? • Is a list existing that covers allergens in use? <allergen list>	• Allergens are not identified and a customer safety issue ensues.	• 21 CFR Part: 130 – Food standards: General • 130.8 Conformity to definitions and 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.
4.19.2	Based on hazard analysis and assessment of associated risks, preventive and control measures shall be in place from receipt to dispatch, to ensure that potential cross contamination of products by allergens is minimised. The potential cross contamination risks related to: • environment • transport • storage • raw materials shall be considered. Control measures shall be verified.	• 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>		• Art. 14 Reg. (EC) No. 178/2002 • Art. 4 (2) Annex II Chap. IX No. 3 Reg. (EC) No. 852/2004 • 21 CFR 117.10 (b) Personnel • 21 CFR 117.35 Sanitary operations
4.19.3	Finished products containing allergens that require declaration shall be declared in accordance with legal requirements. Accidental or technically unavoidable cross-contaminations of legally declared allergens and traces shall be labelled. The decision shall be based on a hazard analysis and assessment of associated risks. The potential cross-contamination with allergens from raw materials processed in the company shall also be taken into account on the product label.	• Has allergen status been documented in specifications? <finished product specifications>	• Allergens are not declared and a safety risk for the consumer occurs.	• Art. 21, 36 (3) (a) Reg. (EU) No. 1169/2011 • 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	**Food Fraud**			• **See IFS Product Fraud Guideline**
4.20.1	The responsibilities for a food fraud vulnerability assessment and mitigation plan shall be clearly defined. The responsible person(s) shall have the appropriate specific knowledge and full commitment from the senior management.	• Who is responsible for food fraud mitigation activities?		• 21 CFR 121.4 Qualifications of individuals who perform activities under subpart C of this part

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
4.20.2	A documented food fraud vulnerability assessment shall be undertaken on all raw materials, ingredients, packaging materials and outsourced processes, to determine the risks of fraudulent activity in relation to substitution, mislabelling, adulteration or counterfeiting. The criteria considered within the vulnerability assessment shall be defined.	• Which is the defined vulnerability assessment methodology • Which criteria are defined for the vulnerability assessment? • Are all raw materials, ingredients and packaging subject to vulnerability assessment? • How often are vulnerability assessments undertaken? Are vulnerability assessments undertaken on all new raw material, ingredient and packaging and the suppliers of these product? <List of raw materials, ingredients and packaging and their suppliers>		• 21 CFR 121.130 Vulnerability assessment to identify significant vulnerabilities and actionable process steps
4.20.3	A documented food fraud mitigation plan shall be developed, with reference to the vulnerability assessment, and implemented to control any identified risks. The methods of control and monitoring shall be defined and implemented.	• What are the control measures applied to mitigate the risk of potential product fraud activity identified? • Within the vulnerability assessment? • Are control measures appropriately and consistently applied in accordance with identified risks? • Who monitors, and where necessary actions, issues identified by the control measures? • Are control measures regularly reviewed for suitability and effectiveness? <Food Fraud Mitigation Plan>		• 21 CFR 121.135 Mitigation strategies for actionable process steps • 21 CFR 121.140 Food defense monitoring • 21 CFR 121.145 Food defense corrective actions
4.20.4	The food fraud vulnerability assessment shall be regularly reviewed, at least annually, and/or in the event of increased risks. If necessary, the food fraud mitigation plan shall be revised/updated accordingly.	• How often is the assessment reviewed? • What are the results? <Meeting minutes>		• 21 CFR 121.157 Reanalysis
5.	**Measurements, Analyses, Improvements**			
5.1	**Internal audits**			
5.1.1 KO	**KO N° 8:** **The company shall have an effective internal audit program in place which shall cover at least all the requirements of the IFS Standard.** **Scope and frequency of internal audits shall be determined and justified by risk assessment.** **The internal audit program shall also apply to off-site storage locations owned or rented by the company.**	• Does an up to date internal audit plan exist? • Is the audit plan based on risk analysis? <audit plan>, <risk assessment>	• No internal audits are performed	• Directly required for infant food: 21 CFR 106.90 Audits of current good manufacturing practice

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)

5.1.2	Internal audits of activities, which are critical to food safety and product quality, shall be carried out at least once a year.	• How often are internal audits performed?
		• 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)
		<audit plan>		

5.1.3	The auditors shall be competent and independent from the audited department.	• Who are the auditors? • How are auditors qualified for this job? • Do auditors have any connection with the audit area? <auditors list>, <continued education evidence>		• 21 CFR 106.90 (b) Audits of current good manufacturing practice
5.1.4	Internal audit results shall be communicated to the senior management and to persons responsible for the concerned activities. Necessary corrective actions and a schedule for implementation shall be determined, documented and communicated to the relevant person. All corrective actions resulting from the internal audits shall be verified.	• How are audit results communicated to the persons in charge? • Is the communication immediate and in time for appropriate measures to be taken? • Are corrective actions documented? • Is a time schedule in place for corrective actions? • Which audits were corrective actions derived from? • How are audit results forwarded to senior management? • How are audit results evaluated? • How is the verification of corrective actions regulated? • Who is in charge of verification and when? <audit report distribution>, <audit report>, <audit report containing corrective actions>, <audit report distribution>, <verification evidence>	• No documented audit results • No corrective actions taken although necessary.	

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
5.2	**Site factory inspections**			
5.2.1	Site and factory inspections shall be planned and carried out for topics, such as: • constructional status of production and storage premises • external areas • product control during processing • hygiene during processing and within the infrastructure • foreign material hazards • personal hygiene. The frequency of inspections shall be justified by risk assessment and be based on the history of previous experience.	• How often are site inspections carried out and who makes them? • What is reviewed during site inspections? • For which areas do site inspections exist? • Are all required areas covered? <site inspections protocol>	• No site inspections are performed.	• Cross reference in product specific regulations (e.g. 21 CFR 108)
5.3	**Process and working environment validation and control**			• **21 CFR Part: 117, § 117.145; § 117.160**
5.3.1	The criteria for process and working environment validation and control shall be clearly defined. Where the control of process and working environment parameters (temperature, time, pressure, chemical properties, etc.) are essential to ensure the food safety and product quality requirements, such parameters shall be monitored and recorded continuously and/or at appropriate intervals.	• How are temperatures monitored? • Where are temperatures recorded? <printed measurement data>	• In case a legality issue occurs due to missing records. 4.12.4.	• Annex III Reg. (EC) No. 853/2004 (as regards temperatures (e. g. freezing/ heating) • Reg. (EC) No. 37/2005 (temperatures/ quick-frozen foodstuffs) • Reg. (EC) No. 543/2008 • 21 CFR 110.80 Processes and controls • 21 CFR 117.80 Processes and controls
5.3.2	All rework operations shall be validated, monitored and documented. These operations shall not affect the food safety and product quality requirements.	• How is it assured that reworks comply to specifications? • Where is rework documented? • Who reviews rework results? • Who decides on the release of rework? • How is it ensured that rework fulfils legal requirements? <model documentation for rework>		• 21 CFR 110.80 Processes and controls
5.3.3	Procedures shall be in place 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.	

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
5.3.4	Process and working environment validation shall be performed using the collected data that is relevant for food safety and the processes. If substantial modifications occur, a re-validation shall be carried out.			
5.4	**Calibration, adjustment and checking of measuring and monitoring devices**			
5.4.1	The company shall identify and record the measuring and monitoring devices required to ensure compliance with food safety and product quality requirements. Their calibration status shall be recorded. Measuring and monitoring devices shall be legally approved, if required by legislation.	• What kinds of monitoring devices exist? • What is demanded of monitoring devices? • What monitoring device is adequate for which kind of measurement? • How are monitoring devices identified? • Do calibrated devices exist? • How is the calibration status of a measuring device identified? <monitoring devices list>, <identification stickers on monitoring devices>, <identification stickers>	• The company has no measuring and monitoring devices.	• Dir. 76/211/ECC • Dir. 2014/31/EU • Dir. 2014/32/EU • 21 CFR 110.40 Equipment and utensils • 21 CFR 117.40 Equipment and utensils
5.4.2	All measuring devices shall be checked, adjusted and calibrated at specified intervals, with a monitoring system. This system shall be in accordance with defined, recognised standard/ methods and within relevant limits of the process parameter values. The results of the checks, adjustments and calibrations shall be documented.	• How is the checking of measuring devices organised? • Who is responsible for calibration? • Are measuring devices regularly calibrated? • How is calibration done? • Does calibration cover the measuring areas? • Where is it documented • What corrective actions are taken when a tolerance deviation is found? • Is calibration up to date? <calibration procedures>, <calibration protocol>, <calibration records>, <corrective actions>, <calibration certificate>	• No calibration is performed.	• 90/384/EEC (non-automatic weighing instruments) • 2004/22/EC (measuring instruments) • 2009/23/EC (non-automatic weighing instruments) **Directives** • Dir. 76/211/ECC • Dir. 2014/31/EU (non-automatic weighing instruments) • Dir. 2014/32/EU (measuring instruments)
5.4.3	All measuring devices shall be used exclusively for their defined purpose. Where the results of measurements or the status of the device indicate a malfunction, the device in question shall be immediately repaired or replaced. Where necessary, corrections and corrective actions on processes and products shall be carried out.	• What actions are taken when measurement results are uncertain? • How are embargoed measuring devices identified? <identification stickers>	• When defective measuring devices are not exchanged and a safety issue ensues. (e.g. defective thermometers)	• 21 CFR 110.40 Equipment and utensils • 21 CFR 117.40 Equipment and utensils

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
5.5	**Quantity control monitoring**			
5.5.1	The company shall define compliance criteria to control lot quantity. A frequent and methodological strategy for quantity control shall be in place to meet legal requirements of the destination country/ies and customer specifications.	• How is it ensured that legal requirements for quantity control are met?	• Legal requirements are not met due to a lack of or due to an insufficient number of measurements being made.	• Dir. 76/211/ECC Art. 23 Reg. (EU) No. 1169/2011 • 21 CFR 101.7 Declaration of net quantity of contents
5.5.2	Checks shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing lot. Results of these checks shall be compliant with defined criteria for all products ready to be delivered.	• Applicable for retail branded products and other labels? <inspection plan> <dealer evidence>		• Dir. 76/211/ECC
5.6	**Product and process analyses**			
5.6.1	Testing plans for internal and external analyses shall be justified by risk assessment to ensure that product safety, quality, legal and specific customer requirements are met. The plans shall cover topics, such as: • raw materials • semi-finished products, • finished products • packaging materials • contact surfaces of processing equipment • relevant parameters for environmental monitoring. All test results shall be recorded.	• Does an inspection plan exist? • Who organizes the inspection plan? • Which products does the inspection plan encompass (raw materials, half-finished and finished products, packaging materials, environmental tests?) • Is the inspection plan based on risk analysis? • Where are the test results documented? • Which physical, chemical or microbiological analyses are made or subcontracted? • Which analyses are performed by own laboratory and which by external? • and how frequently? <inspection plan>, <risk assessment>, <test results>	• No sampling plan based on risks exists. • No results of analyses are available.	**Regulations** • (EEC) 315/93 (procedures for contaminants) • (EC) 396/2005 • (EC) 2073/2005 • (EC) 2074/2005 (total volatile basic nitrogen (TVB-N) limits) • (EC) 1881/2006 • (EC) 37/2010 (pharmacologically active substances)
5.6.2	Analyses which are relevant for food safety, shall preferably be performed by laboratories with appropriate accredited programs/methods (ISO/IEC 17025). If the analyses are performed internally or by a laboratory without the appropriate accredited programs / methods, the results shall be verified on a regular basis by laboratories accredited to these programs / methods (ISO/IEC 17025).	• Is there an analytical laboratory on site? Is it accredited to ISO 17025? • Are internal lab results verified by an accredited lab? • Which external laboratories are used? Are these accredited under ISO 17025 <accreditation evidence>		

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
5.6.3	Procedures shall exist which ensure the reliability of the internal analyses results, based on officially, 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>		
5.6.4	Results of analyses shall be evaluated promptly by competent personnel. Appropriate corrective actions shall be undertaken for any unsatisfactory results. The analytical results shall be reviewed regularly in order to identify trends and, when necessary, corrective actions shall be taken.	• 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.	
5.6.5	Where internal analyses or controls are undertaken, these shall be carried out in accordance with defined procedures, by trained and approved personnel, in defined areas or laboratories, using appropriate equipment.	• Which tests are performed internally? • What qualifications have lab technicians? • Is an internal lab available? • Is an incubator, sterilization equipment available? • How is product contamination by internal lab prevented? <qualification evidence>		
5.6.6	For verification of the quality of the finished product, 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 characteristics. The results of these tests shall be documented.	• When and how are organoleptic tests performed? <inspection plan>, <documentation of organoleptic test results>		• e.g. 21 CFR 111.75 What must you do to determine whether specifications are met? (dietary supplement)
5.6.7	The testing plan shall be regularly reviewed and updated, based on results, changes to legislation or issues that may have an impact on product safety, quality or legality.	For example, if an Alert System informs that a raw material sourced from a specific country regularly has a specific rate of a 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 low risk, the company can decide to decrease the frequency of analysis.		

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
5.7	**Product release**			
5.7.1	A procedure for quarantine (blocking/hold) shall be in place that is justified by risk assessment. The procedure shall ensure that only raw materials, semi-finished and finished products, and packaging materials conforming to product requirements, are processed and dispatched.	• Who quarantines or releases products? • How are quarantined products identified? <job description>	• When no procedures exist for the quarantine or release of products. • When quarantined products go unchecked into further use and a safety issue occurs.	• Regulation 178/2002 • Process authority and/or product release required in product specific regulations (e.g. 21 CFR 106.6 (d), 21 CFR 106.70)
5.8	**Management of complaints from authorities and customers**			
5.8.1	A procedure shall be in place for the management of product complaints and of any written notification from the competent authorities – within the framework of official controls-, any ordering action or measure to be taken when non-compliance is identified.	• How are complaints handled? • What is the range or indicator of complaints raised by consumers, retailers and authorities separately? <complaint handling procedure>	• If there is no procedure for complaint handling.	• Art. 19 Reg. (EC) No. 178/2002 • 21 CFR Part: 7– Enforcement Policy • 7.40 Recall policy • 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 registered, readily available and assessed by competent staff. Where it is justified, appropriate actions shall be taken immediately.	• Who evaluates complaint significance? • Who defines the actions to be taken? • Within what time frame must actions be taken?		• 21 CFR 7.42 Recall strategy.
5.8.3	Complaints shall be analysed with a view to implementing appropriate actions to avoid the recurrence of the non-conformity.	• Who manages complaint statistics? • How often are complaint statistics compiled? • What actions are taken to avoid recurrence? <complaint statistics>	• No corrective actions were taken although a failure comes up more frequently or is considered as serious.	• 21 CFR 7.42 Recall strategy
5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons.	• To whom are complaint statistics data presented? <retailer complaint statistics data>		• 21 CFR 7.49 Recall communications • 21 CFR 7.53 Recall status reports"

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
5.9	**Management of incidents, product withdrawal, product recall**			
5.9.1	A procedure shall be implemented and maintained for the management of incidents and potential emergency situations with an impact on food safety, quality and legality. It shall include, at a minimum: • the decision making process • the nomination of a person, authorised by the company and permanently available, to initiate the incident management process in a timely manner • the nomination and training of an incident management team, • an up to date alert contact list including customer information, sources of legal advice, contacts availability, • a communication plan including authorities.	• Who belongs to the incident management staff? • Who is informed when an incident occurs? • How are incidents managed? • What is an incident? • 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? • Who is informed when a crisis occurs? • When are media involved? <phone list>, <crisis management procedures>, <incident management procedures>, <emergency plan>, <alarm plan	• No incident management is available in the company. • If there is no incident management system implemented.	• Art. 19 Reg. (EC) No. 178/2002 • 21 CFR Part: 7– Enforcement Policy • 7.40 Recall policy • 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	**KO N° 9:** **An effective procedure for the withdrawal and/or the recall of all products shall be in place. This procedure shall include a clear assignment of responsibilities and a comprehensive information policy for customers and consumers.**	• To what extent is distribution involved with incident management? • When and who informs the customer? • A withdrawal / recall management procedure is not enough to define an incident management procedure <alarm plan> <phone list>	• If there is no procedure for recall and withdrawal in place.	• Art. 19 Reg. (EC) No. 178/2002 • 21 CFR 7.42 Recall strategy
5.9.3	The procedures for management of incidents and product withdrawal/recall shall be subject to regular internal testing, at least once a year. This test shall be carried out to ensure the effective implementation and operation of the full procedure and shall include the verification of the updated contact data.	• How is the effectiveness of withdrawal tested? • How often is the 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.	• 21 CFR 7.42 (b) (3) Recall strategy

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
5.10	**Management of non-conformities and non-conforming products**			
5.10.1	A procedure shall be in place for the management of all non-conforming raw materials, semi-finished products, finished products, processing equipment and packaging materials. This shall include, at a minimum: • defined responsibilities • isolation / quarantine procedures • risk assessment • identification including labelling • decision about the further usage like release, rework/post treatment, blocking, quarantine, rejection / disposal.	• What procedures exist for the management of non-conforming products? • How are non-conforming products identified? • What rules exist for product quarantine procedures? <quarantine tickets>	• When no procedures exist for the management of non-conforming products.	• Reg. (EC) 178/2002 • 21 CFR Part: 117, § 117.80 (c) (9) • 21 CFR 189 Substances prohibited from use in human food. • 21 CFR 182 Substances generally recognized as safe • 21 CFR 184 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 procedure for the management of non-conforming products shall be understood and applied by all relevant employees.	• Who is responsible for putting non-conforming products into quarantine? • Who may release quarantined products? • How is it ensured that only authorized persons release quarantined products? <quarantine tickets>	• When employees do not know who is authorized to release quarantined products or when the products are in condition to be released or when products are quarantined and a safety issue occurs.	
5.10.3	Where non-conformities are identified, immediate actions shall be taken to ensure that food safety and product quality requirements are complied with.	• What procedures are implemented with non-conforming products? • Who decides about non-conforming products? <quarantine tickets>		• Art. 19 Reg. (EC) No. 178/2002 • 21 CFR 7.45 Food and Drug Administration-requested recall • 21 CFR 7.46 (a) Firm-initiated recall
5.10.4	Finished products (including packaging) that are out of specification shall not be placed on the market under the corresponding label, unless a written approval of the brand owner is available.	• For example, evidence 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 occurred), by checking the content of the contract.		
5.11	**Corrective actions**	**In case of a recertification assessment: were the corrective actions of the previous IFS Assessment applied?**		
5.11.1	A procedure shall be in place for the recording and analysis of non-conformities and non-conforming products, with the objective to avoid recurrences by preventive and / or corrective actions. This may include a root cause analysis.	• What are corrective action procedures? <corrective actions procedures>	• No corrective action procedures exist.	• 21 CFR 117.150 Corrective actions and corrections • 21 CFR 120.8 HACCP plan • 21 CFR 120.10 Corrective actions

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
5.11.2 KO	**KO N° 10: Corrective actions shall be clearly formulated, documented and undertaken as soon as possible to avoid the further occurrence of non-conformities. The responsibilities and the timescales for corrective actions shall be clearly defined.**	• Which corrective actions were implemented? • Where are corrective actions documented? • Who is responsible for corrective actions? • 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 responsibilities are assigned to implement corrective actions.	• 21 CFR 117.150 Corrective actions and corrections • 21 CFR 120.10 Corrective actions
5.11.3	The effectiveness of the implemented corrective actions shall be assessed and the results of the assessment documented.	• Where are corrective actions documented? • How are corrective actions verified? <model corrective action procedures>, <model with verified corrective action procedures>	• Corrective actions are not documented and/or verified.	• 21 CFR 117.150 Corrective actions and corrections • 21 CFR 120.11 (a) (1) (iv) (B) Verification and validation
6.	**Food defence**	**See specific Food defence Guidelines**		• **See IFS Food Defence Guideline 21 CFR 121 Mitigation Strategies To Protect Food Against Intentional Adulteration**
6.1	The responsibility for the food defence plan shall be clearly defined. Those responsible shall have the appropriate specific knowledge and training, and have full commitment from the senior management.	• Who has the accountability for the food defence program? • What are the competence and qualifications demonstrated for the person(s) responsible for the food defence program? • What is the position of the person(s) responsible for the food defence program with respect to the management team? • How do management teams support the person(s) responsible for the food defence program? • Where are the responsibilities clearly defined? • Was this communicated to the members of the company? How? <Job description>, <training records>		• 21 CFR 121.4 Qualifications of individuals who perform activities under subpart C of this part

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
6.2	A food defence plan and procedure shall be developed based on probability and be implemented in relation to assessed threats. This shall include: • legal requirements • identification of critical areas and/or practices and policy of access by employees • visitors and contractors • any other appropriate control measure. The food defence plan shall be reviewed at least annually, and updated when appropriate.	• What are the legal / customer food defence requirements applicable to the company? • How can the company demonstrate compliance with such requirements? • What is the process / procedure used to perform the hazard analysis 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 defence 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 defence breach? • How does the company evaluate the effectiveness of the food defence program? <food defence plan>, <risk assessment>, <meeting minutes>	• Unauthorised persons freely enter production or storage areas so that a safety risk occurs.	• 21 CFR 121.126 Food defense plan • 21 CFR 121.157 Reanalysis
6.3	The test on the effectiveness of the food defence plan and the related control measures shall be included in the internal audit and the inspection plan.	• Is the effectiveness of the food defence plan tested? • Is the food defence plan included in internal audits? <internal audit plan>, <report on effectiveness check>, <meeting minutes>		

N°	IFS Requirements	Examples of what should be checked and what may be asked	KO / Major	Cross reference (European Legislation,US legislation)
6.4	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 carried out and details of the visit? <procedure to handle inspections>, <report on external inspections>, <meeting minutes>, <training records>		

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