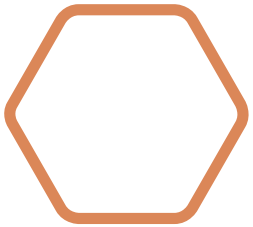
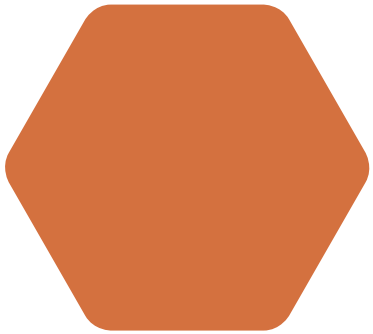
IFS HPC

IFS HPC Version 2 Guideline





Version 1, December 2016

Number	Requirement	Example of questions to be asked	Additional explanations
1			
1.1	**Corporate policy/Corporate principles**		
1.1.1	The senior management shall draw up and implement a corporate policy. The corporate policy shall include as a minimum reference to: • customer and consumer focus, • environmental responsibility, • occupational health, • buildings, • machines and equipment, • product requirements (includes: product safety, quality, legality, process and specification). The corporate policy shall be communicated to all employees.	• How and where is corporate policy documented? • When was the last update of the corporate policy? • What are the contents of the corporate policy? • How was corporate policy communicated to all employees? <corporate policy>, <posters>, <documented evidence of corporate policy communication on product safety> • Here the senior management unambiguously carries the responsibility. The guidelines should be set out in writing and available for members of staff in manuals and notices. The issues mentioned are fundamental for corporate principles. • Is the corporate policy agreed by suppliers and customers?	
1.1.2	The content of the corporate policy shall have been broken down into specific objectives for the relevant departments. The responsibility and the time scale for achievement shall be defined for each department of the company.	• What short, medium and long term quality objectives are addressed? • How are the objectives attained on product and process safety? • What is the time frame to attain the objectives? • Who is responsible for objectives attainment? • What actions are taken by specific departments, e.g. purchase, to attain the objectives? <written review meeting minutes>, <list of attendees at review meeting>, <quality and product safety objectives>, e.g. evaluation based on balanced scorecard system • It should be checked, if the aims are known by the members of staff and if these aims are implemented.	

Number	Requirement	Example of questions to be asked	Additional explanations
1.1.3	From the corporate policy, the quality and product safety objectives shall be communicated to the employees in the respective departments and shall be effectively implemented. The company shall ensure that all relevant information is communicated effectively and in a timely manner to the relevant personnel.	• Are these objectives known by concerned employees? • What tools are used to measure that the objectives have been attained? <list of attendees at review meeting>, <mailing list of review meeting minutes>, <posters showing the different department objectives> • The members of staff should be regularly informed of quality objectives and its importance for their work, e.g. within trainings. By means of questions should be checked, if the members of staff know their obligations and influence capability.	
1.1.4	The senior management shall ensure that the achievement of all objectives is regularly reviewed, as a minimum the objectives shall be reviewed annually.	• How often is this review performed? • Is the extent of the review conforming to the size of the company? <review>, <review minutes>,<internal audit report>, <other review data on product records> • The achievement of objectives should be checked best by Management reviews. The statements of the ISO 9001:2015 could be considered as assistant.	
1.2	**Corporate structure**		
1.2.1	An organization chart shall be available showing the structure of the company.	• Is an organisation chart available? • When was the last update of the organisation chart made? • How is the organisation structured? <Organisation chart> • Organigrams are common and a good possibility to describe structures and processes most realistic	

Number	Requirement	Example of questions to be asked	Additional explanations
1.2.2	Competences and responsibilities, including deputation of responsibility shall be clearly specified.	• For which positions do written job descriptions exist? • What is regulated in the job descriptions? • Who, for example substitutes QA manager during her/his absence? Is a replacement regulation available for all relevant employees? <Responsibility description for important key staff "dedicated to a specific person", e.g. QA Manager, Production Manager, Shift Leader …> • Competences and responsibilities and can also be regulated in job descriptions. Regarding proxy they should be very clear, possibly for description in organigrams.	
1.2.3	**KO N° 1: The senior management shall ensure that employees are aware of their responsibilities relating to product safety and quality. Senior management shall also ensure that mechanisms are in place to monitor the effectiveness of the operation of the employees. 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? Interview Senior Management (which is not automatically the Quality Manager) The senior management is responsible for duties concerning organisation, supervision and control. Basis for the duty of the organisation is a clear assignment of tasks. In this regard organigrams are a good possibility for presentation. Duties concerning supervision and control are mostly delegated to certain persons. They have to ensure that the assigned tasks are realized appropriately. During the audit it should be checked, if the responsibilities are clear for members of staff, if they are implemented, and how they are monitored for example: <Job description, minutes of evaluation meeting of the members of the staff, etc.> • Does the senior management provide sufficient training resources, refresher training and education for relevant employees? • Person in charge of materiovigilance in case of medical devices' suppliers.	

Number	Requirement	Example of questions to be asked	Additional explanations
1.2.4	Employees with influence on product requirements shall be aware of their responsibilities, through job descriptions, and shall be able to demonstrate understanding of their responsibilities.	<Interview of at least: QAM, person responsible for labelling, person responsible for product development, person responsible for production, person responsible for monitoring CP's>	
1.2.5	The company shall have an IFS representative nominated by senior management.	• Who is the IFS representative? • What are the responsibilities of the IFS representative <job description>, <Organigram> The IFS representative can be the representative for quality management. It is important that a contact person for all interest regarding the IFS is available. • Who is the deputy for the IFS HPC representative?	
1.2.6	The senior management shall provide sufficient and relevant resources to meet the product requirements.	• How were the necessary resources defined? <budget plan>, <Investments in equipment etc>, <personal resources>	
1.2.7	The department responsible for quality and product safety management shall have a direct reporting relationship to the senior management.	• Who is the QMD manager? • Who is defined as senior management? • How is ensured, that the senior management is up to date about all relevant qualityand risk management related topics? • To whom does the QMD manager report? <job description>, <Organigram>	
1.2.8	The company shall ensure that all processes (documented and undocumented) are known by the relevant personnel and are applied consistently.	• Which criteria are used to ensure process control? • What is done to ensure that processes are known to relevant personnel (incl. permanent staff and temporary workers)? Process can be understood as ISO processes.	
1.3	**Customer focus**		
1.3.1	A documented process shall be in place to identify fundamental needs and expectations of customers.	• How are customer needs and expectations identified? • How often are these identified? <questionnaire/survey regarding customers' needs and expectations>, <participation at relevant congresses or working groups>, <external support by e.g. opinion reserch centers>, <store checks>	

Number	Requirement	Example of questions to be asked	Additional explanations
1.3.2	The results of this process shall be evaluated and considered to determine quality and product safety objectives.	• What were the results of the last customer survey? <analysis of customer surveys> • How these results were evaluated regarding quality objectives? <quality objectives>, <bench mark tests> • Have identified needs influenced on the production process? <survey analyses>	
1.4	**Management Review**		
1.4.1	Senior management shall ensure that the quality and product safety management systems are reviewed at least annually, or more regularly, if changes occur. Such reviews shall contain at least: • results of audits, • customer feedback, • process compliance and product conformity, • status of preventive and corrective actions, • follow up actions from previous management reviews, • changes that could affect the product safety and quality management system, • complaints from Authorities, • recommendations for improvement.	• When is the quality management system reviewed and evaluated? How often was the system reviewed last year? What was the result of the review? <review report> • Does the management review take into consideration, as a minimum, the assessment of the following: · documents from the previous management review, · results from internal and external audits, as well as inspections, · performance indicators for customers, complaints and withdras/recalls, · incidents, corrective actions, results out of specifications and non confomring materials, · process performance and product compliance, · review of risk management system and changes which may affect quality and product safety system, · evolutions of scientific information related to products, · improvement of quality system efficiency anf production process, · improvement of product, related to customer requirements, · outsourced production · needs in resources (including investments) · Product Defense (if applicable)? • Is the extent of the Management review conforming to the size of the company? • Is the senior management participating at the performance of the management review?	

Number	Requirement	Example of questions to be asked	Additional explanations
1.4.2	This review shall include the evaluation of measures for the control of the quality and product safety management system and for the continuous improvement process.	• Based on the review result, have any actions for improvement been taken? <improvement actions>	
1.4.3	The company shall identify and review regularly (e.g. by internal audits or factory inspection) the infrastructure needed to achieve conformity to product requirements. This shall include, for example, the following items: • buildings, • supply systems, • machines and equipment, • laboratory equipment, • transport. The results of the review shall be considered, with due consideration to risk, for investment planning.	• When is infrastructure (building, machinery, transport) evaluated? • What was the result of infrastructure evaluation? <audit report> • Who evaluated infrastructure? • What were the results of the infrastructure assessment? <corrective actions>, <investment plan> • Were the results used for further infrastructure planning? <investment plan> • What risks were identified according to the results of infrastructure assessment? <risk analysis> • What are infrastructure related investments for the near future? <investment plan>	
1.4.4	The company shall identify and review regularly (e.g. by internal audits or factory inspection) the work environment needed to achieve conformity to product requirements. This shall include for example, the following criteria: • staff facilities, • environmental conditions, • hygienic conditions, • workplace design, • external influences (e.g. noise, vibration). The results of the review shall be considered, with due consideration to risk for investment planning.	• When is the work environment (staff facilities, environmental conditions, safety and security at work, hygienic conditions, workplace design etc.) evaluated? • What was the result of work environment evaluation? <audit report> • Who evaluated work environment? • What were the results of the work environment assessment? <corrective actions>, <investment plan> • Were the results used for further work environment planning? <investment plan> • What risks were identified according to the results of the work environment assessment? <risk analysis> • What are work environment related investments for the near future? <investment plan>	

Number	Requirement	Example of questions to be asked	Additional explanations
2	**Quality and Product Safety Management System**		
2.1	**Quality Management**		
2.1.1	**Documentation requirements**		
2.1.1.1	The quality and product safety management system shall be documented and implemented, and shall be retained in one location (it can be an electronic documented system).	• Where is documentation concerning the quality system for quality assurance and product safety retained? <procedure for document control> The IFS makes no requirements concerning the visual aspects or the content of the quality management manual. The documents have to be centrally stored and available for every member of staff.	
2.1.1.2	A documented procedure shall exist for the control of documents and their amendments.	• What rules exist regarding document control? • Do the documents have an identification code? • How is the identification code structured? • How can a revision be identified? • How and how long are expired documents kept in an archieve? • Who is responsible for changes? <procedure for documents> • How is the approval and release of documents guaranteed? It should be fixed, which documents and in which way they are drawn up in the business (standard documentation). This also applies to labelling and documentation.	
2.1.1.3	All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times.	• Are all documents legible? • Are the documents unambiguous? • Are the documents available at the right places? Also after office hours? • How do relevant employees have access to documents? • How are document changes communicated to relevant employees? • Are there any distribution lists for documents? <Examples>, <procedure>, <distribution lists>	

Number	Requirement	Example of questions to be asked	Additional explanations
2.1.1.4	All documents which are necessary for compliance with the product requirements shall be available in their latest version.	• How is document validity identified? • How is it ensured that only valid documents are in circulation? <for product requirements see IFS glossary>	
2.1.1.5	The reason for any amendments to documents, critical for the product requirements shall be recorded and approved.	• Are the reasons for any amendments to documents, critical for the product requirements recorded? <examples>	
2.1.1.6	Documents shall be removed from the job area and destroyed if they are outdated.	<procedure for documents> • Who is responsible for the exchange of expired documents?	
2.1.2	**Record keeping**		
2.1.2.1	All relevant records necessary for the product requirements shall be completed, detailed and securely maintained (e.g. with backup system) and shall be available on request.	• What records exist? • Are the records complete? • Are the records available? <is availability checked regularly e.g. in a traceability test?> Record can exist as papers or electronically.	
2.1.2.2	Records shall be legible and genuine. They shall be maintained in a way that subsequent manipulation of records is prohibited.	• Are records plausible? • Are records legible? • What kind of assurance is given that records cannot be subsequently manipulated? • Are the records reviewed by a supervisor? • Records may not be taken by pencil.	
2.1.2.3	All records, including records showing the effective control of process, product safety and quality shall be kept in accordance with legal requirements and customer specifications (this includes, for instance and where relevant, the cosmetic product information file). These records shall be kept for a minimum of one year after the end of shelf life period. For products which have no shelf life, the duration of record keeping shall be in line with customers' requirements.	• Where are records stored? • Who stores records? • How long are records kept? • On what basis were record storage times defined? • For products with a short shelflife, was record storage time definition based on risk analysis? <procedure documents>, <risk analysis>	

Number	Requirement	Example of questions to be asked	Additional explanations
2.1.2.4	Any amendments to records shall only be carried out by authorized persons.	• How are amendments to records carried out? • Who is authorized to make amendments? • In case of absence, who is the deputy authorized to make amendments? • How are amendments authorized? Responsibilities have to be well defined.	
2.2	**Product Safety Management**		
2.2.1	**Risk management system (Hazard analysis and Risk assessment)**		
2.2.1.1	Before developing a risk management system, the company shall have implemented all necessary Good Manufacturing Practices (GMP's) which are commonly used in its scope of activity.	• Does the company have implemented good manufacturing practices? Companies have to use the GMPs which are commonly use in their field of activity. e.g. ISO 22716 or Regulation (EC) No 2023/2006 of 22 December 2006, etc.	In cases where there is no specified GMPs in the scope of activity, company can create its own GMPs taken as a model any other GMPs implemented in other HPC scopes. GMP principles shall be based on scientific literature and state of the art for each branch. GMP shall take into account product and process specific quality and risk related production steps and shall cover all basic manufacturing and control activities such as hygiene, chemical safety, equipment etc. The manafacturing against GMP principles is the basis for the implementation of the risk management system. The documentation of GMP and risk management system can be handled separately or in a combined analysis.

Number	Requirement	Example of questions to be asked	Additional explanations
2.2.1.2	The basis of the company's product safety control system shall be a fully implemented, systematic and comprehensive risk management system. It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The risk management system shall be implemented at each production-site. The risk management system shall cover all raw material groups, products or product groups, as well as every process (included outsourced process) from goods receipt to product dispatch, including product development and product packaging.	• The company's risk asssement study is based on which principles? <literature listed in the corresponding risk management procedure> • Has every site/plant a separate risk assessment study? • Which specific regulations are taken care of in the risk assessment study? <risk assessment study> • Are the legal requirements of the destination country are known, especially the labeling regulation?' • How is the customer involved in the labelling process? <responisibilities> • Does the risk management system cover all products (e.g. raw materials, product groups, packaging material …)? • Are support processes such as purchasing or storage implemented in the risk management system? • Does the risk management system cover all processes including outsorcing processes and product development? • What is the categorisation principle? <product group overview>, <flow chart>	The risk management system shall be implemented for each production site taking into account the local situation.
2.2.1.3	The company shall ensure that the risk management system is based upon scientific literature, or technical verified specifications relating to the manufactured products and procedures. The risk management system shall be maintained in line with any new technical and scientific process development.	• Is it based upon scientific literature or technically verified specifications relating to the manufactured products and procedures? <e.g: FME(C)A, RPN, risk matrix, ISO 14971 (medical devices), or HACCP etc.> • How are new technical developments taken care of? <references of used literature, etc.> It should be considered that the system has to be constantly updated. It is the only way to guarantee the functioning of the system.	

Number	Requirement	Example of questions to be asked	Additional explanations
2.2.1.4	Risk management system shall be reviewed and necessary changes shall be made when any modification is made in the product, process or any change that could affect product requirements.	• How are new standards e.g. new version of the IFS HPC introduced in the modification of the risk management system? • What reasons may have an impact on the modification of the risk mangement system? <new products>, <new product goups>, <changes in building and exteriors>, <equipment and machines> Changes in product can be e.g. a change in packaging material (bottle, pot or sachet), change of ingredients (e.g. eco-products, allergens, nano-particles etc.). Changes of process can be caused e.g. by the implementation of new equipment, a new process flow or the transfer of different production steps to a contractor (e.g. co-packing). The system should be reviewed minimum annually by the whole risk management team and if changes occur caused by product modifications, changes in process and steps or changes in equipment and building.	
2.2.2	**Risk management team**		
2.2.2.1	The risk management team shall be multidisciplinary and include operational staff. Personnel appointed as risk management team members shall have specific knowledge of hazards and risks associated to products and processes. Where competent knowledge is not available, external expert advice shall be obtained.	• Who is member of the team? • Which departments/functions are included in the team? • How was qualification for team membership verified? <evidences for education, advanced training>, <Qualification record/evidence list> • What hazards are connected to the product? • Does a contract exist with an external expert? <service contract> • It should be checked if competent knowledge is given by a member of the staff and then trained in the company (a certificate should be available) or if an external expert advice is obtained.	

Number	Requirement	Example of questions to be asked	Additional explanations
2.2.2.2	Those responsible for the development and maintenance of risk management system shall have received adequate training in the application of the risk management principles based on the risk management tool (Risk matrix, FMEA, HACCP, RPN, etc.) which the company uses.	• What is the content of a risk management training course? <Risk management training proofs> • When was the last training course held? <training proofs> • Who participated in this training course? <training proofs> • What is the education and the experience of those responsible for development and maintenance of the risk management system?	
2.2.2.3	The risk management team shall have senior management support and shall be well known and established within the company.	• Is the team well known across the company? • How was it announced? <job descriptions>, <team matrix>, <blackboard notice>, <presence of management in any risk management brief>, <result of risk assessment rewiew included in Management review> • Does the senior management provide sufficient personnel and temporary resources for the risk management team to take care on administration, development and training of risk management requirements?	
2.2.3	**Hazard analysis and risk assessment**		
2.2.3.1	**Describe the product** The assessment shall make reference to the full description of the product including all applicable relevant information on product safety and regulation such as: • composition (raw materials, rework, reprocessing, etc.), • physical, chemical and microbiological parameters, • methods of treatment, • packaging, labeling, • durability (shelf life), • conditions for storage • method of transport.	• Does a product description exist for each product/product group? • What is included in the product description? <product description>, <product specification>, <list of products and specifications> For household and cosmetics CLP	

Number	Requirement	Example of questions to be asked	Additional explanations
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 consumer, taking into account vulnerable groups of consumers.	• What is the intended use of the product? • Is it considered as well the foreseeable use of the product? • Is the forseeable use in all destination countries the same? • The product is unsuitable for which consumer group? • Is the product suitable for children, pregnant women, senior persons?<product description> Vulnerable groups of consumers: babies, children, seniors, allergic person or pregnant woman.	
2.2.3.3	**Construct flow diagram** A flow diagram shall exist for each product, product groups, raw material groups, etc., and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall be dated, and clearly identify each critical control point with the number assigned to it. In the event of any changes the flow diagram shall be revised.	• Are flow charts available for all products? <flow charts for all products> • Are the flow charts dated? In the event of CCPs are identified in the flow chart, are these identified accordingly? • Do they have a number? • Are all flow charts with CCP's up-to date? It may happen that companies don't identify the CCPs within the flow chart. This is not mandatory, although it would be helpful for the company.	
2.2.3.4	**On-site confirmation of the flow diagram** The risk management team shall review the processes at all operation stages against the flow diagram. Where relevant, amendments of the diagram will be made.	• Was the flow chart checked/confirmed during a meeting? <meeting minutes>	

Number	Requirement	Example of questions to be asked	Additional explanations
2.2.3.5	**Conduct a hazard analysis and risk assessment for each step**		
2.2.3.5.1	A hazard analysis shall be available for all physical, chemical and biological hazards that may be reasonably expected. A hazard analysis and a risk assessment shall be conducted for each step from raw materials to the finished products including development and packaging material validation.	• Does a hazard analysis exist for each step ? <hazard analysis> • Which biological, physical and chemical hazards can be expected? <hazard analysis>, <if applicable: allergen-related hazards> The risk assessment shall take into account potential risks for safety and legality. This shall take into account e.g.: • allergen contamination • foreign bodies • microbiological contamination e.g. water The risk assessment shall be the basis for raw material acceptance, testing procedures and supplier approval and monitoring.	The hazard analysis shall cover all products and processes. For each product or product group a full description shall be available, which includes all relevant information on product safety. As an example: • composition • physical or chemical properties that impact product safety • legal requirements • treatment and processing • packaging • labelling • storage and distribution conditions • outsourced processes • instructions for use, potential customer misuse • R&D
2.2.3.5.2	Based on the hazard analysis, the risk assessment shall demonstrate the actions required if a hazard is a risk, taking into account the probability of harm to the consumer and the severity of damage (effect, potential consequences). The methodology for assessing risk shall be documented.	• Does a hazard analysis for all product groups including harm and likelihood exist? <hazard analysis>, <methodology: risk matrix, FMEA, HACCP, RPN, etc.>	

Number	Requirement	Example of questions to be asked	Additional explanations
2.2.3.6	**Determine critical control points** Based on level of acceptability of risk, critical control points shall be identified and documented.	In case the company has identified CCPs: • Which CCPs are defined? • Which prerequisite measures were taken regarding CCPs? • Which prerequisite measures are documented? • How are the measures documented? <hazard analysis>, <flow chart>, <decision tree>, <prerequisite measures> An example for a preventive measure is the documentation at the control of incoming goods (e.g. checking of quality, labelling). • Based on methodology: Did the company identify any CP's? • Which prerequisite measures were taken regarding CP's?	This requirement can not be rated with N/A. See Part 1 of the Standard. Depending its scope of activity and/or production process (es) a company may no have determined CCPs. In the event that a company does not have any CCP's, the company shall document a logical approach which needs to be assessed by the auditor.
2.2.3.7	**Establish critical limits for each critical control point** For each critical control point, the appropriate critical limits shall be defined and validated in order to clearly identify when a process is out of control.	• Is a critical limit defined for each CCP? • What critical limits are defined? • How were the critical limits determined? <risk assessment study>	
2.2.3.8	**KO N° 2: Establish a monitoring system for each critical control point** **Specific monitoring procedures shall be established for each critical control point to detect any loss of control. Records of monitoring shall be maintained for a relevant period. Each defined critical control point shall be under control at all times. Monitoring and control of each critical control point shall be demonstrated by records. The records shall specify the person responsible, as well as the date and result of the monitoring activities.**	• How are CCPs monitored? • Are the CCPs under control? • How is the monitoring of each CCP documented? • Who documents? • Are date, time, responsible employee and result/reading documented? • How long will records be stored? • Where are records stored? <CCP records> • Based on methodology: How are CP's/CCP's monitored? • Are CP's/CCP's under control? • How is the monitoring of each CP/CCP documented? • Who documents? • Are date, time, responsible employee and result/reading documented? • How long will records be stored? • Where are the records stored? <CP/CCP records> This KO requirement could be rated as N/A. See Part 1 of the Standard.	Process monitoring shall be established and adequately controlled to ensure products are produced within the required process specification. All risks that need specific monitoring shall based on methodology be identified as Control Points (CP's) or Critical Control points (CCP's). Clear limits shall be available. For all risks identified as CP's/CCP's the company shall implement, maintain and document specific preventive and corrective measures.

Number	Requirement	Example of questions to be asked	Additional explanations
2.2.3.9	**Establish corrective actions** For each critical control point, corrective actions shall be established. In case the monitoring indicates that a particular critical control point is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any non-conforming products.	• What corrective actions exist ? • When was a corrective action carried out? • Where are corrective actions documented? • Who documents the taken corrective actions? <CCP records>, <corrective actions>, based on methodology: <CCP records>, <corrective actions>	
2.2.3.10	**Establish verification procedures** Procedures of verification shall be established to confirm that the risk management system is effective. Verification of the risk management system shall be performed at least once a year. Examples of verification activities include: • internal audits, • analyses, • sampling, • evaluations, • complaints by authorities and customers. The results of this verification shall be incorporated into the risk management system.	• How often is the system verified? • What was the date of the last verification? • What was the result of the last verification? • Does the system reflect the results of the verification? • What was the last date when the system was changed? <audit reports or other reports for validation> • Was the last verification a routine verification or based on relevant non conformities, recalls, rebuilding activities …?	
3	**Resource Management**		
3.1	**Human resources management**		
3.1.1	All personnel performing work that affects product safety, legality and quality shall have the required competence (demonstrated by education, work experience and/or training) based on hazard analysis and assessment of associated risk.	• How is it ensured that new employees have the right capabilities for the job?	

Number	Requirement	Example of questions to be asked	Additional explanations
3.2	**Personnel hygiene management**		
3.2.1	**Personnel hygiene**		
3.2.1.1	There shall be documented requirements relating to personnel hygiene. These include, as a minimum the following criteria: • protective clothing, • hand washing and disinfection, • eating and drinking, • smoking, • actions to be taken in case of cuts or skin abrasions, • fingernails, jewelry and personal belongings, • hair and beards. The requirements shall be based on hazard analysis and assessment of associated risk in relation to product and process.	• Did the company define different hygiene zones? • What is the policy regarding personal hygiene? <hygiene rules for employees> Based on risk assessment, which are the rules regarding personnel hygiene including hand cleaning, food and beverages, smoking, handling of injuries, finger nails and jewellery, and hair and beards? E.g.: • all hair shall be covered completely if headgear/hair-net/bonnet and/or beard snood is required to prevent product contamination • are fingernails kept short, clean, and unpolished? • false fingernails are not permitted • personal belongings (use of medicines, etc.) • Where is it allowed to smoke? • How should lesions be treated/covered?	Examples of topics which need to be addressed: • management of wearing and changing of protective clothing (including disposable and reusable gloves). • policies relating to the wearing of protective clothing away from the production environment • disposable protective clothing, if used, shall be subject to adequate control to avoid product contamination.

Number	Requirement	Example of questions to be asked	Additional explanations
3.2.1.2	The requirements for personnel hygiene shall be in place and applied by all relevant personnel, contractors and visitors. Compliance with the requirements shall be checked regularly.	• How is the hygiene policy communicated? <hygiene rules for employees> • How is it assured that personnel and external persons know and follow the relevant hygiene rules? <hygiene rules for visitors> • Are employees, visitors and contractors able to understand the hygiene requirements (language)? • How are employees monitored during work? <minutes site inspection>, <list of identified failures>, <results of hygiene monitoring> etc. • Is employee compliance to hygiene rules checked on a regular basis? <minutes site inspection>, <list of identified failures>, etc. To check if In toilets and where appropriate, signs urging staff to wash hands are in place. • Does the auditor recieve an adequate introduction into the hygiene rules before entering the production? • In case contractors come regularly (e.g. maintenance or pest control suppliers), are they trained into the hygiene rules in a defined frequency? • How is the regular training for each single employee of the contractor controlled e.g. using lists? • How are temporary workers trained by the company or the supplier (providing temporary workers)?	
3.2.1.3	Visible jewelry (incl. piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated based on hazard analysis and assessment of associated risk.	• Is it allowed to use jewellery and watches in production areas? <personnel hygiene rules> • Is allowance based on risk hazard analysis? <risk assessment> Explanation regarding differing rules and risk assessment	

Number	Requirement	Example of questions to be asked	Additional explanations
3.2.1.4	Cuts and skin abrasions shall be covered by a colored plaster/bandage (different from the product color). Any exceptions shall have been comprehensively evaluated based on on hazard analysis and assessment of associated risk.	• What colour is the plaster and where is it used? • Does the plaster contain a metal strip? • Is the metal detector abel to detect the plaster? • What is an employee required to observe in case of hand injury? <personnel hygiene rules>	
3.2.1.5	Based on hazard analysis and assessment of associated risk, there shall be a program to control effectiveness of hand hygiene.	• Hand-cleaning is performed at a suitable frequency to maintain hygienic conditions? Mainly applicable for scope 1 and 4. • In case employees wear gloves, how is hand hygiene ensured? (see also 3.2.2.3)	
3.2.2	**Protective clothing for personnel, contractors and visitors**		
3.2.2.1	Company procedures shall exist to ensure that all personnel, contractors and visitors are aware of the rules regarding the management of wearing and changing protective clothing in specified areas in accordance with product requirements.	• What are the rules regarding protective clothing? <personnel hygiene rules> • Are the protective clothing rules based on risk analysis? <risk analysis> • When must protective clothing be changed? <personnel hygiene rules> examples of areas: catering, changing rooms, smoking area, toilets, high risk areas, etc.	
3.2.2.2	In work areas where wearing headgear and/or beard snood (covering) is required, the hair shall be covered completely, so that product contamination is prevented.	• In which production areas is wearing of protective headgear and/or beard snood mandatory? • What kind of headgear is used? • How shall headgear be used? <personnel hygiene rules> • In case beard protection shall be worn, is there a limit until what length a beard is allowed? • Is it based on risk assessment?	
3.2.2.3	Clearly defined usage rules shall exist for work areas/activities where it is required to wear gloves (colored differently from the product color). Compliance with these rules shall be checked on a regular basis.	• In which production areas is wearing of gloves mandatory? <personnel hygiene rules> • What kinds of gloves are used? • When must gloves be changed? • How is the compliance with these rules checked? <glove swab test results>, <on site inspections>	

Number	Requirement	Example of questions to be asked	Additional explanations
3.2.2.4	Suitable protective clothing and devices to ensure personnel safety shall be available in sufficient quantity for each employee, when required.	• Are protective clothing and devices given to the personnel? If so, how many? <examples of devices: plugs, otoplastic, filter masks …> • How many protective suits/uniforms are at the disposal of each employee? • How often is an employee supposed to change her/his protective suit/uniform? • Are there outside pockets in the uniform above the hip? • Are temporary workers included in those rules? • In case the contract company providing temporary workers provides the protective clothing, are the hygiene requirements the same? Any exceptions shall be explained based on risk assessment. For suitable is understood as kept in good conditions, no impact on product safety.	
3.2.2.5	When required, all protective clothing shall be thoroughly and regularly laundered. Based on hazard analysis and assessment of associated risk, taking into consideration the processes and products, the company shall determine if clothing shall be washed by a contract laundry, on-site laundry or by the employee.	Mainly applicable for scopes 1, 3 and 4 • How is protective clothing laundered? <personnel hygiene rules> • Are there any employees who launder their protective clothing at home? If yes, how are they transported to the audited site? • Is there a cleaning instruction for employees cleaning at home? • Is protective clothes laundering based on a risk assessment? <risk assessment> • Cleaning of protective clothing, choice of a contracted laundry etc.	In cases where items of personal protective clothing are not suitable for laundering (such as chain mail, gloves and aprons), these shall be cleaned and sanitized at a frequency based on risk assessment. If necessary, there shall be cleaning devices for boots, shoes and other protective clothing in place and used based on risk assessment.
3.2.2.6	Guidelines shall exist for laundering of protective clothing and a procedure shall be in place for checking its cleanliness, when required.	• How is the laundering procedure checked for effectiveness? <protective clothes swab test results> • What guidelines exist regarding protective clothes laundering? <personnel hygiene rules>	

Number	Requirement	Example of questions to be asked	Additional explanations
3.2.2.7	The company shall review that implemented preventive measures to ensure personnel safety related to hazardous working conditions are effective.	• Does an inspection plan exist? <report of inspection> security tests (simulations in case of fire), automatic stop systems, specific training on working conditions, etc. • Are protective glasses, ear plug or gloves in place? • Is the protective equipment suitable to guarantee personnel safety e.g. type of gloves, facial masks, safety shoes …?	
3.2.3	**Procedures applicable to infectious diseases**		
3.2.3.1	There shall be written and communicated measures for personnel, contractors and visitors in case of any infectious disease which may have an impact on product safety. In case of declaration of infectious disease, actions shall be taken in order to minimize risk of contamination of products.	• How shall personnel and visitors behave in case or suspicion of an infectious disease? • How is it ensured that personnel and visitors know the guidelines? <personnel hygiene rules>, <visitors hygiene rules> Special consideration shall be given to areas where product safety could be compromised. Where there may be risk to product safety, and where legally allowable, visitors and contractors shall be required to complete a health questionnaire prior to entering the raw-material, preparation, processing, packing, and storage areas. This requirement may not be applicable in certain countries taking into account national legislation.	

Number	Requirement	Example of questions to be asked	Additional explanations
3.3	**Training and instruction**		
3.3.1	The company shall implement documented training and/or instruction programs with respect to the product requirements and the training needs of the employees based on their job which shall include: • training contents, • training frequency, • employee's task, • languages, • qualified trainer/tutor, • evaluation methodology.	• Who is responsible for training? <training proof> • What are the evidences for the trainer's qualification? • What was the content of the last training session? <training program> • How are foreign employees trained/instructed? • Who participates in the training sessions? • How are the instruction necessities for each employee determined? • How often are training sessions held? <training schedule> Examples of training content: CP and CCP, personnel hygiene (infectious diseases, vomiting, diarrhea, "Infection Protection Act"), facility hygiene, cleaning and disinfection, GMP's for cosmetics, crisis managements, management of chemicals, etc.) Programs shall take into consideration company's specific issues, product safety, product related legal requirements and product/process modifications.	
3.3.2	The documented training and/or instruction programs shall apply to all personnel, including temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained in accordance with the documented training/instruction programs.	• Are prospective employees (including temporary workers) trained/instructed upon employment? • Which employees are trained/instructed upon employment? • What is the content of these instructions? <training proofs> • Is an introductional training plan implemented for all relevant employees? E-learning and webinars could also fit with the requirement, as long as this can be checked/assessed by the auditor.	

Number	Requirement	Example of questions to be asked	Additional explanations
3.3.3	Records shall be available of all training/instruction events, stating: • list of participants (this shall include their signature), • date, • duration, • contents of training, • name of trainer/tutor. There shall be a procedure or program in place to prove the effectiveness of the training and/or instruction programs.	• Which training courses are undertaken? • Are there any special training courses? • Are training courses documented? • What has been documented? • Have participants signed the training proofs? • How often are hygiene training sessions held? • What was the content of the last hygiene training session? • How the result of the training is evaluated? <training proofs>	
3.3.4	The contents of training and/or instruction shall be reviewed and updated regularly and take into account company's specific issues, product safety, product related legal requirements and product/process modifications.	• Who is responsible for updating the training? • In case of mandatory training e.g. fork lift driving, first aid etc., how is it traced? • What is the frequency of training? • How are training contents reviewed? <review test> • When are training contents reviewed? • When was the latest training content update done?	
3.4	**Staff facilities, sanitary facilities and equipment for personnel hygiene**		
3.4.1	The company shall provide staff facilities, which shall be proportional in size, equipped for the number of personnel and designed and operated so as to minimize product safety risk. Such facilities shall be kept clean and in good condition.	• How many employees are there? • Do they have access to a cafeteria? • Are there locker-rooms? • Where are the restrooms? • Are there bathing facilities? <plant lay-out> • Are they mantained in a good conditions? Staff facilities is for instance changing room, smoking area, dining room, etc.	
3.4.2	There shall be in place rules and facilities to ensure the correct management for personnel belongings and food and other materials brought to work by personnel and shall include, food from dining room and from vending machines. The food and other materials shall only be stored and/or consumed in designated areas.	• How are based on risk assessment food or other personal belongings transferred or stored throught designated areas of a hygiene zone? <any restrictions?>	

Number	Requirement	Example of questions to be asked	Additional explanations
3.4.3	The company shall provide suitable changing rooms for personnel, contractors and visitors. Where necessary, outdoor clothing and protective clothing shall be stored separately.	• Are there locker-rooms for employees and visitors with separation for outdoor and protective clothing? • And for clean and dirty workwear?	Where an operation includes a special hygiene zone, with e.g. clean room technology, personnel shall enter via a specially designated changing facility at the entrance. The changing facilities shall include the following requirements: • clear instructions for the order of changing into dedicated protective clothes to prevent the contamination of clean clothing • adequate footwear shall be provided to be worn in the high-risk area • an effective system shall be provided to segregate areas for wearing hygiene and other footwear, e.g. a barrier or bench system • protective clothing shall be visually distinctive from that worn in other areas and shall not be worn outside of the hygiene zone • hand-washing during the changing procedure shall be incorporated to prevent contamination of the clean protective clothing • on entry to hygiene zone and close to work , hand-washing and disinfection shall be provided.

Number	Requirement	Example of questions to be asked	Additional explanations
3.4.4	Changing rooms shall be separated from production area and shall be sited so that they allow direct access to the areas where products are handled. Based on hazard analysis and assessment of associated risk, exceptions shall be justified and managed.	• Do locker-rooms give direct access to processing areas? • How is protective clothing handled during breaks/intervals? <Personnel hygiene rules> • Does a hazard analysis exist for locker-rooms with no direct access to processing areas? <Hazard analysis> There should not be any long ways or additional rooms between the changing room and the production room to minimize hazards on the way to the production. The changing room shall be separated from the production area (door).	
3.4.5	Toilets shall not have direct access to an area where products are handled. The sanitary facilities shall be equipped with adequate hand washing facilities. Sanitary facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.	• Do toilets open directly into production areas?	
3.4.6	Adequate hand hygiene facilities shall be provided near points of entry to and within production areas, as well as at staff facilities. Based on hazard analysis and assessment of associated risk, further areas shall be similarly equipped.	• Are there enough hand washing facilities available at the entrance to processing areas and in social areas? • Are enough hand cleaning facilities available in the production area itself, in case water is not available at each work station are adequate alternative facilies available? In case of hand hygiene facilities within production process check if the safety of the products is not comprised.	
3.4.7	Hand washing facilities shall provide as a minimum: • water, • liquid soap, • appropriate equipment for hand drying.	This requirement is the minimun expected for companies under scope 2. • Are all hand washing facilities provided with appropriate equipment for hand drying, liquid soap and disinfectant? • In an appropiate amount? • Are all hand washing facilities provided with running potable water at an appropriate temperature for a suitable hand washing? • Are sufficient cleaning and/or disinfectant dispensers available at the entrance of the production area?	

Number	Requirement	Example of questions to be asked	Additional explanations
3.4.8	If necessary, following additional requirements regarding hand hygiene shall also be provided: • hand contact-free fittings, • hand disinfection, • adequate hygiene equipment, • signage highlighting hand hygiene requirements, • waste container with hand contact free opening.	Mainly applicable for companies under scope 1, 3 and 4. <hand disinfection devices and signs or pictograms> <signs/pictograms>	
4	**Planning and production process**		
4.1	**Contract agreement**		
4.1.1	The requirements which are defined in the contract with the customer shall be established, agreed upon and reviewed concerning their acceptability before a supply agreement is concluded. All clauses related to quality and product safety shall be known and communicated to each relevant department.	• What assurances are given that customer requirements and own specifications are in accordance with each other? • Do written supply agreements with customers exist? • Do specific customer requirements for purchased products exist? • Who checks and approves specifications? • Who ensures that the proper raw materials are available whenever needed? • Who is responsible for the transfer of updated specifications? • How is ensured that all relevant departments are informed about changes in specification?	
4.1.2	Changes of existing contractual agreements shall be documented, communicated and updated between the contract partners.	• How is it ensured that customers are informed about product changes? • Who checks and approves specifications? • How is ensured that all relevant departments are informed about changes in contracts?	

Number	Requirement	Example of questions to be asked	Additional explanations
4.2	**Specifications and formulas**		
4.2.1	**Raw Materials (including packaging materials), semi-finished products and rework specifications**		
4.2.1.1	Specifications shall be available and in place for all raw materials (raw materials/ingredients, additives, packaging materials, rework) and where relevant, for semi-finished product. The specifications shall be up to date, unambiguous, available and always in conformance with legal requirements.	• Are specifications available for all raw materials, ingredients, additives, packaging materials and rework? and are relevant also for semi-finished products? • What is the procedure regarding changing of any raw material? • Is the supplier of the raw material dedicated by the customer? • Is the degree of purity e.g. Ph.Eur. dedicated by the customer? • What assurance is given that specifications are followed? <proof of specification compliance, e.g. lab results> • What assurance is given that specifications are in conformance with legal requirements? • Who approves the specifications? • Are all specifications approved? • Is there a system in place which assures that any client is informed when there is a change of a raw material which could have an impact on any client specification and/or on the final products? In the IFS audit is checked by a relevant random sample, if the current specifications are available and valid.	Check if raw material acceptance and its release for use is based on one or a combination of (including outsourced products e.g. raw material, intermeditae products/material, etc.): • visual inspection on receipt (e.g. inspection on presence of pests) • certificates of conformance —specific to each consignment • certificates of analysis • product sampling and testing • free from declaration
4.2.1.2	Identification of raw materials including packaging materials shall contain the following information: • name of the product, • unique identification code, • date or number of receipt (if relevant) • supplier's name, • expiry date, if existing • batch reference given by the supplier and the one given at receipt, if different.	• In case of brokers of raw materials is the name and the production site of the raw material known? • In case of different production sites of one supplier, are all sites released for the designated raw material? <e.g. production hygiene and production equipment of the site might have an impact on the quality of the raw material or packaging material> • Does the COA of alternative suppliers of the same raw material contain the same information? <check of batch labels>, <COA's if applicable>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.2.1.3	A reevaluation of the suitability of raw materials shall be in place, in cases where raw materials are close to the best before date, or when they are returned to storage or other relevant parameters given by the supplier.	• How the best before date is followed? • In case the expiry date of the raw material falls into the life cycle of the finished product, is the efficacy of the finished product (e,g, sun protection, disinfection etc.) still guranteed?	
4.2.1.4	When raw materials including packaging materials are repacked, the new label shall contain the relevant information as on the original label.	• How are raw materials identified after repacking ?	
4.2.1.5	Where relevant, raw material specifications identifying allergens requiring declaration shall be available. The company shall maintain a continuously up to date listing of all raw materials containing allergens used at its premises, which also identifies all blends and formulas to which such raw materials containing allergens are added.	Mainly applicable for scopes 1 and 2 • Are allergens identified in specifications? E.g: some fragrances • Does a list exist that covers allergens in use? <allergen list> In case of perfumes or essential oils, it must be guaranteed by tests of the finish product that no allergens are developing by so called precursor substances. This is relevant for household chemicals as well as for cosmetic!	
4.2.2	**Finished product specifications**		
4.2.2.1	Specifications shall be available for all final products and shall be agreed upon in writing with customers. The specifications shall be up to date, traceable, unambiguous, available to relevant personnel and always in conformance with legal and customer requirements.	• How are specifications compiled, checked and approved? • Are there specifications for all final products? • How are up to date specifications recognizable? <specifications>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.2.2.2	**KO N° 3: Current and approved finished product specifications shall be the basis for the composition of products. They shall also be the basis for the control of the production process and to monitor the finished products' compliance.**	• What assurance is given that specified recipe is followed? • How is recipe compliance checked? • What assurance is given that specifications are followed? <proof of specification compliance, e.g. lab results> • What assurance is given that specifications are in conformance with legal requirements? Here the abidance can be tested. Therefore a comparison of recipe and specification of the end product and the end product respectively is important. This should be tested regularly in internal audits.	
4.2.2.3	Where customers specifically require that products are "free from" certain substances or ingredients, or that certain methods of treatment or production are excluded, verifiable procedures shall be in place.	• Do customers demand that certain substances are not included in the product? • If so, how is it managed by QA? • In case the customer requires an agreed product specification, is it signed from both sides?	
4.2.2.4	There shall be a procedure for the creation, the modification and approval of specifications for all parts of the process, which shall include the preliminary acceptance of the customer, if specifications have been agreed with customers.	• Who writes, amends, checks and approves specifications? • How are updated specifications communicated to all relevant departments? <adaption of analytical methods>, <limits, tolerances>, <claims>, <stability, challenge tests>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.2.2.5	The specification control procedure shall include the update of finished product specification in case of any modification requested by the customer and/or defined by the company, related to: • raw material, • formula/recipe, • process with influence on the final product, • packaging with influence on the final product.		• Check if correct packaging and labels are used and how it is documented and approved. This shall be regularly checked, at least before a new label is issued for use and checks shall be documented. • Check if a modification of raw materials causes changes in safety, legality, performance, labelling or stability of the finished product • Check if a modification of formula causes changes in safety, legality, performance, labelling or stability of the finished product • Check if a modification of processs causes changes performance or stability of the finished product • Check if a modification of the packaging causes changes in safety, legality, performance, labelling or stability of the finished product

Number	Requirement	Example of questions to be asked	Additional explanations
4.3	**Legislative framework and R&D process**		
4.3.1	**Legislative framework**		
4.3.1.1	The company shall comply with the current applicable legislation and shall be able to demonstrate its own role in the supply chain.	• How is the legislation followed? • How is the legislation followed for each destination country? • How are the updates of the legislative texts or other managed? • Who is responsible? <procedure>, <text> The target is to check that the company knows and applies the legislation applicable to the products which are manufactured/conditioned on-site. Examples of EU relevant legislation: liability for defective products, general product safety, cosmetics, aerosol, dangerous chemicals, biocides, medical device directive, REACH, Cosmetic GMP, Classification Labelling and Packaging, detergents, food contact materials, etc.	
4.3.1.2	The company shall have a system in place to ensure that it is kept informed of all relevant legislation on product safety and quality issues, scientific and technical developments and industry codes of practice. Legislation shall be understood and applied.	• How does management ensure that all relevant legislation 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? <laws subscription>, <training> • How does management ensure that manufactured products comply with all relevant legislation? • Does the company use additional external support?	
4.3.1.3	For all relevant raw materials, safety data sheets shall be available in the format required by the destination country and kept up to date.	Mainly applicable for scopes 1 and 2 (mandatory for scope 2) <AR>, <new GHS labelling>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.3.1.4	Where relevant, the safety data sheet and/or composition for final products shall be provided and communicated to the appropriate organizations (e.g. national safety centers, public website, etc.), taking into consideration the current legislation of the destination country.	<CPNP notification for cosmetics>, <CE-labelling for medical devices>, <REACH>, <ChemBiozidMeldeV notification of biocidal products>	
4.3.1.5	In accordance with the current legislation, the company shall mandate a qualified safety assessor to consider the general toxicological profile of the ingredients, their chemical structure and exposure level, and finally provide the company with a safety assessment of the finished product regarding human health.	Mainly applicable for scope 1 <check qualification of the safety assessor>, <check if the report includes all necessary information e.g. toxicological, microbiological, allergen, packaging material etc.>	
4.3.1.6	A process shall be in place to ensure that labelling complies with current legislation of destination country and customer requirements.	• How is the company informed about the country of deliveries? • Does the country know which are the countries of deliveries? • Who is responsible of the label's validation? • How are integrated all legislatives requirements?	
4.3.1.7	The conformity of the product with its labeling shall be reviewed each time before a new label is issued for use. Such review shall take into account the product requirements and particular relevant legislation in the destination countries.	• 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? • There should be a procedure for control of conformity. • Are valid legal texts available?	
4.3.2	**R & D process**		
4.3.2.1	The company shall have an implemented procedure for R&D that takes into account risks and patents and that demonstrates that all existing and new products are designed to meet legal requirements.	• How new development is validated? • Who is responsible? • Is there a legal department for validation? <procedure> In case external support is necessary: • Is the supplier qualified? • Is a contract available?	

Number	Requirement	Example of questions to be asked	Additional explanations
4.3.2.2	The progress and the results of R&D shall be properly recorded.	• Are all steps and test results for product development properly recorded? <product development documentation> • Is the R&D plan considered in the risk management system?	
4.3.2.3	Without the authorization from the patent holder, the company shall not use raw materials, or composition and shall not process finished products that are already patented.	• How the validation of absence of patent is made for a new development? How to check the patent free aspect: the company shall provide written evidence that the products are free of any patent or agreement of licensing processes. <Name of patent lawyer>	
4.3.2.4	Product formulation, manufacturing processes and the fulfilment of product requirements shall have been ensured by factory trials, performance tests, stability tests, organoleptic assessments where relevant and product testing.	• What do product development procedures look like? <product development procedures> • What tests are made while a product is developed? <test results> • Is developed product submitted to trial runs? <trial run documentation> • Does the company use external support? <qualification>	
4.3.2.5	Where relevant, shelf life tests shall be carried out taking into account product formulation, packaging, manufacturing and storage conditions. The shelf life (e.g. best before date) of the labeled goods shall be calculated accordingly, from the original production date. Where relevant, for products with shelf lives, tests shall be done at the end of the product shelf life on retained samples.	Mainly applicable for scopes 1, 2 and 4 • How are shelf lives determined? • How are PAO's (relevant for cosmetics) determined? <microbiological tests>, <state of aggregation> • Are products submitted to shelf-life tests? <shelf-life test results>	
4.3.2.6	Where specific R&D tests are needed, equipment shall be available and pertinent (such as dosages for regulated ingredients, preservatives, biocides etc.). In case tests are not performed on-site, results of these external tests shall be available.	• Are there all necessary equipments to validate a new product? <records> • Is the technical equipment state of the art?	

Number	Requirement	Example of questions to be asked	Additional explanations
4.3.2.7	Claims shall be supported by scientific evidence (e.g. sun screen formulations, detergents, etc.) in order to ensure that the product meet the stated claim.	• How the validation of claims is made? For scope 1: Is the legislation taken into account to declare claims on the products? E.g. Regulation (EU) No 655/2013 on claims used in cosmetic products Any efficacy and especially safety related claims about a product, e.g., a weight limit for a trampoline or sun protection factor (Cosmetovigilance) on a cream, shall be fully validated to ensure that products meet the stated claim.	
4.3.2.8	Where relevant, pilot equipment(s) shall be available and used in order to warranty good formulation's industrialization.	Mainly applicable for scopes 1 and 2 • Are there pilot equipments?	
4.3.2.9	The consumer packaging shall be designed and labelled to prevent non intended use in order to protect the safety of the potential user. The risk assessment shall address this topic.	• How the consumer packaging is validated for the safety aspect? • Is any change in consumer packaging (material, size, type) considered in the safety report (relevant for cosmetics)? • Who is responsible for labelling? <procedure>	
4.3.2.10	If required by law and based on hazard analysis and assessment of associated risk, the company shall verify the capability of the packaging material for each relevant product (e.g. organoleptic tests, storage tests, chemical analysis).	Mainly applicable for scopes 1 and 2 • How is it ensured that packaging materials have no negative effects on the product? • Did the company consider migration tests (mandatory for cosmetics)? • Has a risk assessment been performed in relation to suitability of packaging material? <risk assessment> Packaging material should be tested concerning negative influences on the product. The results should be documented. • Which frecuency? • Are all components of the packaging material considered?	

Number	Requirement	Example of questions to be asked	Additional explanations
4.4	**Purchasing**		
4.4.1	The company shall control purchasing processes to ensure that all externally sourced materials (raw materials, including packaging materials) and services, which have an impact on product safety and quality, comply with requirements. Where a company chooses to outsource any process that may have an impact on product safety and quality, the company shall ensure control over such processes and fulfill requirements ref. 4.4.8	• How is it ensured that purchased products and services conform to specifications?	
4.4.2	Purchased products and services shall conform to current specifications and contractual agreements.	• How is it ensured that purchased products and services conform to specifications? Regarding purchased products relevant control of incoming goods should be realized. Additionally the services should be checked regularly within internal audits.	
4.4.3	The schedule of these checks shall take into account the product requirements, supplier status and the impact of raw materials on the finished product.	• How are purchased products and their specifications reviewed? <incoming product check-list>, <lab tests> • Does a test schedule exist? <test schedule>	
4.4.4	There shall be a procedure for approval and monitoring of suppliers (internal and external), outsourced production and sub-processes. In case of any kind of outsourced production, the customer shall always be informed.	• Which suppliers are monitored? <raw material suppliers, packaging material suppliers, service suppliers>, <list of service suppliers: external labs, maintenance, placement officer, cleaning personnel, pest control etc.> • How are wholesalers monitored? • Does an approval procedure exist for new suppliers and co-packers? <supplier procedures> • How are supplies monitored? • Are suppliers graded? <supplier grading systems> • Have suppliers been barred? • How is a barred supplier identified? • How is the qualification of suppliers ensured? <product entry monitoring>, <supplier audits>, <lab tests> • Are there any co-packers? <co-packers list> • How are co-packers monitored? • Are co-packers IFS certified? <certificate> An assessment of suppliers with consistent, defined criteria is a practical possibility.	Make sure that if the production site changes raw materials but not supplier, the company has to ensure that new material is also assessed.

Number	Requirement	Example of questions to be asked	Additional explanations
4.4.5	The approval and monitoring procedure shall contain clear assessment criteria such as: audits, certificates of analysis, supplier reliability and complaints, as well as required performance standards based on hazard analysis and assessment of associated risk.	• How often are external audits made? <external audit plan> • Which criteria are consulted for supplier assessment? • Which supplier has analysis certificates? <analysis certificates> • How was the risk analysis for supplier approval performed? <risk analysis>	
4.4.6	The results of supplier's assessment shall be reviewed regularly. There shall be records of the reviews and of the actions taken as a consequence of assessment.	• Who reviews the results of supplier assessments? • How often are the results of supplier assessments reviewed? • What actions are taken after review of the results for supplier assessments? <audit results>	
4.4.7	There shall be records to identify which raw material including packaging and semi-finished products are sourced from each supplier.	• What products come from which supplier? <in case of multi-site suppliers, which site> • Is there a list available with all current suppliers? <supplier list>	
4.4.8	**Outsourced production (if applicable)**		
4.4.8.1	Control of outsourced processes shall be identified, risk assessed and documented within the product safety and quality management system.	<quality management system>, <risk management system>, <GMP>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.4.8.2	A contract shall exist between the company and its subcontractor.	<contract> e.g. information that the contract could contain: a) Concerning the product : • Product description • Product composition (including technical file and SDS of the raw material) • Product use (intended and foreseeable) • Product specifications (physical, …) • Product information (on the packaging) • Packaging specifications (including composition, parameters, …) • Product legislation including generic product safety regulation, general legislation (REACh, waste, …), specific legislation (plastic materials, GMP, …) • Product conformity test report, coming from an accredited laboratory (microbiology, etc.) b) Concerning the subcontractor itself : • Description of subcontracted operation (production of …) • Description of quality control operations (type & frequency) • Description of traceability from raw material to delivery • Description of requested documents for delivery (certificate of conformity, certificate of analysis, etc.) • Obligation to have a legislation update	

Number	Requirement	Example of questions to be asked	Additional explanations
4.4.8.3	Based on hazard analysis and assessment of associated risk, the company shall regularly audit the subcontractor, by using an audit checklist covering IFS HPC requirements (including e.g. relevant documented risk management system, control plan, traceability system, crisis management, etc.). Documents of such checks shall be available.	<current IFS HPC checklist> In the event that the subcontractor is already IFS HPC certified or under any other product safety scheme should be taken into account in order to decrease the frequency of the audits/checks to the subcontractor.	*"the company shall regularly audit the subcontractor…"* As this is a risk based process, it is responsibility of company A (being IFS HPC certified) to establish the frequency of the visits to its subcontractor (company B). The following factors shall be taken into consideration for that purpose (by no means exhaustive): • A first visit to company B is highly recommendable in order to ensure the product safety of the goods provided. • If company B is or not IFS HPC certified or certified under any other product safety scheme. This could be used as an evidence to decrease or increase the frequency of the visits. • Every time there is a change in company's B process (es), or change of raw materials, equipment etc. that could affect the safety/compliant of the product(s) delivered to company A. • In the event of complaints from customers and/or authorities.

Number	Requirement	Example of questions to be asked	Additional explanations
			"by using an audit checklist covering IFS HPC requirements …" It means to cover specific chapters of the IFS HPC related to product(s)/process (es) safety.
4.4.8.4	The checks performed at the subcontractor shall be performed by a qualified auditor/inspector.	• Who is/are the auditor(s)? <auditors list> • How are auditors qualified for this job? <continued education evidence>	
4.4.8.5	If relevant, the company shall check the products on receipt from its subcontractor.	<COA's>, <testing plan for incoming goods>, <external tests in preferable ISO 17025 accredited labs>	
4.5	**Factory location**		
4.5.1	**Site security**		
4.5.1.1	Senior management shall ensure that hazards related to site security (fire, explosions, electrical devices, flooding) are identified and preventive measures are managed.	Suitable equipment and installation shall be in place to ensure site security (e.g. fire extinguishers). • Which equipments or installations are in place to ensure site security? • Does the emergency plan include business continuity aspects?	

Number	Requirement	Example of questions to be asked	Additional explanations
4.5.1.2	The production and storage areas of the site shall be secured effectively by controlled access in order to prevent unauthorized entry.	• How is it ensured that unauthorized persons have no access to production and storage areas? • What control measures are in place in order to control the entrance to those areas? • Do entry controls exist? • How are external activities under responsibility of the company monitored like transport or storage? • Based on the hazard analysis and assessment of associated risks, what areas have been identified as critical? • What control measures are in place in order to control the entrance to those areas? • How does the company maintain control over who enters to the premises and critical areas? • What are the access controls applicable to the following people? · Temporary employees · Contractors · Visitors · Employees · Carrier drivers See Product Defense guideline (requirement 6,2,1)	

Number	Requirement	Example of questions to be asked	Additional explanations
4.5.2	**Factory exterior**		
4.5.2.1	The company shall investigate to what extent the factory environment (e.g. ground, air) may have an adverse impact on product safety and product quality. In each case, appropriate measures shall be established. The effectiveness of the established measures shall be periodically reviewed (examples: extremely dusty air, strong smells).	• Does a location investigation exist? • Can a location have a negative influence on product quality? <location analysis>, <neighbouring companies> • What protective measures have been established if potentially damaging materials/substances are nearby? <protective measures>, <corrective actions> • Is efficiency of protective measures regularly reviewed? • Who reviews the efficiency of the established protective measures? • How is efficiency of established protective measures reviewed? Check if the factory environment (e.g. ground, air, toilets, cleaning facilities, handling of waste, chemical canisters and catering facilities) has no adverse/negative impact on product safety and product quality (examples: extremely dusty air, strong smells, tape management, non-separated toilets with direct access to hygiene areas like production, flaking paint, drum-nippel, chains of conveyor belts). Waste collection rooms and containers (incl. presses) shall be designed to be kept clean and minimize animal and pest attraction.	
4.5.2.2	The factory exterior shall be sustainable maintained, clean and tidy. The external condition of the premises shall be considered within the internal audit process.	• Are factory exteriors tidy? • Are factory exteriors reviewed through internal audits? <audit results>	
4.5.2.3	All grounds within the site shall be in good condition. Where natural drainage is inadequate, a suitable drainage equipment shall be installed.	• Are grounds within the factory premises in good condition? • Is natural drainage sufficient? • If natural drainage is insufficient, has a suitable drainage system been installed?	Check if piping is self-draining and arranged that process waste water goes directly to drain. Where significant amounts of water are used, floors have adequate draining to avoid ponding.

Number	Requirement	Example of questions to be asked	Additional explanations
4.5.3	**Plant layout and process flow**		
4.5.3.1	Plans clearly describing internal flows of finished products, raw materials including packaging materials, waste, personnel, water, etc. shall be in place. A site map covering all buildings of the facility shall be available.	• How is it ensured that cross-contamination is avoided? <waste elimination plan>, <personnel flow plan>, <materials flow plan>, <process flow plan>, <hydraulic plan>	
4.5.3.2	The process flow, from receipt of goods to dispatch, shall be organized so that a contamination of raw materials including packaging materials, semi-processed, rework and finished products is avoided. The risk of cross-contamination shall be minimized through effective measures.	• How is cross-contamination avoided within factory premises? <process flow-diagram>, <in case of co-packers/ subcontractors, transport-/storage-suppliers: additional flow diagram> Documented procedures shall be established to ensure the effective management of e.g. allergenic materials to prevent cross-contamination into products not containing the allergen.	
4.5.3.3	Where relevant, products shall not be produced, stored and filled on the same equipment as products with another intended use, unless evidence is available that there is no negative effect on the products.	Mainly applicable for scope 1 and 2 • How is it ensured that cross-contamination is avoided? <waste elimination plan>, <personnel flow plan>, <materials flow plan>, <process flow plan>, <hydraulic plan>, <process validation>, <cleaning validation>	
4.5.3.4	If production areas are identified as microbiologically sensitive (e.g. clean room technology), a positive air pressure equipment shall be installed. Assessment of the level of the microorganisms shall be performed at risk based intervals.	Mainly applicable for scopes 1, 3 (food contact materials) and 4 • Are there high care areas? • (How) Are high care areas ventilated? • How often are air borne micro-organism counts made? <micro-organism count results> • Who carries out the micro-organism measurements?	

Number	Requirement	Example of questions to be asked	Additional explanations
4.5.4	**Buildings and facilities**		
4.5.4.1	**Building and internal structures**		
4.5.4.1.1	All buildings used in the manufacture or storage of products shall be designed and constructed in order to allow unobstructed installation, ease of maintenance, efficient pest control and easy cleaning of the equipment, as well as compliance with all relevant legislation.	Visit and inspection of buildings	
4.5.4.1.2	Rooms where the products are prepared, treated, processed and stored shall be designed and constructed, so that product compliance and product safety is ensured.	Visit and inspection of rooms	
4.5.4.1.3	Walls shall be constructed to prevent the accumulation of dirt, to reduce condensation and mold growth, and to facilitate cleaning.	• Are walls mouldy? Check if the accumulation of dirt, condensation and mould growth is minimised, and adequate cleaning is possible.	
4.5.4.1.4	Floors shall be in good condition and shall be designed to meet production requirements (e.g. mechanical loads, cleaning materials, etc.) and to facilitate cleaning and disinfection, where required.	• Are floors cleanable? • How often are floors cleaned? <cleaning schedule>, <cleaning evidence>	
4.5.4.1.5	Ceilings (or, where no ceilings are fitted, the undersides of roofs) and overhead fixtures (incl. piping, cables, lamps) shall be suitable for the process and shall be designed and constructed to minimize the accumulation of dirt, the detachment of paints or other coating materials, condensation and mold growth. Ceilings and overheads shall be designed to facilitate cleaning and prevent product contamination.	• How often are ceilings cleaned? <cleaning schedule>, <cleaning evidence> If ceilings and overhead fixtures are present, check if there is adequate access to the cavity in order to facilitate the control of pest activity, unless the cavity is completely sealed.	
4.5.4.1.6	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? Check if the accumulation of dirt, condensation and mould growth is minimised, and adequate cleaning is possible.	
4.5.4.1.7	Doors and gates shall be in good condition and easy to clean.	• Are doors damaged? Are doors sealing completely ? In general check if walls, floors, drainage, windows, ceilings and overhead fixtures are in good condition, constructed and maintained to prevent the risk of product contamination (e.g. no splittering parts, liveries or corrosion).	

Number	Requirement	Example of questions to be asked	Additional explanations
4.5.4.1.8	Drainage equipment shall be designed to facilitate cleaning and to minimize the risk of product contamination (e.g. adverse impact, ingress of pests, environment impact etc.). The hygienic disposal of waste water shall be ensured.	• How is waste water disposal ensured? • How often are gullies cleaned? <cleaning evidence>, <drainage schedule>	
4.5.4.1.9	Where relevant, for laboratories: • location of laboratories at the factory shall not affect product safety • microbiological laboratory shall be physically separated from chemical laboratory • suitable equipment and environment shall be available for all tests performed.	Mainly applicable for scope 1 (microbiology: mainly applicable for scopes 1 and 4) • Visit of lab • Who have access to the laboratories and especially to the microbiological laboratory? • If there is no own microbiological laboratory, but microbiological analysis necessary, who performs the microbiological analysis and how often?	
4.5.4.2	**Lighting, air conditioning/ventilation**		
4.5.4.2.1	All working areas shall have adequate lighting.	• What is the assurance that all working areas are adequately illuminated?	
4.5.4.2.2	Based on hazard analysis and assessment of associated risk, all lightning equipment and electric fly killer units shall be protected. The factory areas where this clause shall apply: • handling of unpackaged products, • storage of raw materials, including packaging materials, • handling of raw materials, • changing rooms. This does not preclude that other areas cannot have protected lighting equipment or electric fly killer units.	• Where are fly killing units mandatory? <fly trap plan> • Are all fly killing units and lamps protected by splinter shields? <lighting protectors>	
4.5.4.2.3	Adequate natural and/or artificial ventilation shall exist in all areas.	• How is ventilation reviewed? • How are air filters maintained and cleaned? <maintenance schedule>, <maintenance documentation>, <cleaning protocols> • Check the risk of contamination by using air in the production within a risk assessment	
4.5.4.2.4	If ventilation equipment is installed, filters and other components which require cleaning or replacement shall be easily accessible.		

Number	Requirement	Example of questions to be asked	Additional explanations
4.5.4.2.5	The use of air in the production (e.g. compressed air supply) shall avoid contamination and be based on hazard analysis and assessment of associated risk.	• Is the use of air during production based on risk assessment? <risk assessment> • Are there production areas with underor over-pressurization? Compressed air, which is used in direct contact with the product must be filtered.	
4.5.4.2.6	Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated.	Mainly applicable for scope 3, 4, also for scope 2 (e.g. washing powders) • Are there areas where large amounts of dust are formed? • How are cross contaminations avoided? <weighting areas> • Do dust extraction devices exist in these areas?	
4.5.4.3	**Water quality**		
4.5.4.3.1	All process waters (including water used as an ingredient) shall be tested regularly for compliance with chemical, physical and microbiological specifications. Special attention shall be paid after periods of no water consumption (e.g. after a weekend or holiday period). The risk assessment shall address this topic. The company shall demonstrate the effectiveness of its water treatment and usage.	Mainly applicable for scopes 1 and 2 <control plan of the water>	
4.5.4.3.2	A water monitoring program (especially in the case of cold mixing operations) shall verify that the water treatment is adequate and effective on a risk based plan.	Mainly applicable for scopes 1 and 2 • Is water treated on site (water hardness correction, chlorination, sterilization, filtration …)? • Is water analysed according to legal requirements (own water supply, outside supply). • Do results comply with standards? <control plan of the water>, <several analysis results>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.5.4.3.3	Recycled water which is used in the process shall not pose a contamination risk. The water shall comply with applicable legal requirements for potable water; records of compliance testing shall be available.	• What for is water used in the company (social facilities, cleaning procedures, product ingredient, etc)? • 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 analyses results>	
4.6	**Cleaning and disinfection**		
4.6.1	Based on hazard analysis and assessment of associated risk, cleaning and disinfection schedules shall be available and implemented. These shall specify: • objectives, • responsibilities, • the products used and their instructions for use, • the areas to be cleaned and/or disinfected, • cleaning frequency, • documentation requirements, • hazard symbols (if necessary). These schedules shall be documented.	• Who is in charge of cleaning and disinfection? <cleaning schedule> • What kind cleaning products and disinfectants are used? <up to date cleaning products and disinfectant list> • What must be observed when using different cleaning products and disinfectants? <product instructions> • What areas are cleaned and disinfected? <cleaning schedule> • How often are areas cleaned and disinfected? • Where are cleaning and disinfection procedures documented? <cleaning procedures documentation> • Do hazard symbols exist? • Does a contract exist for external service provider? <external services contract> • How is it ensured that disinfectant will not be in contact with processed products?	Documented cleaning procedures shall be in place and maintained for the building, plant and all equipment. These include special cleaning work such as cooling unit, fans and intermediate disinfection etc. Cleaning procedures shall as a minimum include the: • functionality • responsibility for cleaning • item/area to be cleaned • frequency of cleaning • method of cleaning, including dismantling equipment for cleaning purposes where required • cleaning chemicals and concentrations • cleaning materials to be used • cleaning records and responsibility for verification • hazard symbols
4.6.2	Where relevant, only qualified personnel shall be allowed to undertake cleaning and disinfection. The personnel shall be trained and retrained to carry out the cleaning schedules.	Mainly applicable for scopes 1, 2 and 4 • Are cleaning personnel qualified? <training proof> • How often are they trained? • Who trains them? • Are these trainings documented? • Are there any checks on topics learnt after training?	

Number	Requirement	Example of questions to be asked	Additional explanations
4.6.3	Based on hazard analysis and assessment of associated risk, the effectiveness and safety of the cleaning and disinfection measures shall be verified, validated for equipment and documented according to a sampling schedule by using appropriate procedures. Resultant corrective actions shall be documented.	• How are cleaning and disinfection controls performed? <cleaning controls> • Who performs these controls? <cleaning controls> • How often are cleaning and disinfection controls performed? <cleaning controls> • Where are cleaning and disinfection controls documented? • When are corrective actions executed? <corrective actions> • Who executes corrective actions? • Who reviews effectiveness of corrective actions? • Where are corrective actions documented? • How are cleaning methods validated? • Does the company consider all relevant product groups? • Is the validation performed for all relevant process steps e.g. mixing and filling? • In case of personal care and household care products on the same production lines: Is the cleaning validation performed based on risk assessment? Limits of acceptable and unacceptable cleaning and disinfection performance (also for intermediate disinfection) shall be defined, based on the potential hazards (e.g. microbiological, allergen or foreign body contamination). Acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques, microbiological testing or chemical testing (e.g. CIP-equipment, resiued of liquids in food boxes/containers, etc.) as appropriate. The cleaning and disinfection procedures and frequency shall be validated and records maintained. Derived corrective actions will be documented and tracked.	The frequency and methods of cleaning shall be based on risk. Cleaning activities take place in periods without production, or they do not affect product quality. The procedures shall be implemented to ensure appropriate standards of cleaning are achieved.

Number	Requirement	Example of questions to be asked	Additional explanations
4.6.4	Cleaning and disinfection measures shall be validated according to any changing circumstances (e.g. construction work, new products, new machines, changes of climate etc.). Where necessary, the cleaning and disinfection schedules shall be adapted.	Mainly applicable for scopes 1 and 2 • When are cleaning and disinfection procedures validated? • Who adapts cleaning and disinfection procedures? • How often are cleaning and disinfection schedules changed? It has to be assured that the measures of cleaning and disinfection are effective. It is possible to ensure it by hygiene monitoring. • In case of personal care and household care products on the same production lines: Is the cleaning validation performed based on risk assessment?	
4.6.5	Current safety data sheets (SDS) and instructions for use shall be always available on-site for chemicals and cleaning agents. Personnel responsible for cleaning shall be able to demonstrate their knowledge of such instructions.	• Are material safety data sheets available for all cleaning agents? • Are material safety data sheets available for chemicals? <Example of chemicals: e.g lubricants, etc.> • Are these no older than two years? • Are cleaning chemicals instructions up to date? • How are instructions transmitted to personnel in charge of cleaning procedures? • Where and when can the instructions be inspected?	
4.6.6	Cleaning utensils and chemicals shall be clearly identified, used and stored appropriately, to avoid contamination or unintended use.	• How are cleaning utensils and chemicals recognizable? <chemicals list> • Where are cleaning utensils and chemicals stored? <chemicals storage list> Check, if chemical canisters, purge lines, etc. in production and storage areas do not affect product safety.	
4.6.7	The cleaning of production tools shall, if relevant, be carried out at specific locations or specific time periods separated from the production process. If this is not possible, these operations shall be controlled as to not affect the product safety and quality.	• Where are containers cleaned? • When and where are tools cleaned? • Where are containers and tools dried? • How do the company avoid, if applicable, crosscontaminations from the cleaning chamber to the production area? <cleaning evidence>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.6.8	Where a company hires a third-party service provider for cleaning and disinfection activities, all requirements specified within section 4.6 shall be clearly defined in the respective contract.	• How is the external cleaning personnel trained	
4.7	**Waste Disposal**		
4.7.1	A waste management procedure shall exist and shall be implemented to avoid cross contamination.	<plan>	
4.7.2	All current legal requirements for waste disposal shall be met.	• How is it ensured that current legal waste disposal requirements are met? <certificates, contracts and delivery notes of external suppliers> • How is waste material disposed of? Where licensing is required for the disposal of categorised waste, it shall be removed by licensed contractors and records of disposal shall be maintained and available for audit.	
4.7.3	Waste collection containers and, where existing, compactors shall be clearly marked, suitably designed, in good state of repair, easy to clean, and disinfected where necessary.	• What kind of waste exists? • What wastes are collected in separate containers? • How are waste containers marked? • Can waste containers easily be cleaned? • How often are the containers discharged, for each kind of waste? <cleaning protocol>	Waste collection rooms and containers (incl. presses) shall be designed to be kept clean and minimise animal and pest attraction.
4.7.4	Waste shall be collected in separate containers in accordance with the intended means of disposal. Such waste shall be disposed by authorized third parties only. Records of waste disposal shall be kept by the company. Whenever possible, destruction of waste shall be intended to avoid re-use of unfit products.	• What kinds of waste disposal records exist? Who is responsible for waste disposal? <waste disposal registry>, <is dangerous waste handled and stored correctly> unfit product = not intended to be re-used or recycled.	

Number	Requirement	Example of questions to be asked	Additional explanations
4.8	**Risk of foreign materials**		
4.8.1	Based on hazard analysis and assessment of associated risk, procedures shall be in place to avoid contamination with foreign material.	• What kinds of foreign bodies may be found? • Where foreign body sources identified through risk assessment? <risk assessment> • Are staples or needles used? • How are contaminated products handled? <segregation records> • What is done in case of glass breakage? <glass breakage prevention procedures> • What shall be considered when glass fixtures are replaced? <glass handling procedures>	
4.8.2	In all areas, i.e. handling of raw materials including packaging materials, processing and storage, where risk assessment has identified the potential for product contamination, the use of wood shall be excluded. Where the use of wood cannot be avoided, the risk shall be controlled.	• Under what circumstances is the use of wood allowed? <risk analysis> • Is the wooden tool in use in good and clean conditions? Who inspects and how often is the wooden tool condition inspected? <plant inspections> If there are wooden items used, check the condition of wood. This items have to be in good condition and free from damage or splinters which could contaminate products. Continually monitored to ensure the conditions.	

Number	Requirement	Example of questions to be asked	Additional explanations
4.8.3	Where metal and/or other foreign material detectors are required, they shall be installed to ensure efficiency of detection, in order to avoid subsequent contamination.	Mainly applicable for scopes 1 and 4 • Where are the metal/foreign body detector installed? <equipment lay-out>	Check if the detection is subjected to interference factors (e.g. X-Ray, metal etc.), the detection is placed at an appropriate step of the process flow, and if possible, after the product has been packed. Retained or removed material is examined and recorded to identify contamination risks. Checks of proper function of detectors are carried out regularly by qualified personnel. In case of malfunction or failure of a metal and/or foreign material detector, corrective actions shall be defined, implemented and documented.
4.8.4	The accuracy of detectors shall be specified. Checks of proper function of detectors shall be carried out regularly. In case of malfunction or failure of foreign material detector, corrective actions shall be defined, implemented and documented.	Mainly applicable for scopes 1 and 4 • Is the detection limit based on risk assessment? <are all test pieces smaller than the potential hazarduous foreign body?> • How often are detector accuracies checked? • Who checks detector accuracy? <metal detector check-list> • What corrective actions exist when a detector is defective? • Are corrective actions verified? • Are operational defects documented? <defect/failure protocols>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.8.5	Potentially contaminated products shall be isolated. Access and actions for further handling or checking for these isolated products shall be carried out only by authorized personnel according to defined procedures. If product's contamination is confirmed, those shall be treated as non-conforming products.	• Are potentially contaminated products automatically isolated? • Who may handle/has access to isolated products? • How are isolated products handled? <non-conforming products list>, <isolation protocol>	
4.8.6	A glass and brittle material management shall be implemented, taking into account preventive and corrective measures; the system shall include reference to procedures in the event of glass or brittle material breakage. Where a risk assessment has identified a potential for product contamination, the presence of brittle material (including glass) shall be excluded or, if this is not possible, the risk shall be managed.	• Is every glass breakage documented? <glass breakage registry> • In case of glass breakage: Is the potential risk for product contamination evaluated? (link to 4.8.5) • Where is glass breakage documented? <glass register> • Are there exceptions to documentation? • Are exceptions based on risk assessment? <risk assessment> All stationary objects made of or incorporating glass or brittle material, which are present in areas of handling of raw materials, processing, packing and storage, should be listed in a specific register including details of their exact location, number, type and condition (except when used as part of the product).	Documented procedures detailing the action to be taken in case of breakage of glass or other brittle items shall be implemented and include the following: • quarantining the products and production area that were potentially affected • cleaning the production area • inspecting the production area and authorising to continue production • changing of workwear and inspection of footwear • breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented in the risk assessment • specifying those staff authorised to carry out the above mentioned/listed points
4.9	**Pest Monitoring/Pest Control**		

Number	Requirement	Example of questions to be asked	Additional explanations
4.9.1	The company shall have a pest control system in place which is in compliance with local legal requirements, and as a minimum shall cover the following criteria: • the factory environment (potential pests), • site plan with area for application (bait map), • identification of the baits on-site, • responsibilities (in-house/external), • used products/agents and their instructions for use and safety, • the frequency of inspections. The pest control system shall be based on hazard analysis and assessment of associated risk.	• How is pest control organized? <pest control procedures> • Which pests are controlled? • Which kinds of baits are used? • Are safety data sheets for the used agents available, are the safety data sheets up to date? <pest control chemicals list> • Is product contamination through baits being prevented? <bait map> • Who is responsible for pest control? • What is inspection scheduled?	
4.9.2	The company shall have qualified and trained in-house staff and/or employ the services of a qualified external provider. Where an external provider is used, the activities required on-site shall be specified in a written contract.	• Is pest control executed by own staff members? • Who is responsible for pest control? • What kind of training has the responsible person? <training evidence> • Is pest control executed by external services provider? • Does a written contract exist between services provider and company? <written contract> • What is the content of the contract? • What kind of training has the external services provider? <training evidence>	
4.9.3	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded.	• Where are inspections and resulting corrective actions documented? <inspection results> • Are documents signed and dated by both parties? • Which corrective actions were executed lately?	

Number	Requirement	Example of questions to be asked	Additional explanations
4.9.4	Baits, traps and insect exterminators shall be functioning, in sufficient number and placed in an appropriate position. They shall be constructed and positioned as not to cause any contamination.	• Where are electrical fly killers installed? • How the correct position of the killing units was defined? <fly killer map> • Are all fly killers correctly working and connected? • Is the number of insects and the type evaluated? Baits, traps and insect killers (electric fly killers, etc.) are fitted correctly in sufficient number available and at a suitable location. Bait stations, fly-killing devices and/or pheromone traps shall be robustly constructed, operational, and effective in eliminating the target pests, and be positioned to avoid potential contamination of materials and products.	
4.9.5	Incoming deliveries shall be checked on receipt for the presence of pests. Any infestation shall be documented and control measures taken.	• Are incoming goods where applicable inspected for pest contamination? • Where is this documented? <incoming goods inspection> • Is pest presence documented? <incoming goods inspection> • What control measures are taken when pests are found? <corrective actions> • Where are these control measures documented? <corrective actions>	
4.9.6	If windows pose a risk of a source of contamination such as the ingress of pests, windows and roof glazing shall remain closed and sealed during production. If they are designed to be opened for ventilation purposes, they shall be sealed by easy removable pest screens or other measures in order to avoid any contamination.	• Are windows sealed with insect gratings? <pest control schedule> • Is integrity of gratings regularly reviewed? <monitoring schedule>	
4.9.7	Based on hazard analysis and assessment of associated risk, external doors and gates shall be designed to prevent the ingress of pests; if possible, they shall be self-closing.	• Do outer doors prevent pest entrance into production areas? • Do outer doors directly lead to the production area where open products are handled?	

Number	Requirement	Example of questions to be asked	Additional explanations
4.10	**Receipt of goods and storage**		
4.10.1	All incoming goods, including packaging materials, shall be identified and checked for conformity against specifications/other legally required documentation and to a determined control plan. The control plan shall be risk based. Test results shall be documented.	• What goods are inspected when received? <receipt checks> • What is checked when received? • Is receipt documented? • Who checks?	
4.10.2	The storage conditions and locations of raw materials including packaging materials, semi-processed and finished products as well as working materials shall in each case correspond to product requirements, shall not be detrimental to other products and shall minimize cross contamination.	• Where are raw materials, semi-finished products and packaging materials stored? <storage plan> • How is cross-contamination avoided? <product flow plan> This also applies to supplies, auxiliaries and additives High outside temperatures shall be taken into consideration when storing outside products.	
4.10.3	Where relevant, for semi-finished products, maximum duration for storage shall be defined. When this duration is reached, the semi-finished product shall be re-evaluated before use.	<take into account that the expiry date of the finished product might be influenced by the expiry date of the semi-finished product> Check if somewhere it's addressed that semi finished products are checked against best before date	
4.10.4	Outdoor storage shall be kept to a minimum. Where goods are stored outside, hazard analysis and assessment of associated risk shall be undertaken in order to ensure that there is no risk of contamination or adverse effect on quality and product safety.	• Are goods stored outdoors? • What is stored outdoors? • Are temperature and hygiene conditions adequate? <silos> • What rules exist for outdoor storage? • Is outdoor storage based on risk assessment? <risk assessment>	
4.10.5	When relevant, sampling of raw materials and of bulk product shall be performed in an appropriate manner and by authorized personnel.	Mainly applicable for scopes 1, 2 and 4 • Where are raw materials sampling performed? • Is for microbiologically sensitive materials an adequate sampling cabin available? • Who is responsible of this performance? <procedure>, <job instruction>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.10.6	Products shall be clearly identified on receipt and when stored. Use of products shall be undertaken in accordance with the principles of First In/First Out and/or First Expired/First Out, in accordance with relevant industry best practices.	• How is "FIFO" ensured? Use of products is undertaken in accordance with the principles of First In/First Out and/or First Expired/First Out.	
4.10.7	Periodic inventory shall be performed to ensure stock reliability. Any significant discrepancy shall be investigated and corrective action taken.	• How is made the periodic inventory? All products shall be clearly identified.	
4.10.8	Where a company hires a third-party storage service provider, the service provider shall be subject to IFS Logistics requirements. If the third party service provider is not certified to IFS Logistics, all relevant requirements equivalent to the company's own warehousing practices shall be fulfilled and this shall be clearly defined in the respective contract.	• Is storage leased to storage service provider? • Does a contract exist? <service provider contract> • What is specified in the contract? • Has storage service provider an IFS Logistics certification? <certificate copy>	
4.11	**Transport**		
4.11.1	Before loading transport vehicles, their condition (e.g. absence of strange smells, high dust load, adverse humidity, absence of contamination, pests, mold) shall be checked and actions taken, if necessary. At the raw materials and packaging materials receipt, checks shall be made in order to assess that transportation has taken place under in good conditions.	• What is checked before loading? <expedition inspection> • Where is inspection documented? • What corrective actions are taken?	
4.11.2	In case of transport of dangerous goods, the company shall ensure that all the relevant legislative requirements are fulfilled.	• How do they ensure that legislation is consistenly applied? • Who verifies this? <CLP regulation>, <dangerous goods safety advisor>	
4.11.3	Adequate hygienic requirements for all transport vehicles and equipment used for loading/unloading (e.g. hoses of silo installations) shall exist. There shall be records of the actions taken.	• Are transport vehicles cleaned? • Where are cleaning procedures documented? <cleaning protocol>	
4.11.4	Where relevant, loading and unloading areas shall have equipment in place to protect transported products from external influences.	• How is goods reception organized? • How is loading organized?	

Number	Requirement	Example of questions to be asked	Additional explanations
4.11.5	Security of transport vehicles shall be appropriately maintained.	How are transport vehicles checked?	
4.11.6	Where a company hires a third-party transport service provider all the requirements specified within section 4.11 shall be clearly defined in the respective contract or the service provider shall be subject to IFS Logistics requirements.	• Are there internal or external transportation regulations? • Does a contract exist with a transportation services provider? <service provider contract>	
4.12	**Maintenance and repair**		
4.12.1	An adequate system of maintenance shall be in place. This system shall be maintained and documented, covering all critical equipment (incl. transport) for compliance with product requirements. This applies both for internal and external maintenance activities.	• How is maintenance organized? <maintenance plan> • Where are maintenance procedures documented? • Which equipments are subject to external maintenance?	
4.12.2	Product requirements and prevention of contamination shall be ensured during and after maintenance and repair work. Records of maintenance and repair work and of corrective actions taken shall be kept.	• How is it ensured that maintenance and repair works do not affect product safety? • How are lighting fixtures repaired? • Where are repair works documented? • Are corrective actions necessary after repair works? • What rules are in place for re-activating equipment when maintenance is completed? <examples for repair works and maintenance>	Check if, the company ensures that safety and/or legality of product is not jeopardised during maintenance and subsequent cleaning operations. Maintenance work and resulting cleaning operations are documented on production protocols. Tape engineering is minimized to an unavoidable level.
4.12.3	All materials used for maintenance and repair shall be fit for the intended use.	• How is it ensured that materials used in maintenance or repair work are fit for intended use? • What kinds of greases are used? <grease list> (e.g. food-grade oils, non-toxic solvents, etc.). Check if maintenance tools like oil and grease/lubricant used in production are food approved. Tool box is clean and no equipment is missing.	

Number	Requirement	Example of questions to be asked	Additional explanations
4.12.4	Failures of plant and equipment (incl. transport) covered by the maintenance system shall be documented and reviewed so as to adapt the maintenance system accordingly.	• Are processing interruptions documented? <processing interruptions> • Are processing interruptions considered in maintenance planning?	
4.12.5	Temporary repairs shall be carried out so that product requirements are not affected. Such work shall be documented and a short-term deadline set for eliminating the fault.	• Are temporary repairs allowed? • Where are these documented? • How fast must temporary repairs be definitely mended? • Who verifies this?	
4.12.6	Where a company hires a third-party maintenance and repair service provider, all the company specified requirements regarding material and equipment shall be clearly defined, documented and maintained.	• Does a contract exist with a maintenance and repair services provider? <service provider contract>, <training of subcontractor>	
4.13	**Equipment**		
4.13.1	Equipment shall be suitably designed and specified for the intended use. Before commissioning, it shall be verified that the product requirements are complied with. Consumables used for equipment should not affect the quality of the product.	• Are equipments and consumables suitably designed and were they checked before start up? <start up protocol>	
4.13.2	Equipment shall be designed and locationed so that cleaning and maintenance operations can be effectively performed.	• Are equipments suitably designed and were they checked before start up? <start up protocol> • What rules exist for start up of new equipments? • Were new equipments immediately considered in maintenance plan? • Does an equipment installation plan exist? <machinery installation plan>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.14	**Traceability**		
4.14.1	**KO N° 4: A traceability system shall be in place which enables the identification of product lots and their relation to batches of raw materials, packaging in direct contact with product and packaging intended or expected to be in direct contact with product. The traceability system shall incorporate all relevant processing and distribution records. Traceability shall be assured and documented until delivery to the customer.**	• How is traceability ensured? <traceability procedures> • What products come from which supplier? • Is there a list available with all current suppliers? <supplier list> • Are test results, specifications, amounts, delivery notes and dates or retain samples traceable?	The company shall test the traceability system across the range of product groups to ensure traceability can be determined from raw material to finished product and vice versa, including quantity check/mass balance. Where rework or any reworking operation is performed, traceability shall be maintained. This shall occur at a predetermined frequency and results shall be retained for inspection. It's expected that the company is able to identify if a batch of raw materials is used for the production of several batches of products.
4.14.2	Downstream and upstream traceability records (from production-sites to the customers) shall be available. The timeframe for producing these records for review shall be compliant with customer's requirements.	<traceability test records>	
4.14.3	Traceability shall be in place to identify the relationship between batches of final products and their labels.	<check of labels>	

Number	Requirement	Example of questions to be asked	Additional explanations
4.14.4	The traceability system shall be tested on a periodic basis at least annually, and each time the traceability system changes. The test shall verify downstream and upstream traceability (from raw materials to delivered products and vice versa), including quantity checking. Test results shall be recorded.	• When was the last traceability test in both directions done? <traceability test results> • What percentage of total amount was traced? • How big is a lot? • Does the test also consider test results, retain samples and delivery notes? • Who is participating at the test? • How long does the test need?	
4.14.5	Based on hazard analysis and assessment of associated risk, on legal requirements and on customer specifications, traceability shall be ensured at all stages, including work in progress, post treatment and rework.	• Can rework be completely traced? <results from rework traceability test> • How is rework documented? • Can packing be completely traced?	Traceability shall include rework in all cases. Although in some situations (e.g. paper), this is not risky and traceability is not a must. Example: cutting scrap from the paper production can be used as raw material in the paper mill and it is not always possible to trace it to each lot of finished product. It may be possible for the company to treat this paper-rework as a known raw material.
4.14.6	Where relevant, it shall be possible to identify at all times all major equipment used for the production of finished product (containers of raw materials and of semi-finished products, mixers, filling lines, etc.).	Mainly applicable for scopes 1, 2 and 4 • Where have you registered equipments used for the production?	
4.14.7	Identified samples representative of the manufacturing batch shall be stored appropriately and kept until expiration date of the finished product and, if necessary, for a determined period beyond this date (“sample bank”).	• How many samples do you keep and during how much time? • How these samples are identified? • Do you visit the storage of this samples and check the respect of the requirements customers? • Do the samples take into account potential interaction between packaging material and product?	

Number	Requirement	Example of questions to be asked	Additional explanations
5	**Measurements, analyses, corrective actions and management of incidents**		
5.1	**Internal audits**		
5.1.1	Effective internal audits shall be conducted according to a defined agreed audit program and shall cover at least all requirements of the IFS HPC Standard. Scope and frequency of internal audits shall be determined by risk assessment. This is also applicable for off-site storage locations owned or rented by the company.	• Does an up to date internal audit plan exist? <audit plan> • Is audit plan based on risk assessment? <risk assessment> • Is a checklist available? <is the checkliset based on IFS HPC requirements> The auditors shall be competent and independent from the audited department. The results of these reviews influence a risk-based investment planning.	
5.1.2	Internal audits shall be carried out at least once a year in all departments.	• How often are internal audits performed? <audit plan> The following issues can be taken into consideration for internal audits: all production steps (packaging area, labeling, GMP's, CCP's) traceability, control plan (analysis, calibration) documentation management (updates) management of non-conformities (complaints, internal non-conformities, withdrawal, recall)	
5.1.3	The auditors shall be competent and independent from the audited department.	• Who are the auditors? <auditors list> • Who is auditing the QM-/RM-responsible? • How are auditors qualified for this job? <continued education evidence> • Have auditors any connection with audit area? • Gets the company external support, external auditors for internal audits, at multinational companies special auditor teams?	

Number	Requirement	Example of questions to be asked	Additional explanations
5.1.4	Audit results shall be communicated to the senior management and to responsible persons of concerned department. Necessary corrective actions and a schedule for implementation shall be determined, documented and communicated to every relevant person.	• How are audit results communicated to the persons in charge? <audit report distribution> • Are corrective actions documented? <audit report> • Is a time schedule in place for corrective actions? <audit report> • From which audits were corrective actions derived? <audit report containing corrective actions> • How are audit results forwarded to senior management? <audit report distribution> • How are audit results evaluated?	
5.1.5	It shall be documented, how and when the corrective actions resulting from the internal audits shall be verified.	• How is the corrective action verification regulated? <verification evidence> • Who verifies and when?	
5.2	**Factory inspections**		
5.2.1	Regular factory inspections shall be planned and carried out to assess criteria such as product control, hygiene, foreign material hazards, personal hygiene, and housekeeping. Any deviation and the associated corrective actions shall be documented.	• How often and who makes site inspections? <site inspections protocol> • What is reviewed during site inspections? • For which areas do site inspections exist? Topics to be included within the factory inspection could be for instance: hygiene, building, foreign bodies, safety, etc.	
5.3	**Manufacturing process validation and control**		
5.3.1	The criteria for process validation and control shall be clearly defined. All processes critical to product safety and product compliance shall be validated.	• How the start up of production is validated? <production records> • How are new products/processes validated?	

Number	Requirement	Example of questions to be asked	Additional explanations
5.3.2	Processing operations shall be carried out in accordance with processing control documentation, and shall include: · suitable equipment, · composition of the product, · list of all raw materials identified according to relevant documents indicating batch numbers and quantities, · detailed processing operations for each stage, such as addition of raw materials, temperatures, mixing times, sampling and semi-finished product transfer. Where applicable, a batch number shall be assigned.	• How are following the processing operation? • Where are present informations for the production? • What kinds of monitoring exist? <fabrication order>, <job instruction>, <nomenclature produit>	
5.3.3	In circumstances where the control of process and working environment parameters (temperature, time, pressure, chemical properties etc.) is essential to ensure the product requirements are met, such parameters shall be monitored and recorded continuously and/or at appropriate intervals.	<printed measurement data>	
5.3.4	The company shall ensure that in the event of changes to processing methods, equipment and product formulation (including rework and packaging material), process characteristics are reviewed in order to assure that product requirements are complied with. If relevant, customers shall be informed accordingly.	• What happens when a failure occurs? • What happens when cold chain is interrupted? <machinery stand still protocol>	
5.3.5	Where relevant, all rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.	Mainly applicable for scopes 1, 2 and 4 • How is it assured that reworks comply to specifications? • Where is rework documented? <model documentation for rework> • Who reviews rework results? • Who decides rework liberation? • What kinds of rework are used in practice? <use of product in a following lot>, <adaption of chemical parameters: pH, viscosity …>, <relabelling of the consumer-packaging/outer box>, <re-packing of finished products> • Is all rework performed internally? • Is the traceability of rework tested regularly?	

Number	Requirement	Example of questions to be asked	Additional explanations
5.3.6	There shall be appropriate procedures for prompt notification, recording and monitoring of equipment malfunction and process deviations.	<printed measurement data>	
5.3.7	Process validation shall be performed using the collected data that is relevant for product safety and the processes. If substantial modifications occur, a revalidation shall be carried out.	How is process validation mathematically firmed?	
5.4	**Calibration, adjustment and checking of measuring and monitoring devices**		
5.4.1	The company shall identify the measuring and monitoring devices required to ensure compliance with product requirements. These devices shall be listed and clearly identified.	• What kinds of monitoring devices exist? <monitoring devices list> • What is demanded of monitoring devices? • What monitoring device is adequate for which kind of measurement? • How are monitoring devices identified? <identification stickers on monitoring devices> • Do calibrated devices exist? <monitoring devices list>	Check if measuring equipment used to ensure and monitor product safety and legality are: • documented –> list of equipment and location • an identification code and calibration due date • prevention from adjustment by unauthorised staff • protection from damage, deterioration or misuse. • at a predetermined frequency, based on risk assessment Results shall be documented.

Number	Requirement	Example of questions to be asked	Additional explanations
5.4.2	All measuring devices shall be checked, adjusted and calibrated, under a monitoring system, at specified intervals and in accordance with defined recognized standard/methods. The results of these checks, adjustments and calibrations shall be documented. Where necessary, corrective actions on devices and on processes and products shall be carried out.	• How is measuring devices check organized? <calibration procedures> • Are measuring devices regularly calibrated? <calibration protocol> • Who is responsible for calibration? • How is calibration done? • Where is it documented? <calibration records> • What corrective actions are taken when a tolerance deviation is found? <corrective actions>, <calibration protocol> • Is calibration up to date? <calibration certificate> • Do the company perform additional internal checks of measuring devices on a risk based frequency?	
5.4.3	All measuring devices shall be used exclusively for their defined purpose.	• What actions are taken when measurement results are uncertain? • How are embargoed measuring devices identified? <identification stickers>	
5.4.4	The calibration status of the measuring devices shall be clearly identified (labelling on the device or on a list of tested devices).	• How is calibration status of measuring device identified? <measuring devices list>, <software solution>	
5.5	**Quantity checking (quantity control/filling quantities)**		
5.5.1	The frequency and methodology of quantity checking shall be determined so that the legal requirements and customer specifications, or if relevant, guidelines for nominal quantity are met.	• How is it ensured that legal requirements for amount control are met? • How is it ensured that customer requirements for amount control are met? Check if the frequency and methodology of quantity checking meet the requirements of appropriate legislation governing quantity verification. Records of checks shall be kept. The scales are used for weight-labelling to identify labelling of the consumer packaging, shall be adjusted/calibrated/officially certified. Furthermore, the adjustment of the scales (bubble level) should be taken into consideration.	

Number	Requirement	Example of questions to be asked	Additional explanations
5.5.2	A procedure shall exist to define compliance criteria for lot quantity checking.	<procedure for quantity checking (frequency)>, <comliance criteria>	
5.5.3	Checks shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing lot.	<sampling plan based on scientific literature>	
5.5.4	Results of these checks shall be compliant with defined criteria for all products ready to be delivered.	<compliance criteria>, <tolerances>	
5.5.5	If relevant, all equipment used for final checking shall be legally approved.	• Are measuring devices in use regularly calibrated? • Where is calibration recorded? <calibration protocol> • Are there calibrated measuring devices? <calibration certificate> Or close to the date to be approved (transition period).	
5.6	**Product analysis (including quality checks)**		
5.6.1	There shall be procedures ensuring that all specified product requirements are met, including legal requirements, performance and specifications. Results of microbiological, physical and chemical analysis required for that purpose shall be available.	• Which physical, chemical or microbiological analyses are made or subcontracted? <analyses results>, <Analytical methods and parameters shall be agreed with the customer, if applicable external analytics shall be performed in desgnated laboratories.> Performance tests.	Check if the quality of the finished product/s is reviewed regularly by carrying out internal tests according to the specification. • tests shall be in accordance with specifications and related to the impact on respective parameters of product characteristic • Durability studies including sensory tests • Consideration of the product formulation • Microbiological, chemical criteria • packaging, production and storage conditions • migration tests if needed.

Number	Requirement	Example of questions to be asked	Additional explanations
			The results of these tests shall be documented, evaluated and possible optimizing should be derivated. If necessary the results are communicated to the customer. The testing programs shall cover based on risk assessment, on product requirements and customer requirements e.g. for cosmetics pH, viscosity, total viable count (microbiology), density or refraction index etc., for diapers e.g. absorption, retention time, content of super absorber etc., kitchen towels e.g. weight per squaremeter, size, perforation, wet and dry strength cross and machine direction etc.
5.6.2	Analyses, which are relevant for product safety and legality, shall preferably be performed by laboratories having appropriate accredited programs/methods (ISO 17025). If the analyses are performed by a factory internal or a laboratory not having appropriate accredited programs/methods, the company shall be able to demonstrate that the results are reliable.	• Is there an analytical laboratory on site? • Is it accredited under ISO 17025? <accreditation evidence> • Are internal lab results verified by an accredited lab? • Which external laboratories are used? • Are these accredited under ISO 17025? • For non accredited test methods, how the reliability of the results could be demonstrated? <accreditation evidence>	
5.6.3	Documented evidence shall exist, which ensure the reliability of the internal analysis results, on the basis of official and non-official recognized analytical methods.	• How are the analysis methods validated? • Are analytical methods state of the art? • Does the company perform ring tests or other tests to show the reliability of methods?	

Number	Requirement	Example of questions to be asked	Additional explanations
5.6.4	A control plan shall be drawn up for internal and external analysis, based on hazard analysis and assessment of associated risk and based on additional information regarding product quality (e.g. complaints). This plan shall cover raw materials, semi-processed and finished products and shall include the types of tests, their frequency and critical limits, which are linked to the specification limits. The test results shall be documented.	• Does an inspection plan exist? <inspection plan> • Who organizes inspection plan? • Which products are encompassed by inspection plan? (raw materials, half-finished and finished products, packaging materials, environmental tests?) <inspection plan> • Is inspection plan based on risk assessment? <risk assessment> • Where are test results documented? <test results>	
5.6.5	The analytical results shall be reviewed regularly and trends identified. Appropriate measures shall be introduced promptly for any unsatisfactory results, or where such trends indicate unsatisfactory results.	• Who reviews analytical results? • How are analytical results verified? • Are trends investigated? • Are corrective actions introduced when results are unsatisfactory? <corrective actions>	
5.6.6	Where internal analysis is undertaken, qualified and trained personnel shall be in place, as well as appropriate equipment and premises.	• Which tests are performed internally? • What qualifications have lab technicians? <qualification evidence> • Is an internal lab available? • Is an incubator, sterilization equipment available? • How is product contamination by internal lab prevented?	
5.6.7	Results of checks on finished products including rework material shall be reviewed by authorized personnel in order to verify the conformity of the finished and semi-finished products with the acceptance criteria.	• Which tests are performed internally? • What qualifications have lab technicians? <qualification evidence> • Is an internal lab available? • Is an incubator, sterylization equipment available? • How is product contamination prevented by internal lab?	
5.6.8	Where relevant, for verification of finished product quality, organoleptic tests shall be carried out regularly. These tests shall be in accordance with specifications and related to the impact on respective parameters of product characteristic. The results of these tests shall be documented.	• When and how are organoleptic tests performed? <inspection plan>, <documentation of organoleptic test results>	

Number	Requirement	Example of questions to be asked	Additional explanations
5.6.9	Based on any internal or external information on product risk which may have an impact on product safety and/or quality, the company shall update its control plan and/or take any appropriate measure to control the compliance of the finished products.	For example, if an Alert System informs that a raw material sourced from a specific country regularly has specific rate of dangerous substance, and if the company is used to buying this specific raw material, the company shall increase the frequency of analysis of this raw material, to improve monitoring. On the other hand, if results of analysis always show good results, and if the raw material is considered as a low risk the company can decide to decrease the frequency of analysis.	
5.7	**Product quarantine (blocking/hold) and product release**		
5.7.1	A procedure shall be in place for the quarantine and release of all raw materials including packaging materials, semi-processed and finished products, and processing equipment. The procedure shall ensure that only products and materials conforming to product requirements are processed and dispatched.	• Who quarantines or releases products? <job description>, <procedure> • How are quarantined products identified and stored? • How are quarantined product marked and blocked?	
5.8	**Management of complaints from authorities and customers**		
5.8.1	A system shall be in place for the management of product complaints and, when relevant, shall take into account specific procedures (e.g. undesirable effects).	• How are complaints handled? <complaint handling procedure> For scope 1 and 4 (where applicable), presence of cosmetovigilance and materiovigilance .	All objection/complaints relating to product safety, legality, and unusual or critical quality defects shall be documented, investigated and assessed by the appropriated competent staff. Where it is justified, appropriate actions (to seriousness and frequence of the problems identified) shall be taken by trained staff, if necessary, immediately and tracked and preventive actions should be initiated to avoid recurrence.

Number	Requirement	Example of questions to be asked	Additional explanations
5.8.2	All complaints shall be assessed by competent staff. Where it is justified, appropriate actions shall be taken immediately.	• Who ponders about complaint significance? • Are R&D and quality control involved? • Who defines the actions to be taken? • Within what time frame must actions be taken? <complaints registration>	
5.8.3	Complaints shall be analyzed with a view to implementing preventive and corrective actions which avoid the recurrence of the non-conformity.	• Who manages complaint statistics? <complaint statistics> • How often are complaint statistics compiled? • What actions are taken to avoid recurrence? <corrective action form> • A systematic evaluation of complaints shall be done.	
5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons and to the senior management.	• To whom are complaint statistics data presented? <retailer complaint statistics data>	
5.9	**Management of incidents, product withdrawal and product recall**		
5.9.1	A documented procedure shall be defined for management of incidents and of potential emergency situations that impact product safety, legality and quality. This procedure shall be implemented and maintained. This includes as a minimum: the nomination and training of a crisis team, an alert contact list, sources of legal advice (if necessary), contacts availability, customer information, and a communication plan, including information to consumers.	• What kind of crisis management is implemented? • Who belongs to incident management staff? <phone list> • Who is informed when an incident occurs? • How are incidents managed? <crisis management procedures> • What is an incident? <incident management procedures>	Depending on contracts, private labels'producers don't have to address requirements about information to consumers. It's not expected that the company (in case of private label products) informs to customers, but they should address in their procedure how the customers are finally informed. If the health and safety of the consumer is seriously compromised an immediate information to the consumer shall be guaranteed.

Number	Requirement	Example of questions to be asked	Additional explanations
5.9.2	Updated emergency contact details (such as names and phone numbers of suppliers, customers and competent authorities) shall be available. A person of the company, who has the authority to initiate the incident management process, shall be permanently available.	• Is a list of important telephone numbers available? <phone list>, <emergency plan> • How often this list is checked/updated? • Who is informed when a crisis occurs? <alarm plan>, <phone list> • When are media involved? <incident management procedures>	
5.9.3	The company shall assign the responsibility (ies) for the external communication (crisis management, authorities and communication with media) to specific personnel.	• Who is responsible for communication with customers, press/media and authorities? • Is a list of important telephone numbers available? <phone list>, <emergency plan>	Within an organigram the responsibilities can be easily shown. The communication in small businesses could also be done by one person.
5.9.4	**KO N° 5: There shall be an effective procedure for the withdrawal and recall of all products, which ensures that involved customers are informed, as soon as possible. This procedure shall include a clear assignment of responsibilities.**	• How much is distribution involved with crisis management? • When and who informs customer? <alarm plan>, <phone list> A withdrawal/recall management procedure is not enough to define an incident management procedure.	
5.9.5	The feasibility, effectiveness and timeliness of implementation of the withdrawal procedure shall be subject to regular internal testing, based on hazard analysis and assessment of associated risk, but carried out at least once a year. This shall be carried out in a manner to ensure the effective implementation and operation of the procedure.	• How is effectiveness of withdrawal tested? • How often is effectiveness of withdrawal tested? <withdrawal test results> • Is the whole recall-/withdrawal team participating at the test? <test protocol>, <if applicable: Is the security company part of the test>, <if applicable: are external partners such as logistic companies, warehouse partners tested> • How long does a test need? • Is the test performed in accordance to the standard operation procedure for recall/withdrawal.	Results of the test shall be retained and shall include timings of key activities. The results of the test and of any actual recall shall be used to review the procedure and implement improvements as necessary. The corrective actions after a recall/a withdrawal will be tracked and processed.

Number	Requirement	Example of questions to be asked	Additional explanations
5.10	**Management of non-conformities and non-conforming products**		
5.10.1	A procedure shall exist for the management of all non-conforming raw materials including packaging materials, semi-finished and finished products and processing equipment. This procedure shall include always the following criteria, but may include other requirements: • isolation/quarantine procedures, • risk assessment, • identification (e.g. labeling), • decision about the further use (e.g. release, destruction, rework/post-treatment, blocking, customer information, rejection/disposal).	• What procedures exist for non-conforming products management? • How are non-conforming products identified? • What rules exist for product quarantine procedures? • Where are stored the non-conforming products? <quarantine tickets>, <template corrective of registration form>, <procedure>	Concerning the procedure of non-conforming products (quarantine zone), it should be explained that this not only applies to finished products but also to raw materials and semi-finished products).
5.10.2	The responsibilities for the management of non-conforming products shall be clearly identified. The procedure for the management of non-conforming products shall be understood by all relevant employees.	• Who is responsible for putting non-conforming products into quarantine? • Who may release quarantined products? • How is it ensured that only authorized persons release quarantined products? <quarantine tickets>, <procedure>	
5.10.3	Where non-conformities are present, immediate corrections shall be taken to ensure that product requirements are complied with.	• What procedures are implemented with non-conforming products? • Who decides about non-conforming products? <quarantine tickets>, <procedure>	
5.10.4	Out of specification finished goods or finished goods that do not meet other legal and/or customer requirements are not allowed to be placed on the market. In case of private labels, exceptions shall be agreed in writing with the contract partners.	For example, evidences can be provided to show that products have not been placed on the market (e.g.contracts with external waste destroying service providers). Exceptions can be checked with examples (situations which already occured), by checking the content of the contract. Check if these products (out of specification, etc.) are clearly marked and separated.	

Number	Requirement	Example of questions to be asked	Additional explanations
5.11	**Corrective actions**		
5.11.1	A procedure shall be in place for the recording and analysis of the non-conformities with the objective to avoid recurrences by the provision of preventive actions and/or corrective actions.	• What are corrective actions procedures? <corrective actions procedures>	
5.11.2	**KO N° 6: Corrective actions shall be clearly formulated, documented and undertaken, as soon as possible to avoid further occurrence of non-conformity. The responsibilities and the timescales for corrective actions shall be clearly defined. The documentation shall be securely stored and easily accessible.**	• Which corrective actions were implemented? <model corrective action procedures> • Where are corrective actions documented? <model corrective action procedures> • Who is responsible for corrective actions? <model corrective action procedures> • How long may it take to implement corrective actions? <model corrective action procedures> The documentation shall be adapted to the company that means it can also be documentation in hand writing. But it has to be unambiguous.	Corrective actions shall be clearly formulated, documented and undertaken, as soon as possible to avoid further occurrence of non-conformity. The documentation shall be securely stored, and easily accessible. The company shall have a documented procedure for handling non-conformances identified within the scope of this Standard. This shall contain at least: • clear documentation of the non-conformity • assessment of consequences by a suitably competent and authorised person • identification of the corrective action to address the immediate issue • identification of an appropriate timescale for correction • identification of personnel with appropriate authority responsible for corrective action

Number	Requirement	Example of questions to be asked	Additional explanations
			• verification that the corrective action has been implemented and is effective • identification of the root cause of the non-conformity and implementation of any necessary corrective action to be checked specifically for: • complaints by retailer • corrective actions.
5.11.3	The effectiveness of the implemented corrective actions shall be documented and shall be validated.	• Where are corrective actions documented? <model corrective action procedures> • How are corrective actions verified? <model with verified corrective action procedures> • The documentation and effectiveness shall be checked within the internal audits	
6	**Product Defense (optional)**	**See Product Defense guideline**	
6.1	**Senior Management Responsibility**		
6.1.1	The company shall have a documented product defense procedure in place to address product defense risk from products and establish, implement and maintain a system to reduce or eliminate the identified risk.		
6.1.2	A product defense assessment shall be conducted annually or upon changes that affect product integrity.		
6.1.3	Responsibilities for product defense shall be clearly defined. Those responsible shall be key staff or shall have access to the senior management team.		
6.1.4	Senior management shall have an internal communication system to inform and update staff about relevant security issues.		

Number	Requirement	Example of questions to be asked	Additional explanations
6.2	**Site security**		
6.2.1	Based on the product defense procedure and legal requirements, the senior management should define and communicate the areas in which authorized personnel are allowed to access.		
6.3	**Visitor and Personnel Security**		
6.3.1	Visitor policy shall contain requirements relating to product defense.		
6.3.2	Employee hiring and employment termination practices shall consider security aspects as permitted by law.		
6.3.3	The company shall incorporate product security awareness, including information on how to prevent, detect and respond to tampering or other malicious, criminal, or terrorist actions or threats, into training programs for staff, including temporary, contract, and volunteer staff. The training shall regularly take place and shall be documented.		
6.4	**Documentation requested by legislation**		
6.4.1	If legislation makes registration or on-site inspections necessary, these shall be carried out and evidence shall be provided.		
6.4.2	A documented procedure shall be in place for managing external inspections and regulatory visits (if applicable). Relevant personnel shall be trained to execute the procedure.		

ifs-certification.com