IFS
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IFS HPC Auditor Guideline

VERSION 3

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ENGLISH

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	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
1	**Governance & Commitment**	
1.1	**Policy**	
1.1.1	The senior management shall develop, implement and maintain a corporate policy, which shall include, at a minimum: • product requirements, • customer focus, • product safety culture, • sustainability. This corporate policy shall be communicated to all employees and shall be broken down into specific objectives for the relevant departments.	• How and where is corporate policy documented? • What are the contents of the corporate policy? • How was corporate policy communicated to all employees? • Does the corporate policy include a commitment regarding product safety culture? • Does the corporate policy include a commitment regarding sustainability? • What kind of mechanisms are used to verify that the policy is understood and applied within the organisation? • Is the corporate policy available to the relevant interested parties? • Have specific objectives been established for the relevant departments ? • Who is responsible for the fulfilment of objectives? • What actions have been taken by specific department to meet the objectives? (e.g. by purchasing) • What quality objectives are defined? • Are these objectives known by the employees concerned? • Are the objectives clearly formulated and measurable? • What is the timeframe to attain the objectives? • What tools are used to measure whether the objectives have been fulfilled? <corporate policy>, <documented evidence of corporate policy communication>, <written review meeting minutes>, <list of attendees at review meeting>, <mailing list of review meeting minutes>, <overview of quality objectives>,<posters showing the different department objectives>, <internal audit report>
	Additional Information *Auditors are not required to thoroughly check the part of the policy related to sustainability. Only make sure that company has included sustainability topics within the corporate policy. E.g. climate strategy, recycling, human rights, etc.*	

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
1.1.2	All relevant information related to product requirements shall be communicated effectively and in a timely manner to the relevant personnel.	• How is relevant information related to product requirements transmitted to concerned persons? <posters>, <distribution of meeting minutes>
1.2	**Corporate structure**	
1.2.1*	**KO N° 1:** The senior management shall ensure that employees are aware of their responsibilities related to product requirements and that mechanisms are implemented to monitor the effectiveness of their operation. Such mechanisms shall be clearly identified and documented.	• How does senior management ensure that employees know their responsibilities related to product requirements? • Are the employees aware of how they contribute to the effectiveness of the product safety and quality management system? • Are the employees aware of the implications of not conforming with product requirements or with the product safety and quality management system requirements? • How does the senior management take accountability for the effectiveness of the product safety and quality management system?
1.2.2	The senior management shall provide sufficient and appropriate resources to meet the product and process requirements.	• How were the necessary resources defined? • How does the company ensure that all critical functions are covered by competent personnel at all times? <budget plan>, <Investments in equipment etc>, <personal resources>

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
1.2.3	The department responsible for product safety and quality management shall have a direct reporting relationship to the senior management. An organizational chart shall be documented and maintained showing the structure of the company.	• Is there an organizational chart showing the structure of the company available? • Who is the quality manager? • Who is defined as senior management? • How is it ensured that the senior management is up to date about all relevant quality and risk management related topics? • To whom does the quality manager report? • In what manner (coordination/communication) and in what form (resources) is the hazard analysis/risk assessment team supported by the senior management? • Is the hazard analysis and risk assessment team known throughout the company? How has it been communicated? <job description>, <Organigram>
1.2.4	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)?
1.2.5*	The senior management shall ensure that the certification body is informed of changes that may affect its ability to conform with the certification requirements. This includes at a minimum: • any legal entity name change, • any production site location change. In addition, for the following specific situations: • product recall(s) by official order and/or any visit from the authorities which results in notification and/or penalties related to product safety and/or legality, the certification body shall be informed within three (3) working days.	• Has the company changed the legal entity name or production site location? If so, did the company inform the certification body within three (3) working days? • Have there been any regulatory actions against the company? • If yes, has the CB been notified within three (3) working days? • What is the name of the authorities and when was the last visit? <CB notifications>, <RASFF>, <European Safety Gate>, <company webpage>, etc.

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
1.3	**Management review**	
1.3.1	The senior management shall ensure that the product safety and quality management system is reviewed. This activity shall be planned within a 12-month period and it is execution shall not exceed 15 months. Such reviews shall contain at least: • a review of policy(ies) and objectives, • review of the product safety culture, • results of audits and site inspections, • positive and negative customer feedback, • process compliance and product conformity, • status of corrections and corrective actions, • notifications from authorities.	• When is the quality management system reviewed and evaluated? • Is the review planned within a12-month period and will the execution take place within 15 months? • How often was the system reviewed last year? • What was the result of the review? • Does the management review assess a minimum of the following: ◦ documents from the previous management review, ◦ policy (ies) and objectives, ◦ product safety culture, ◦ results from internal and external audits, as well as inspections, ◦ performance indicators for customers (positive and negative feedback), complaints and withdraws/recalls, ◦ incidents, corrections, corrective actions, results out of specification and non-conforming materials, ◦ notifications from authorities, ◦ process performance and product compliance, ◦ review of the hazard analysis and risk assessment and changes which may affect the quality and product safety system, ◦ developments in scientific information related to products, ◦ improvement of quality system efficiency and production process, ◦ improvement of product, related to customer requirements, ◦ needs in resources (including investments)? • Are the product safety culture objectives reviewed during the annual management review? <review report>

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
1.3.2	Actions from the management review shall be clearly aimed at supporting improvement. The management review shall assess follow-up actions from previous management reviews and any change that could affect the product safety and quality management system. The management review shall be fully documented.	• Did the management review assess follow-up actions from previous management reviews and any changes that could affect the product safety and quality management system? • Is the management review fully documented? • What conclusions did the senior management draw from the last management review? • Which actions from the previous management review were implemented? <improvement actions>
1.3.3	The senior management shall identify and review at least once within a 12-month period, or whenever significant changes occur (e.g. by internal audits or site inspection) the infrastructure and work environment needed to achieve conformity to product requirements. This shall include at a minimum the following: • buildings (including external conditions of the premises), • supply systems, • machines and equipment, • transport, • staff facilities, • environmental conditions, • hygienic conditions, • workplace design, • external influences (e.g. noise, vibration). Based on risks, the results of the review shall be considered for investment planning.	• How often does the senior management review the infrastructure and work environment? • When is infrastructure and work environment evaluated? • Does the infrastructure evaluation include internal flows (work, materials, waste, personnel, water, etc)? • Does the evaluation include: buildings; external conditions of the premises; supply systems,machines and equipment,transport,staff facilities,environmental conditions,hygienic conditions,external influences? • What was the result of the evaluation? • Who evaluated the infrastructure and work environment? • What risks were identified according to the results of the assessment? • What are the related investments for the near future? <review>, <review minutes>,<internal audit report>, <investment plan>, <corrective actions>, <risk assessment>

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2	**Product safety and quality management system**	
2.1	**Quality management**	
2.1.1	**Document management**	
2.1.1.1	The product safety and quality management system shall be documented, implemented and maintained and shall be kept in one secure location. This applies to both physical and/or digital documented systems.	• Where is documentation concerning the product safety and quality management system retained? • Are the documents (physical and digital) related to the product safety and quality management system securely stored? <procedure for document control>
2.1.1.2	All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times.	• Are all documents legible and unambiguous? • Are there any distribution lists for documents? • Do the documents have an identification code? • How is the identification code structured? • How can a revision be identified? • Who is responsible for changes? • How are the documents made available to the employees? • How are document changes communicated to relevant employees?
2.1.1.3	A procedure shall be documented, implemented and maintained to control of documents and their amendments. All documents which are necessary for compliance with the product requirements shall be available in their latest version. The reason for any amendments to documents critical for those requirements shall be recorded.	• How do relevant employees have access to documents? • How are document changes communicated to relevant employees? • Are there any distribution lists for documents? • How is document validity identified? • How is it ensured that only valid documents are in circulation? • Are the reasons for any amendments to documents critical for the product requirements recorded? • How is the approval and release of documents guaranteed? <procedure>, <distribution lists>, <review of examples>

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2.1.2	**Records and documented information**	
2.1.2.1	All relevant records and documented information necessary for the product requirements shall be completed, detailed and securely maintained 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?> Records can exist in paper form or electronically.
2.1.2.2	Records and documented information shall be legible and genuine. They shall be maintained in a way that subsequent revision or amendment is prohibited unless amendments are done by authorized personnel. If records are documented electronically, a system shall be in place to ensure only authorized personnel have access to create or amend those records (e.g. password protection).	• What records/documented information exist? • Are the records/documented information complete, available, legible, etc.? • What kind of assurance is given that records/ documented information cannot be subsequently manipulated? • Are the records/documented information reviewed by a supervisor? • How are amendments to records/documented information carried out? • Who is authorized to make amendments? • How are amendments authorised? • If records are documented electronically, what is the system in place to manage these records? Is it secure? <review of examples>
2.1.2.3*	All records shall be kept in accordance with legal and customer requirements. If no such requirements are defined, records and documented information shall be kept for a minimum of one year after the shelf life. For products which have no shelf life, the duration of record and documented information keeping shall be justified and this justification shall be documented.	• Where are records/documented information stored? • Who stores records/documented information? • How long are records/documented information kept? • On what basis were records/documented information storage times defined? • For products with a short shelf life: was record/documented information storage time definition based on risk analysis? <procedure documents>, <risk assessment>

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
2.2	**Product safety management**	
2.2.1	**Risk assessment framework**	
2.2.1.1	Before developing the hazard analysis and risk assessment, the company shall have implemented all necessary good manufacturing practices / best practices which are commonly used in its scope of activity.	• What kind of legal/regulatory requirements, good manufacturing practices (GMP's), and industry guidelines are relevant for the scope of activity and product requirements? • Has the company assessed the adequate implementation of relevant legal/regulatory requirements, (GMP's), and industry guidelines? • What was the result of the assessment? If gaps were identified, have the necessary corrective actions been implemented?
	Additional Information *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, etc*	
2.2.1.2	The basis of the company's product safety management 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 hazard analysis and risk assessment shall be adequate and implemented at each production site.	• What principles are the company's hazard analysis and risk assessment based on? • Does every site/plant have a separate hazard analysis and risk assessment? • Which specific regulations are taken care of in the hazard analysis and risk assessment? • Are the legal requirements of the destination country known, especially the labelling regulations? <risk assessment>
2.2.1.3	The hazard analysis and risk assessment shall cover all raw material groups, products or product groups, as well as every process (included outsourced processes) from incoming goods until the dispatch of final products, including product packaging material management.	• Does the hazard analysis and risk assessment cover raw materials, product packaging material, products or product groups as well as every process (including outsourced process) from incoming goods up to the dispatch of finished products? • Which processes are performed? • If the company has outsourced processes and/or product development, are these included in the hazard analysis and risk assessment? <product group overview>, <flow chart>

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2.2.1.4	The company shall ensure that the hazard analysis and risk assessment shall be based upon scientific literature or technical verified specifications relating to the manufactured products and procedures. This information 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.>
	Additional Information *It should be considered that the system has to be constantly updated. It is the only way to guarantee the functioning of the system.*	
2.2.1.5	In the event of changes to raw materials, packaging materials, processing methods, infrastructure and equipment, the hazard analysis and risk assessment shall be reviewed in order to ensure that product safety requirements are complied with.	• Have changes occurred since the last review? If so, what were the changes? Was the hazard analysis and risk assessment reviewed due to the changes?
2.2.2	**Risk assessment team**	
2.2.2.1	The risk assessment team shall be multidisciplinary and include operational staff. Personnel appointed as risk assessment 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 are the members of the team? • Which personnel/departments are included in the team? • How was qualification for team membership verified? • Does a contract exist with an external expert? • What hazards are connected to the products and processes? <service contract>, <evidences for education, advanced training>
2.2.2.2	Those responsible for the development and maintenance of product safety management system shall have received adequate training in the application of the risk management principles based on the risk assessment tool (Risk matrix, FMEA, HACCP, RPN, etc.) which the company uses.	• Were those responsible trained in the application of the hazard analysis and risk assessment principles? • When was the last training course held? • What were the contents of the training course? • How was the knowledge verified?

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2.2.2.3	The risk assessment team shall have senior management support and shall be well known and established within the company.	• Is the team well known throughout the company? • How was this communicated? <job descriptions>, <team matrix>, <black-board 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 assessment team to take care of administration, development and training of risk assessment requirements?
2.2.3	**Hazard analysis and risk assessment**	
2.2.3.1	**Describe the product** A full description of the product shall be documented and maintained and shall contain all applicable relevant information on product requirements, at a minimum: • composition (including rework when applicable), • physical, chemical and microbiological parameters, • methods of treatment, • packaging, • durability (shelf life), • conditions for storage, methods of transport and distribution.	• 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>
2.2.3.2	**Identify intended use and foreseeable use** The intended use and foreseeable 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/ foreseeable use of the product? • For which consumer group is the product unsuitable? • Is the product suitable for children, pregnant women, senior persons, people with allergies? • Are there any restrictions for usage? • Is the foreseeable use of the product also considered? • Is the foreseeable use in all destination countries the same? <product description>

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2.2.3.3	**Construct flow diagram** A flow diagram shall be documented and maintained for each product or product groups, raw material groups and for all variations of the processes and sub-processes (including rework, outsourcing and reprocessing). The flow diagram shall determine every step and clearly identify each critical control point and other control measures. It shall be dated and in the event of any changes the flow diagram shall be updated.	• Are flow charts available for all products? <flow charts for all products> • Are the flow charts dated? • Are other control measures, and CCPs, if existing, identified in the flow chart? • In the event that CCPs are identified in the flow chart, are these identified accordingly? and do they have a number? • Are all flow charts with CCPs up-to date?
2.2.3.4	**On-site confirmation of the flow diagram** The risk assessment team shall verify the flow diagram by on-site checks at all operation stages. Amendments to the diagram shall be made, where appropriate.	• Was the flow chart verified on-site? In which shift? • Was the flow chart confirmed during a meeting? <meeting minutes>
2.2.3.5	**Conduct a hazard analysis and risk assessment for each step**	
2.2.3.5.1	A hazard analysis shall be conducted covering all possible and reasonably expected physical, chemical (including allergens) and biological hazards. A hazard analysis and a risk assessment shall be conducted for each step of the process from raw materials to the finished products. The analysis shall include also hazards linked to materials in direct contact with the product.	• Does a hazard analysis and risk assessment exist for each step? • Are all hazard and relevant risks included? • Which biological, physical and chemical hazards (including allergens) can be expected? • How was the hazard analysis performed? Compare information from the on-site tour with the hazard analysis, • are all observed hazards addressed? • are the assigned risk levels appropriate? <hazard analysis>, <risk assessment>
2.2.3.5.2	The hazard analysis shall consider the likely occurrence of hazards and severity of their adverse health effects. Consideration shall be given to the specific control measures that shall be applied to control each hazard. The methodology for assessing the 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.>

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2.2.3.6*	**Determine critical control points and other control measures** The determination of relevant CCP's and other control measures shall be facilitated by the application of a decision tree or other tool(s), which demonstrates a logical reasoned approach.	• How were the CCPs and other control measures determined? • How many CCPs and other control measures exist? • Of the defined CCPs, can the process be influenced in order to prevent, eliminate or reduce a product safety hazard? • Which prerequisite measures were taken regarding CCPs? • Which prerequisite measures are documented? • How are the measures documented? <hazard analysis>, <flow chart>, <risk assessment>, <decision tree>, <prerequisite measures>
2.2.3.7	**Establish validated critical limits for each critical control point** For each critical control point critical limits shall be defined and validated to 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? • Have the limits been validated? <risk assessment>
	Additional Information *In case no CCP has been determined, this requirement can be scored as N/A.*	
2.2.3.8*	**KO N° 2: Establish a monitoring system for each critical control point** Specific monitoring procedures in terms of method, frequency of measurement or observation and recording of results shall be documented, implemented and maintained for each CCP to detect any loss of control at that CCP. Each defined CCP shall be under control. Monitoring and control of each CCP shall be demonstrated by records.	• How are CCPs monitored? • Who documents the CCPs? • Are CCPs under control? • Are date, time, responsible employee and result/reading documented? • How long will records be stored? • Where are the records stored? <CCP records> <risk assessment>, <overview of CCPs with limits>
	Additional Information *This KO requirement could be rated as N/A. See Part 1 of the Standard.*	

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2.2.3.9	Records of CCP's monitoring shall be verified by a responsible person of the company and maintained for a relevant period.	• Who is responsible for verifying the records of CCP monitoring? • For how long are records of CCP monitoring kept?
	Additional Information *Clarification for auditors/company detailing what is meant by "relevant period" as stated in 2.1.2.3* • *Accordance with legal and customer requirements.* • *If no such requirements exist, records and documented information shall be kept for a minimum of one year after the specified shelf life.* • *For products which have no shelf life, the duration of record and documented information keeping shall be justified and this justification shall be documented.*	
2.2.3.10	The operative personnel in charge of the monitoring of CCP's and other control measures shall have received specific training/instruction.	• What training has been performed? <Review of training records> • Has the person responsible for monitoring been trained in relation to these activities? • Is the person responsible for monitoring aware about what should be done in case the limits are not under control?
2.2.3.11	The control measures other than CCPs, shall be monitored, recorded and controlled by measurable or observable criteria.	• Who is responsible for monitoring other records of control measures? <Review of other records of control measures>
2.2.3.12	**Establish corrective actions** In the event that the monitoring indicates that a particular CCP or control measure other than CCPs is not under control, corrective actions shall be documented and implemented. Such corrective actions shall also take into account any action taken relating to non-conforming products and identify the root cause for the loss of control of CCPs.	• What corrective actions exist for each CCP? • When was a corrective action carried out? • Where are corrective actions documented? • Who documents the corrective actions taken? <CCP records<corrective actions>

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2.2.3.13*	**Establish verification procedures** Procedures of verification shall be documented, implemented and maintained to confirm that the hazard analysis and risk assessment are effective. Verification activities of the hazard analysis and risk assessment include for example: • internal audits, • testing, • sampling, • evaluations, • deviations and non-conformities, • complaints. The results of this verification shall be performed at least once within 12-month period or whenever significant changes occur and shall be incorporated into the hazard analysis and risk assessment.	• How often is the hazard analysis and risk assessment verified? • What was the date of the last verification? • What was the result of the last verification? • Does the hazard analysis and risk assessment reflect the results of the verification? • On what date was the hazard analysis and risk assessment last changed? <audit reports or other reports for verification>
3	**Resource management**	
3.1	**Human resources**	
3.1.1	All personnel performing work that affects product safety, legality and/or quality shall have the required competence by education, work experience and/or training, commensurate with their role.	• How are the competencies determined? • How is it assured that new employees have the right capabilities for the job?
3.1.2	The responsibilities, competence and job descriptions for all job titles having an impact on product safety and product quality, shall be documented, implemented and maintained. Assignment for key roles shall be defined.	• For which positions do written job descriptions exist? • What is regulated in the job descriptions? • Who, for example, substitutes the QA manager during their absence? • What is the content of the job descriptions? • For which positions do job descriptions exist? <Responsibility description for important key staff "dedicated to a specific person", e.g. QA Manager, Production Manager, Shift Leader …>

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3.2	**Personal hygiene**	
3.2.1*	Risk based requirements relating to personnel hygiene shall be documented, implemented and maintained. These include at a minimum the following fields: • hair and beards, • protective clothing (including use in staff facilities), • hand washing, disinfection and hand hygiene, • eating, drinking and smoking/vaping or other use of tobacco, • actions to be taken in case of cuts or skin abrasions, • fingernails, jewellery and personal belongings (including personal medication), • notification of infectious diseases / health issues.	• What is the policy regarding personal hygiene? • Are the rules based on a risk analysis? • The rules regarding personnel hygiene include hand cleaning, food and beverages, smoking, handling of injuries, fingernails and jewellery, hair and beards? • Where is smoking permitted? • How should lesions be treated/covered? • What kinds of hair restraints are required in which areas? Example of results from the hazard analysis and assessment of associated risks: if gloves are used, then hand disinfection is not required for low risk production. <hygiene rules for employees>, <risk assessment>
	Additional Information *Examples of protective clothing: suits, overalls, smocks, jackets, aprons, sleeves, among others. It also includes disposable garments (e.g. shoe covers, coveralls) and personal protective elements (e.g. hard hats, earplugs, face masks with filters, reusable gloves).* • *Fingernails include the usage of varnishes, acrylic nails, etc.* • *Jewellery includes watches, earrings, necklaces, piercings, wedding bands, etc.* • *Personal belongings include medicines, keys, mobile phone, etc.* • *Some examples of the result from the hazard analysis and assessment of associated risks are:* *(1) The use of gloves is required. If so, control activities shall be in place to prevent product contamination due to its misuse (e.g. glove colour shall contrast with product colour, check gloves condition)* *(2) The usage of headgear is required. Considerations: If so, control activities shall be in place to prevent product contamination due to its misuse (e.g. check if the headgear covers the hair completely)* *(3) The usage of wedding bands is allowed as an exception (after evaluation and justification). If so, relevant control activities shall be in place to avoid product contamination due to the exception.*	

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3.2.2	The requirements for personal hygiene shall be understood and applied by all relevant personnel, contractors and visitors. Compliance with the requirements shall be checked regularly.	• How are the hygiene requirements communicated to personnel, contractors and visitor? • How is it assured that personnel, contractors and visitors know, understand and follow the relevant hygiene rules? (taking different languages into account for example) <hygiene rules for employees>, <hygiene rules for visitors>, <observation on the shop floor.>, etc.
3.2.3	Visible jewellery (incl. piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated based on risks.	• Is it permitted to wear jewellery and watches in production areas? • Is authorisation based on risk hazard analysis? <risk assessment>, <personnel hygiene rules>
3.2.4	Cuts and skin abrasions shall be covered with a coloured plaster/bandage that shall not pose contamination risks. Plaster/ bandage shall be waterproof and coloured different from the product colour. Where appropriate: • plasters/bandages shall contain a metal strip, • single use gloves shall be worn.	• What colour is the plaster and where is it used? • When metal detectors are used, does the plasters/bandage contain a metal strip? Is the metal detector able to detect the plasters/bandage? • What is an employee required to observe in case of a hand injury? <personnel hygiene rules>
3.3	**Protective clothing for personnel, contractors and visitors**	
3.3.1	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.

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3.3.2	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 protective headgear and/or beard snood mandatory? • What kind of headgear is used? • How shall headgear be used? <personnel hygiene rules> <observation during plant tour>
3.3.3	Usage rules shall be implemented for work areas/activities where it is required to wear gloves (coloured differently from the product colour).	• In which production areas is it mandatory to wear gloves? • What kinds of gloves are used? • When must gloves be changed? • How is compliance with these rules checked? <glove swab test results >, <on-site inspections>, <observation during plant tour>, <personal hygiene rules>
3.3.4	When required, suitable protective clothing to ensure personnel safety shall be available in sufficient quantity for each employee.	• Is protective clothing given to the personnel? If so, how many items are provided?? • What are the rules regarding protective clothing? • How often is an employee supposed to change their protective clothing?
3.3.5	All protective clothing shall be thoroughly and regularly laundered. Based on risks, the company shall determine if clothing shall be washed by a contract laundry, on-site laundry or by the employee according to a documented guidelines which shall include the checking of its cleanliness.	• 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 assessed site? • Are there cleaning instructions for employees cleaning their clothing at home? • Is protective clothes laundering based on a risk assessment? <risk assessment> • Cleaning of protective clothing, choice of a contracted laundry etc. • How is it ensured that clothing is appropriate for use after cleaning? What checks are done to prove it? <visual inspection> ;<swab>

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3.4	**Procedure applicable to health and infectious diseases**	
3.4.1	There shall be written and communicated measures for personnel, contractors and visitors in case of any health issue or infectious disease which may have an impact on product safety. In case of declaration of any, actions shall be taken to minimize risk of contamination of products (if applicable to product or activity).	• How shall personnel and visitors behave in case of the presence or suspicion of an infectious disease? • What kind of actions are taken when these issues are notified by the personnel, contractors and/or visitor? • Have restrictions for external personnel been implemented? • How is it ensured that personnel and visitors know the guidelines? <personnel hygiene rules>, <visitors hygiene rules>
	Additional Information *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.*	
3.5	**Training and instruction**	
3.5.1	Documented training and/or instruction programs shall be implemented with respect to the product and process requirements and the training needs of the employees based on their job and shall include: • training contents, • training frequency, • employee's task, • languages, • qualified trainer/tutor, • training effectiveness.	• Who is responsible for training? • What evidence is there of the trainer's qualification? • What was the content of the last training session? • How are foreign employees trained/ instructed? • Who participates in the training sessions? • How are the instruction necessities for each employee determined? • How often are training sessions held? <training program>, <training schedule>, <training proof>
3.5.2	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 seasonal and temporary workers) trained/instructed upon employment? • Which employees are trained/instructed upon employment? What is the content of these instructions? • Is an introductional training plan implemented for all relevant employees?

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3.5.3	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.	• When did the last training take place? • Is all evidence of training comprehensive? • Do all records contain all necessary information?
3.5.4	The contents of training and/or instruction shall be reviewed and updated when necessary. Special considerations shall be given at a minimum to these specific issues: • product safety and quality (e.g. GMPs, risk assessment, etc.). • product safety culture, • product defence, • product related legal requirements, • product/process modifications, • feedback from the previous documented training/instruction program.	• Who is responsible for the review and update? • How are the training contents reviewed and updated? • When was the latest training content review and update done? • Are the listed topics included in the contents of training and / or instruction? <assessment results>, <product safety culture>, <product defense>, <reviews>, <tests> specific issues: non-conformitites, failure, complaints, etc.
3.6	**Staff facilities**	
3.6.1	Adequate staff facilities shall be provided and shall be proportional in size, equipped for the number of personnel, designed and controlled so as to minimize product safety risks. Such facilities shall be maintained in a way to prevent contamination.	Staff facilities = e.g. changing room, smoking area, dining room, etc. • How many employees are there? • Do they have access to a cafeteria? Are there locker-rooms? • Where are the restrooms? • Are there bathing facilities? <plant lay-out>
3.6.2	Product contamination risks by food and drink and/or foreign materials shall be minimized. Consideration shall be given to food and drink from vending machines, canteen and/or brought to work by personnel.	• May employees bring food from home? • May employees take medicine along to their work place? • Any restrictions? • Does a risk analysis exist regarding foreign bodies from social facilities? <risk assessment>, <personal hygiene rules>
3.6.3	The company shall provide suitable changing rooms for personnel, contractors and visitors. Where necessary, outdoor clothing and protective clothing shall be stored separately.	• How is protective clothing handled during breaks/intervals? • Does a risk analysis exist for locker rooms with no direct access to processing areas? <risk assessment>, <personal hygiene rules>

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
3.6.4	Changing rooms shall be located so that they allow direct access to the areas where products are handled. Any exceptions shall have been comprehensively evaluated based on risks.	• Do locker rooms have direct access to processing areas? • Does a risk assessment exist for changing rooms with no direct access to processing areas? • Are there locker rooms for employees and visitors with separation for outdoor and protective clothing?
3.6.5	Toilets shall not have direct access to an area where products are handled. Any exception shall be comprehensively evaluated based on risks. The sanitary facilities shall be equipped with adequate hand washing facilities. The sanitary facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.	• Where are toilets located? • How does the ventilation system for toilets work? • Do toilets pose any risk to production? • Do toilets open directly into production areas?
3.6.6	Hand hygiene facilities shall be provided near points of entry to, and within production areas, as well as at staff facilities. Based on risks further areas shall be similarly equipped.	• Are there enough hand washing facilities available at the entrance to processing areas and in social areas? • Are there enough hand cleaning facilities available in the production area? In case water is not available at each work station, are adequate alternative facilities available?
	Additional Information *In case of hand hygiene facilities within production process check if the safety of the products is not comprised.*	
3.6.7	Hand hygiene facilities shall provide: • running potable water at an adequate temperature, • adequate cleaning and/or disinfection equipment, • adequate means for hand drying.	• Are all hand hygiene facilities provided with appropriate cleaning and disinfection equipment and appropriate means for hand drying? • Are all hand washing facilities provided with running potable water at an appropriate temperature? • Are sufficient cleaning and/or disinfectant dispensers available at the entrance of the production area?

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3.6.8	Based on risks 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.	• Are all areas where extended hygiene requirements are necessary due to risk assessment equipped with hand contact-free fittings, hand disinfection and waste containers with contact free openings? <signs/pictograms>
3.6.9	A risk based program shall be implemented and maintained to control effectiveness of hand hygiene.	• Hand-cleaning is performed at a suitable frequency to maintain hygiene conditions? • How is the effectiveness of hand hygiene controlled? • In case employees wear gloves, how is hand hygiene ensured?
4	**Operational processes**	
4.1	**Customer focus and contract agreement**	
4.1.1	A process shall be implemented and maintained to identify fundamental needs and expectations of customers. The feedback from this process shall be taken as input for company's continuous improvement.	• How are customer needs and expectations identified? • How often are these identified? • What were the results of the last customer survey? • How were these results evaluated regarding quality objectives? • Do identified needs influence the production process? <questionnaire/survey regarding customers' needs and expectations>, <analysis of customer surveys>, <quality objectives>, <survey analyses>
4.1.2	All requirements related to product safety and quality within customer agreement, and any revision of these clauses between the contract partners, shall be documented, communicated and implemented by each relevant department.	• What assurance is given that customer requirements and own specifications are in accordance with each other? • Do written supply agreements with customers exist? • Do specific customer requirements for purchased products exist? • Who checks and approves specifications? • Who ensures that the proper raw materials are available whenever needed? • How is it ensured that customers are informed about product changes? • Who checks and approves specifications?

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4.1.3	In accordance with customer requirements, the senior management shall inform their affected customers as soon as possible, of any issue related to product safety or legality, including deviations and non-conformity/ies identified by competent authorities.	• What system is in place to inform the customer of any issue related to product safety or legality?
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 documented and implemented for all raw materials (raw materials/ingredients, additives, packaging materials, rework) and where relevant, for semi-finished products. 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 they also relevant for semi-finished products?
		• What is the procedure for replacing a raw material?
		  ◦ Is the supplier of the raw material determined by the customer?
		  ◦ Is the degree of purity e.g. Ph.Eur. determined by the customer?
		  ◦ How is it ensured that the specifications are met?
		
		<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?

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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>
4.2.1.3	A re-evaluation of the suitability of raw materials and semi-finished products shall be in place in cases where they are close to the best before date/expiry 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/ semi-finished product fall into the life cycle of the finished product, is the efficacy of the finished product (e,g, sun protection, disinfection etc.) still guaranteed? <take into account that the expiry date of the finished product might be influenced by the expiry date of the semifinished product> Check if it's addressed that semi finished products are checked against best before date.

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4.2.1.4	For all packaging materials which could have an impact on products, relevant documents (e.g. DoC, etc.) shall exist which attest compliance with legal requirements. In the event that no specific legal requirements are applicable, evidence shall be available to demonstrate that packaging materials are suitable for use. This applies for packaging materials which could have an influence on semi-finished and finished products.	• Who verifies the conformity of packaging? • What evidence is gathered to confirm that packaging materials are suitable for use?
	Additional Information *Examples of declarations accepted:* *It is hereby declared that the packaging/packaging part/packaging material complies with the provisions of the following regulations, rules and/or recommendations:* *Regulation (EU) 1935/2004* *Regulation (EU) No. 10/2011* *Regulation (EC) No. 1895/2005* *German Commodities Regulation based on the Food, Commodities and Feed Code – Section 5* *Recommendations of the Federal Institute for Risk Assessment (BfR)* *Declaration of substances/additives which are added for the purpose of special functions and/or during manufacturing (e.g. lubricants, antistatic agents)* *For colorants: CoE Resolution AP (89) 1 "On the use of colorants in plastic materials coming into contact with food" and Recommendation No. IX of BfR "Colorants for the colouring of plastics and other polymers for commodities" (Status: 01.01.2010).* *Declaration about the use of biocidal active substances in accordance with Regulation (EU) No. 528/2012 (Biocidal Products Regulation)* *Declaration/exclusion of special substance groups (SVCH, heavy metals...)* *Exclusion/restriction of specially declared substance*	
4.2.1.5	The company shall define the key parameters for the packaging materials in detailed specifications complying with the current relevant legislation and other relevant hazards or risks.	• Are specifications available for the packaging materials? • Have specifications been developed on a risk basis?
	Additional Information *Article 3 and 17 of the Cosmetics Regulation (EC) No. 1223/2009* *Annex I Part A Clause 4 of the Cosmetics Regulation (EC) No. 1223/2009*	
4.2.2	**Finished product specifications**	
4.2.2.1	Specifications shall be documented and implemented for all finished products. They shall be up to date, traceable, unambiguous, relevant to all personnel and in compliance with legal and customer requirements. Where required by customers, product specifications shall be formally agreed.	• How are specifications compiled, checked and approved? • Are there specifications for all final products? • How are up to date specifications recognizable? <specifications>

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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.	• Which assurance is given that the 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?
4.2.2.3	Where products are requested to be labelled and/or promoted with "free from" certain substances or ingredients, or where certain methods of treatment or production are excluded, measures shall be implemented to demonstrate compliance with such statement.	(e.g. free-from Bisphenol A, phthalates, allergens, etc.). • Does the customer have specific requirements related to the exclusion of certain methods of treatment or production, or the absence of specific components or ingredients? • Have these specific requirements been included in specifications? • Has the company implemented procedures to verify and ensure these specific customer requirements? • How are claims verified and ensured by the company? • What kind of tests/analysis and scientific evidence are available to support claims?
4.2.2.4	A procedure to control the creation, approval and amendment of specifications shall be documented, implemented and maintained and shall include where required, the acceptance of the customer(s). This procedure shall include the update of finished product specifications in case of any modification related to: • raw materials, • formulas/recipes, • processes which impact the finished products, • packaging materials which impact the finished products.	• How are specifications compiled, checked and approved? • Are there specifications for all final products? • How are up to date specifications recognizable? <specifications>

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4.3	**Legislative framework and product development**	
4.3.1	**Legislative framework**	
4.3.1.1	The company shall comply with the current applicable legislation and where relevant, register its activity of production to the local authorities. The company 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> • Does the company need a specific registration number according to their scope of activity? e.g. biocidal registration, etc.
4.3.1.2	The company shall have a system in place to ensure: • it is kept informed of all relevant legislation on product safety and quality issues, • scientific and technical developments, • industry codes of practice. Legislation shall be understood and applied.	• How does management ensure that all relevant legislation is in place and acknowledged? • 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.	<AR>, <GHS labelling>
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>

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4.3.1.5	If applicable, the company shall mandate a qualified safety assessor in accordance with the current legislation 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.	<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 procedure shall ensure that labelling complies with current legislation of destination country and customer requirements.	• How is the company informed of the delivery countries? • Does the country know which are the countries of delivery? • Who is responsible for label validation? • How are all legislative requirements integrated?
4.3.1.7	The company shall ensure that in the event of changes to • process characteristics, • product formulation including rework, • packaging material, • legal requirements, • product quality requirements, • customer requirements, labelling shall be reviewed and adapted when necessary.	• Who reviews and ensures that specifications are met in the event of changes to the recipe or processes?
4.3.2	**Product development/ product modification/ modification of production process**	
4.3.2.1	The company shall have an implemented procedure for product development/modification that takes into account risks and patents and that demonstrates that all existing and new products are designed to meet legal requirements. Legal changes, e.g. ingredients, etc. which make it necessary to change products and/or subjected to deadlines, shall be coordinated with customers as soon as possible.	• How new development is validated? • Who is responsible? • Is there a legal department for validation? <procedure> • Do processing procedures for product development also contain a hazard analysis? • What do product development procedures look like?

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4.3.2.2	The product development/modification process shall result in specifications about formulation, packaging requirements, manufacturing processes, process parameters related to the fulfilment of product requirements. The progress and results of product development shall be properly recorded and have to be ensured by checks such as: • factory trials, • performance tests, • stability tests, • organoleptic tests, • product testing, • compatibility tests.	• Are specifications developed about formulation, packaging requirements, production and process parameters related to the fulfilment of product requirements? • What factory trials and product test/ analysis are made while a product is developed and/or a process is modified? • Is the developed product submitted to trial runs and product testing? • Are records of progress and results of the product development/modification and modification of production/convertion process available?
4.3.2.3	Without the authorization from the patent holder, the company shall not use raw materials, composition or production processes or other intellectual properties which are already patented.	• How is the non-existence and the existence of a patent for a new development taken into account? <Name of patent lawyer>
4.3.2.4	Where relevant, shelf life tests / stability tests shall be carried out taking into account product formulation, packaging, manufacturing and storage conditions. The shelf life (e.g. expiry date, best before, PAO) of the labelled 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.	• How is a shelf life determined? • Are test results considered for shelf life determination? • Are products submitted to shelf life tests? <shelf-life test results>, <microbiological tests> • How are PAOs (relevant for cosmetics) determined? <microbiological tests>, <state of aggregation>
4.3.2.5	Where specific 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.	• Is all necessary equipment available to validate a new product? <records> • Is the technical equipment state of the art?
4.3.2.6	Claims shall be supported by scientific evidence (e.g. sun screen formulations, detergents, etc.) to ensure that the product meets the stated claim.	• How is a claim validated? • Is the legislation taken into account to declare claims on the products? • Are specific scientific guidelines followed?

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4.3.2.7	Where relevant, pilot equipment(s) shall be available and used in order to guarantee the possible scale-up.	• Is pilot equipment available?
4.3.2.8	Recommendations/instructions for application and/or use of the products shall be validated and documented, where appropriate.	• How are preparation recommendations and/or product use established? • How are consumer requirements taken into consideration during product development? <example>
4.3.2.9	The finished product shall be designed and labelled to prevent non intended use to protect the safety of the potential user. The risk assessment shall address this topic.	• How is the consumer unit validated for the safety aspect? • Is any change in consumer unit (material, size, type) considered in the safety report (relevant for cosmetics)? • Who is responsible for labelling? <procedure>
4.3.2.10	Based on risks, the company shall check and verify the suitability and interaction between the product and packaging in direct contact and intended or expected to be in direct contact, and it shall take into account: • physical and functional characteristics, • organoleptic characteristics (if applicable), • microbiology and chemical parameters (e.g. migration test results).	• How is it ensured that packaging materials have no negative effects on the product? • Did the company consider migration tests? • Has a risk assessment been performed in relation to suitability of packaging material? <risk assessment> Packaging material shall be tested concerning negative influences on the product. The results should be documented. • Which frecuency? • Are all components of the packaging material considered?
4.4	**Purchasing**	
4.4.1	The purchased materials shall be evaluated based on risks, and supplier´s status for product safety, legality and quality. The results shall be the basis for the testing and monitoring plans.	• How is it ensured that sourced materials and services conform to specifications?

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4.4.2	The purchasing services, which have, based on risks, an impact on product safety and product quality, shall be evaluated to ensure they comply with defined requirements. This shall take into account at a minimum: • the service requirements, • the supplier's status (according to its assessment), • the impact of the service on the finished products.	• How does the company check the conformity of the products purchased? • How is the authenticity of products checked? • Does a sampling plan exist? • How is the frequency and scope of the sampling plan determined? • How is the supplier status identified? • What kind of impact does the supplier status have on the determination of frequency and scope of the sampling plan?
4.4.3	A procedure for the sourcing of raw materials, semi-finished products and packaging material, and the approval and monitoring of suppliers (internal and external) shall be documented, implemented and maintained. This procedure shall contain at a minimum: • raw materials and/or supplier´s risks, • required performance standards (e.g. certification, origin, etc.), • exceptional situations (e.g. emergency purchase), and based on risks, additional criteria, for instance: ◦ audits performed by an experienced and competent person, ◦ testing results, ◦ supplier reliability, ◦ complaints, ◦ supplier questionnaire.	• How is the impact of the service on the finished product determined? • How does the company check the conformity of the services purchased? • At what frequency are the purchased services checked? • How is the supplier status identified? • What kind of impact does the supplier status have on the schedule of checks?

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4.4.4	Where a company outsources a part of the product processing and/or primary packing and/or labelling, it shall have it documented in the product safety and quality management system and ensure control over such processes to guarantee that product safety and product quality are not compromised.	• Does an approval procedure exist for new suppliers? • How does the company inform the suppliers about the approval requirements? • How does the company handle the non-approved suppliers and ensure that no goods/services are procured from them? • How are supplies monitored? • Are suppliers graded? • How is the qualification of suppliers ensured? • Which criteria are included in the supplier assessment? • How often are assessments made? • Which supplier has analysis certificates? • How is supplier reliability assessed and measured? • Does the supplier reliability include complaints and non-conformities? • What kind of performance standards are requested?
4.4.5	When required by the customer, there shall be evidence that the customer has been informed and has agreed to such outsourced process.	• Who reviews the results of supplier assessments? • How often are the results of supplier assessments reviewed? • What actions are taken after a review of the results for supplier assessments? • If there are outsourced processes, are they communicated to customers? What evidence is available?

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4.4.6	An agreement shall be documented and implemented covering the outsourced processes and describing any arrangements made in connection with it including in-process controls, testing and monitoring plans.	• How is the qualification of suppliers ensured? • Are there any co-packers? / suppliers of the outsourced processes? • How are they monitored? <lab tests>, <suppliers of outsourced processes list>, <certificate for suppliers>, external audit plan>, <supplier audits>, • What are the hazards / risk identified in the hazard analysis and risk assessment for the outsourced process(es)? • What are the specific controls defined to control each hazard and relevant risks identified for the outsourced process(es)? How are the controls carried out and documented? • How frequently are the controls for the outsourced process(es) carried out? Who is responsible for controls?
4.4.7	Suppliers of outsourced processes shall be approved through: • certification against IFS HPC or equivalent, or • documented supplier audit performed by an experienced and competent person, which shall include at a minimum, requirements for product safety, quality and legality, or • in case of a private label (e.g. retailer brand), the customer is expressively accepting other conditions.	• Are the suppliers of the outsourced processes IFS certified? Or certified to other equivalent product safety certification standard? <certificates> • If not, was a documented supplier audit performed? By whom? <lab tests>, <suppliers of outsourced processes list>, <certificate for suppliers>, <external audit plan>, <supplier audits> • In the case of private labels, does the customer agree with other conditions? What evidence is there that the customer has accepted other conditions?
4.4.8	The company shall check the products on receipt from its subcontractor based on a documented sampling plan.	• Is there a documented sampling plan?
4.4.9	The sourcing of materials and supplier audits shall be reviewed at least once within a 12-month period or whenever significant changes occur. Records of the reviews and the consequential actions of the audit shall be documented.	• How often is the sourcing of materials and the results of supplier audits reviewed? • Are records of reviews and actions after audits kept?

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4.5	**Factory exterior**	
4.5.1*	Potential adverse impact on product safety and quality from the factory environment (e.g. ground, air) shall be investigated. Where risks have been identified, measures shall be documented, implemented and reviewed for effectiveness (e.g. extremely dusty air, strong smells) at least once within a 12 month period or whenever significant changes occur.	• Does a location investigation exist? • Can a location have a negative influence on product safety and product quality? • What kind of control activities have been established if potentially damaging materials / substances are nearby? • Is efficiency of control activities regularly reviewed? • Who reviews the efficiency of the established control activities? • How is efficiency of established control activities reviewed?
4.5.2	The factory exterior shall be clean, tidy and maintained in good condition.	• Are factory exteriors tidy? • Are factory exteriors reviewed through internal audits?
4.5.3	All grounds within the site shall be clean, tidy and maintained in a way to prevent contamination. 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?
4.6	**Plant layout and process flows**	
4.6.1	Site plan(s) covering all buildings shall be documented and shall describe, maintained at a minimum the process flow of: • finished products, • packaging materials, • raw materials, • semi finished products including rework, • waste, • personnel, • water.	• Is the site map available? • Does the site map cover all production site buildings? • Are plans available that describe the listed process flows? • In regard to the described process flows, is cross-contamination avoided? <waste elimination plan>, <personnel flow plan>, <materials flow plan>, <process flow plan>, <hydraulic plan>
4.6.2	The process flow from receipt of goods to dispatch, shall be implemented and maintained, reviewed and where necessary, modified to ensure that the microbiological, chemical and physical contamination risks of raw materials, packaging materials, semi-finished, rework and finished products are avoided. The cross-contamination risks 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.

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4.6.3	Where relevant, products shall not be produced, stored and filled on the same equipment as products with another intended use unless validated results are available that there is no negative effect on the products.	• 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>
4.6.4	Based on risks, areas sensitive to microbiological, chemical and physical hazard(s) shall be designed and operated to ensure product safety is not compromised.	• Are there sensitive areas? • How often are airborne micro-organism counts made? • What sensitive areas were defined? What were the risks identified? • What kind of controls are implemented?
4.6.5*	Where relevant for laboratories: • location of laboratories at the factory shall not affect product safety, • microbiological laboratory shall be physically separated from chemical laboratory.	• Is there a laboratory on-site? • Does the lab have direct access to production premises? • Can lab waste (e.g. lab waste water) contaminate the production premises? Visit of lab • Who has access to the laboratories and especially to the microbiological laboratory? • If there is no microbiological laboratory onsite but microbiological analysis is necessary, who performs the microbiological analysis and how often?
4,7	**Production and storage premises**	
4.7.1	**Constructional requirements**	
4.7.1.1	All premises used in the manufacture and storage of products shall be designed, constructed and maintained to allow unobstructed installation, ease of maintenance, efficient pest control and easy cleaning of the equipment, as well as compliance with all relevant legislation.	
4.7.1.2	Premises where the products are prepared, treated, processed and stored shall be designed and constructed so that product safety and quality is ensured.	• Are the premises designed and constructed to ensure product safety? • Are the premises in good condition?
4.7.2	**Walls**	
4.7.2.1	Walls shall be constructed to meet production requirements in a way to prevent contamination to reduce condensation and mold growth, and to facilitate cleaning.	• Are walls mouldy?

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4.7.2.2	The surfaces of walls shall be maintained in a way to prevent contamination and easy to clean. Based on risks they shall be impervious and wear-resistant to minimize product contamination risks.	• How often are walls cleaned? <cleaning schedule>, <cleaning evidence>
4.7.3	**Floors**	
4.7.3.1	Floors shall be easy to clean and designed and constructed to meet production requirements (e.g. mechanical loads, cleaning materials, etc.).	• Are floor easy to clean? • How often are floors cleaned? <cleaning schedule>, <cleaning evidence>
4.7.4	**Ceilings /Overheads**	
4.7.4.1	Ceilings (or, where no ceilings exist, the inside of roofs) and overhead fixtures (including piping, cableway, lamps, etc.) shall be designed, constructed and maintained to minimize the accumulation of dirt and condensation and shall not pose any physical and/or microbiological contamination risks.	• How often are ceilings cleaned? <cleaning evidence>
4.7.4.2	Where false ceilings are used, access to the vacant area shall be provided to facilitate cleaning, maintenance and inspection for pest control.	• How often are false ceilings cleaned? <cleaning evidence>
4.7.5	**Windows and other openings**	
4.7.5.1	Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in a way to prevent contamination.	• Can dirt accumulate on window sills?
4.7.5.2	Where there are contamination risks, windows and roof glazing shall remain closed and fixed during production.	• Are windows kept open?
4.7.5.3	Where windows and roof glazing are designed to be opened for ventilation purposes, they shall be fitted with easily to clean pest screens or other measures to prevent any contamination.	• Are windows sealed with insect gratings? • Is the integrity of gratings regularly reviewed? <monitoring schedule>, <pest control schedule>
4.7.6	**Doors and gates**	
4.7.6.1	Doors and gates shall be maintained in a way to prevent contamination and easy to clean. Based on risks, they shall be constructed to avoid: • splintering parts, • flaking paint, • corrosion.	• Are doors and gates damaged?

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4.7.6.2	Plastic strip curtains separating areas shall be maintained in a way to prevent contamination and easy to clean.	• Are curtains damaged?
4.7.7	**Drainage system**	
4.7.7.1	Drainage systems shall be easy to clean and designed to minimize product contamination risks (e.g. entry of pests, transmission of odour or contaminants). The hygienic disposal of waste water shall be ensured.	• Is natural drainage sufficient? • If natural drainage is insufficient, has a suitable drainage system been installed? <audit results>
4.7.7.2	Water or other liquids shall reach drainage using appropriate measures without difficulties. Puddles shall be avoided.	• Is there water or puddles of other liquids • on the floors of production areas?
4.7.8	**Lighting**	
4.7.8.1	All working areas shall have the levels of light according to the activities carried out.	• Is there a legal requirement applicable regarding lighting? • Which are the criteria defined by the company to determine light conditions? • How is this checked? • What is the assurance that all working areas have adequate levels of light according to the activities carried out?
4.7.8.2	Based on risks, all lighting equipment and electric fly killer units shall be protected. The factory areas where this clause shall apply: • handling of unpackaged products and raw materials, • storage of raw materials including packaging materials, • changing rooms. This does not preclude that other areas shall not 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> <fly killer map>
4.7.9	**Air conditioning / ventilation**	
4.7.9.1	Natural and/or artificial ventilation covering process/product needs shall exist in all areas.	• If required due to product and/or process requirements, Is the air adequate in terms of volume, condition and/or quality? • How is ventilation reviewed?
4.7.9.2	If ventilation equipment is installed, filters and other components shall be easily accessible and monitored, cleaned or replaced as necessary.	• How are air filters maintained and cleaned?

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4.7.9.3	Air conditioning equipment and artificially generated airflow shall not compromise product safety and quality.	• Is the use of air during production based on risk analysis? • Are there production areas with under- or over-pressurization? <risk assessment>
4.7.9.4	Dust extraction equipment shall be designed, constructed and maintained in areas where considerable amounts of dust are generated.	• Are there areas where large amounts of dust are formed? • Do dust extraction devices exist in these areas?
4.7.10	**Water**	
4.7.10.1*	A water monitoring program shall exist covering all process waters (e.g. water used in the facilities, for cleaning activities, used as an ingredient, etc.). The testing of all process waters shall incorporate at a minimum: • chemical, physical and microbiological specifications, • frequency, • method of water treatment depending on product requirement (e.g. deionization, distillation, • etc.). Special consideration shall be given after periods of no water consumption (e.g. after a weekend or holiday period) and when the stagnation of water cannot be avoided. The risk assessment shall address this topic.	• 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>
	Additional Information *Uses of water (in general):* • *Active principle vehicle* • *raw material solvent* • *Washing and rinsing fluid* • *cooling fluid and sterilizing element (steam, autoclaves)* *Main risks coming from plants and products: long pipes, ventilation, storage and demineralization should be considered as risk factors.*	
4.7.10.2	A water monitoring program shall verify that the water treatment is adequate and effective in a risk-based sampling plan.	• Is sampling plan based on risk analysis?
4.7.10.3	Recycled water which is used in the process shall not pose a contamination risk. Records of compliance testing shall be available.	• Is recycled water under control?

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4.7.10.4	If applicable, different process water quality shall be clearly distinguished throughout the site and shall not pose a risk of contamination.	• Is the drinking water system completely separated from non-potable water piping? • What other systems are there (e.g. used water, cooling water, water used for firefighting)? • Are water systems properly marked and where are they located? • Is reflux avoidance equipment installed wherever necessary?
4.7.11	**Compressed air**	
4.7.11.1	The quality of compressed air that comes in direct contact with the product or packaging intended to be in contact with the product shall be monitored based on risks. Compressed air shall not pose contamination risks.	• Is compressed air used in direct contact with products or surfaces? If compressed air is used: • What kind of hazard / risks has the company identified and assessed? • In regard to the identified and assessed hazard / risks, what kind of controls has the company implemented?
4.8	**Cleaning and disinfection**	
4.8.1	Risk based cleaning and disinfection schedules shall be validated, documented and implemented. These shall specify: • objectives, • responsibilities, • the products used and their instructions for use, • methods of cleaning (including dosage of cleaning and disinfection chemicals), • the areas and timeslots for cleaning and disinfection, • documentation requirements, • cleaning in place (CIP) criteria, if applicable, • hazard symbols (if necessary).	• Who is in charge of cleaning and disinfection? • What kind of cleaning products and disinfectants are used? • Are the instructions for use in place? • What shall be observed when using different cleaning products and disinfectants? • Is the dosage of cleaning and disinfection chemicals defined and controlled? • What areas are cleaned and disinfected? • How often are areas cleaned and disinfected? • Where are cleaning and disinfection procedures documented? • Do hazard symbols exist? • Does a contract exist for external service providers?

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
4.8.2	Defined methods for monitoring shall be adequately documented and implemented. Monitoring records for cleaning and disinfection shall be available.	• Where are the cleaning and disinfection methods documented? • How is their adequate implementation monitored? • How are the cleaning and disinfection methods validated? • Who performs such monitoring?
4.8.3	Cleaning and disinfection activities shall be documented and implemented and shall result in effectively cleaned premises, facilities and equipment.	<Observation>
4.8.4	Only competent personnel shall perform cleaning and disinfection activities. The personnel shall be trained and retrained to carry out the cleaning schedules.	• Are cleaning personnel qualified? • How often are they trained? • Who trains them? • Are these training documented?
4.8.5	The effectiveness of the cleaning and disinfection measures shall be verified. The verification shall rely on a risk-based sampling schedule and shall consider one or several actions like for example: • visual inspection, • rapid testing, • analytical testing methods. Resultant actions shall be documented.	• How are cleaning and disinfection controls performed? • Who performs these controls? • How often are cleaning and disinfection controls performed? • Where are cleaning and disinfection controls documented? • When are corrective actions executed? • Who executes corrective actions? • Who reviews effectiveness of corrective actions? • Where are corrective actions documented? <cleaning controls>, <cleaning controls>, <corrective actions>
4.8.6	Cleaning and disinfection activities shall be reviewed and modified 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.	• When are cleaning and disinfection procedures validated? • Who adapts cleaning and disinfection procedures? • How often are cleaning and disinfection schedules changed?

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4.8.7	Current safety data sheets (SDS) and instructions for use shall be always available on-site for chemicals and cleaning agents. Personnel responsible for cleaning and disinfection activities 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?
4.8.8	Cleaning utensils and chemicals shall be clearly identified, used and stored appropriately to avoid contamination or unintended use.	• How is the intended use of utensils identified? • What kinds of control activities are in place to avoid the contamination of utensils? • Where are utensils stored?
4.8.9	If relevant, the cleaning of production tools shall 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? • If applicable, how does the company avoid cross contamination between the cleaning chamber and the production area? <cleaning evidence>

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4.8.10	Where a company hires a third-party service provider for cleaning and disinfection activities in production areas, all above-mentioned requirements shall be documented in the service contract.	• Which areas are cleaned and disinfected by a third-party service provider?
	Additional Information *If a third-party service provider for cleaning and disinfection activities is hired:* • *Where has the company defined the requirements for the third-party service provider?; are the relevant requirements included?* • *Does the contract include requirements about personal hygiene, declaration of health issues or infectious diseases, or any other control activities (e.g. access restrictions, training, etc.), in order to prevent any negative impact on products?* • *If absences of external personnel occur, what kind of actions are taken by the third-party service provider and the company?* • *Are requirements about personal hygiene, declarations of health issues or infectious diseases, or any other control activities (e.g. access restrictions, training, etc.), included in the contract to prevent any negative impact on products?* • *How does the company monitor the execution of the hired activities?* • *How does the company verify the effectiveness of the hired activities?* • *Who is responsible for the monitoring and verification activities?; what are the competencies defined for the responsible person?*	
4,9	**Waste management**	
4.9.1	A waste management procedure shall be documented, implemented and maintained to prevent cross contamination.	• Has the company implemented a waste management procedure? • What kind of waste has the company defined? • What controls are defined to manage waste and avoid cross-contamination? • How is the waste collected and stored?
4.9.2	All local legal requirements for waste disposal shall be met.	• How is it ensured that current legal waste disposal requirements are met? • How is waste material disposed of?
4.9.3	Product waste and other waste shall be removed from areas where product is handled. The accumulation of waste shall be avoided.	• How often is waste and other waste removed from product handling areas? • Who is responsible for waste removal?

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4.9.4	Waste collection areas and waste containers (incl. compactors) shall be maintained tidy, clean to minimize pest attraction, and where necessary disinfected. Waste containers shall be clearly marked, suitably designed and in a good state of repair.	• What kind of waste exists? • What waste is collected in separate containers? • When appropriate, are hands free openings utilised? • How are waste containers marked? • Can waste containers be easily cleaned? • How often are waste containers cleaned? • Are waste containers in a good state of repair? • Are the waste collection rooms and containers kept clean and tidy? • Are waste collection rooms protected from pests? • If applicable, how are waste containers disinfected and how often?
	Additional Information *Marking could be also defined by colour: if marking is done by e.g. adhesive foil - it could become loose and be a source of product contamination.*	
4.9.5	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 non-compliant products.	• What kinds of waste disposal records exist? • Who is responsible for waste disposal? <waste disposal registry>, <waste disposal licencey>
4.10	**Foreign material risk mitigation**	
4.10.1	The products being processed shall be protected against physical contamination, which includes but is not limited to: • environmental contaminants, • oils or dripping liquids from machinery, • dust spills. Special consideration shall also be given to product contamination risks caused by: • equipment and utensils, • pipes, • walkways, • platforms, • ladders. If for technological characteristics and/or needs, the products cannot be protected, control measures shall be implemented.	<site inspection>

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
4.10.2*	Based on risks, procedure(s) shall be documented, implemented and maintained to prevent contamination with foreign material.	• What kinds of foreign material may be found? • Where are sources of foreign material identified through hazard analysis? • Are staples used? • How are contaminated products handled? <risk assessment>, <glass handling procedures>, <segregation records>, <glass breakage prevention procedures>
4.10.3	In areas where raw materials, semi-finished and finished products are handled the use of wood shall be avoided. Where the presence of wood cannot be avoided the risks shall be controlled and the wood shall be clean and pose no risks to product safety.	• Under what circumstances is the use of wood permitted? • Is the wooden tool in use in a good and clean condition? • Where is the use of wood allowed and what kinds of conditions were defined for this? • Are the wooden surfaces/tools in use in good conditions (clean, free from splinters or other sources of physical contamination)? • Who inspects and how often is the condition of the wooden tool inspected? • Are pallets checked to verify that they are clean, sound, dry, free from damage and contamination?
4.10.4	Where metal and/or other foreign material detectors are required, they shall be installed to ensure maximum efficiency of detection to prevent subsequent contamination. Detectors shall be subjected to maintenance to avoid malfunction at least once within a 12-month period, or whenever significant changes occur.	• Where are the foreign material detectors installed? • How are the metal parts found in the product? • What effects do the shape, position and type of metal have on the detection? • Has the position of the test sample been correctly chosen? • Is the text sample size and material appropriate for the product? • Has the functioning of the metal detector been validated regarding products, processes and process conditions?
	Additional Information *The need for detectors can be based on HA RA and/or based on customer requirement.*	

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4.10.5	The accuracy of all equipment and methods designed to detect and/or eliminate foreign materials shall be specified. Functionality tests of such equipment and methods shall be carried out at least at the start and end of production as well as at every product changeover. In case of malfunction or failure, the impact on products and processes shall be assessed.	• How often are the detectors checked for accuracy? • Who checks functionality and accuracy of equipments? • What corrective actions exist when a detector is defective? • Are corrective actions verified? • Are operational defects documented? • Is the detection limit based on risk assessment? <are all test pieces smaller than the potential hazardous foreign body?>
4.10.6	Potentially contaminated products shall be isolated. Access and actions for further handling or testing for these isolated products shall be carried out only by authorized personnel.	• Are contaminated products automatically isolated? • Who may handle / has access to isolated products? • How are isolated products handled? <non-conforming products list>, <isolation protocol>

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4.10.7	A glass and brittle material procedure shall be implemented taking into account preventive and corrective measures; the procedure 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? • 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).
	Additional Information *In areas where unpackaged products are handled, windows shall be protected against breakage. 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*	

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4.11	**Pest monitoring and control**	
4.11.1*	Risk based pest control measures shall be documented, implemented and maintained. They shall comply with local legal requirements and shall take into account at a minimum: • factory environment (potential and targeted pests), • type of raw material / finished products, • site plan with area for application (bait map), • constructional designs susceptible for pest activity, for example ceilings, cellars, pipes, corners, • identification of the baits on site, • responsibilities, in-house / external, • agents used and their instructions for use and safety, • frequency of inspections, • rented storage if applicable.	• How is pest control organised? • Which pests are controlled? • Which kinds of baits are used? • Is product contamination through baits prevented? • Who is responsible for pest control? • What is the inspection schedule? • In case of the identification of pest activity, what were the corrective actions? <pest control procedures>, <pest control chemicals list>, <bait map>
4.11.2	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded. Any infestation shall be documented and control measures taken.	• Is pest control executed by own staff members? • Who is responsible for pest control? • What kind of training does the responsible person have? • Is pest control executed by an external service provider? • Where are inspections and resulting corrective actions documented? • Are documents signed and dated by both parties? • Which corrective actions were executed lately? • Are control activities defined in case an infestation occurs? What kind of control measures are defined? In the case of an intervention threshold, how is it notified and controlled? • Are the personnel aware of the need to report any evidence of a plague to the responsible persons?

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4.11.3	Baits, traps and insect exterminators shall be fully functioning, sufficient in number, designed for purpose, placed in appropriate positions and used in a way to avoid contamination.	• Where are electrical fly killers installed? • Are all fly killers connected and properly functioning? <fly killer map>
	Additional Information *Baits, traps and insect killers (electric fly killers, etc.) are fitted correctly in sufficient number 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.*	
4.11.4	Incoming deliveries shall be inspected on arrival for the presence of pests. Any findings shall be recorded.	• Are incoming goods inspected for pest contamination? • Where is this documented? • Is pest presence documented? • What control measures are taken when pests are found? • Where are these control measures documented? <corrective actions>, <incoming goods inspection>
4.11.5	Based on risks, 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?
4.11.6	The effectiveness of the pest control measures shall be verified, including trend analysis to allow timely appropriate actions. Records of this verification shall be available.	• Is trend analysis being carried out? • Is it documented? • Are conclusions drawn from trend analysis

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4.11.7	Where a company hires a third-party service provider for pest control, all above mentioned requirements shall be documented in the service contract. A person at the company shall be appointed and competent to monitor the pest control activities. Even if the pest control service is outsourced, responsibilities for the necessary actions (including ongoing supervision of pest control activities) shall remain within the company.	• Where has the company defined the requirements for the third-party service provider?; are the relevant requirements included? • What kind of training does the external service provider have? • Does the contract include requirements about personal hygiene, declaration of health issue or infectious disease, or any others measures (e.g. access restrictions, training, etc.), in order to prevent any negative impact on products? • If absences of external personnel occur, what kind of actions are taken by the third-party service provider and the company? • Are control activities to manage the incidents and/or potential emergency situations which could have an impact on the product requirements and/or the provision of services included in the contract? • How does the company monitor the execution of the hired activities? • How does the company verify the effectiveness of the hired activities? • Who is responsible for the monitoring and verification activities?; What are the defined competencies for the responsible person?
4.12	**Receipt and storage of goods**	
4.12.1	All incoming goods including packaging materials and labels, shall be checked for compliance against specifications and a determined risk-based monitoring plan. The inspection plan shall be justified by risk assessment. Records of those inspections shall be available.	• What goods (including semi-processed products) are inspected when received? • What is checked when received? • Is receipt documented? • Who checks the goods? <receipt checks>
4.12.2	A system shall be implemented and maintained to ensure storage conditions and locations of raw materials including packaging materials, semi-finished and finished products correspond to product specifications and shall not have any negative impact on other products.	• Where are raw materials, half finished products and packaging materials stored? • How is cross-contamination avoided? <product flow plan>, <storage plan>

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4.12.3	Outdoor storage shall be kept to a minimum. Where products are stored outside it shall be ensured that there is no risk of contamination or adverse effect on product safety and quality.	• Are products stored outdoors? Including raw materials, packaging, semi-finished and finished products • 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> • What kind of storage regulations exist? • Are pests taken into account during storage? • Are pallets located approximately 1m from walls? <preventive measures>, <pest control schedule>, <plant inspection protocol>, <materials flow-diagram>
4.12.4	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 ?
4.12.5	All products shall be identified. Use of products shall be undertaken in accordance with the principles of First In / First Out and/ or First Expired / First Out, and in accordance with relevant industry best practices.	• How is "FIFO" ensured?
4.12.6	Periodic inventory shall be performed to ensure stock reliability. Any significant discrepancy shall be investigated and corrective action taken.	• How is the periodic inventory carried out?

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4.12.7	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 defined in the respective contract.	• Is storage leased to a storage service provider? • Does a contract exist? • What is specified in the contract? • How does the company monitor the execution of hired activities? • Does the storage service provider have an IFS Logistics certification? <certificate copy>, <service provider contract>
4.13	**Transport**	
4.13.1	The transport vehicles used to transport goods shall be in good condition and shall protect the products from adverse weather conditions and external influences. The conditions inside the vehicle for example: • absence of strange smells, • high dust load, • adverse humidity, • pests, • mould, • vehicle integrity, shall be checked and documented before loading and unloading to ensure compliance with the defined conditions.	• What is checked before loading? • Where is inspection documented? • What corrective actions are taken? <expedition inspection>
	Additional Information *At the reception of raw materials and packaging materials, checks shall be made to assess that transportation has taken place under good conditions.*	
4.13.2	Procedures to prevent contamination during transport (as well as internal transport) including loading and unloading shall be documented, implemented and maintained.	• Can goods be transported alongside other type of (non-) HPC products? • How is cross-contamination prevented?
4.13.3	Risk-based hygienic requirements for all transport vehicles including tank trucks and equipment used for loading/unloading (e.g. hoses of silo installations) shall be implemented. There shall be records of the measures taken.	• Are transport vehicles cleaned? • Where are cleaning procedures documented? <cleaning protocol>

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4.13.4	Loading and unloading areas shall have equipment in place to protect transported products from external influences.	• How is goods reception organised? • How is loading organised? External influences: e.g. pollen, climate, etc.
	Additional Information *The loading/unloading areas shall be appropriate for their intended use. They shall be constructed in a way that:* • *the risks of pest intake are mitigated* • *products are protected from adverse weather conditions* • *accumulation of waste is avoided* • *condensation and growth of mould are prevented* • *cleaning can be easily undertaken.*	
4.13.5	Where a company hires a third-party transport service provider all the requirements specified within section 4.13 shall be defined in the respective contract or the service provider shall be subjected to IFS Logistics Requirements or equivalent standard.	• Are there internal or external transportation regulations? • Does a contract exist with a transportation service provider? • Does the storage service provider have an IFS Logistics certification? <service provider contract>, <certificate copy>
4.14	**Maintenance and repair**	
4.14.1	A maintenance plan shall be documented, implemented and maintained that covers all critical equipment (including transport) for compliance with product requirements. This applies both to internal maintenance activities and service providers. The plan shall include responsibilities, priorities and due dates.	• How is maintenance organised? • Where are maintenance procedures documented? • Which equipment is subject to external maintenance?
4.14.2	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? • What rules are in place for re-activating equipment when maintenance is completed?
4.14.3	All materials used for maintenance and repair shall be fit for the intended use and not pose contamination risks.	• 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.).

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4.14.4	Failures and malfunctions of premises and equipment (incl. transport) essential for product safety and quality shall be identified, documented and reviewed to enable prompt actions and to improve the maintenance plan.	• Are processing interruptions documented? • Are processing interruptions considered in maintenance planning? <processing interruptions>
4.14.5	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 carried out? • Who verifies this? By temporary repairs, we also refer to temporary repairs on the building etc.
4.14.6	Where a company hires a third-party maintenance and repair service provider, all the company requirements regarding material, equipment and operational rules shall be defined, documented, and maintained in the service contract, to prevent any product contamination.	• Does a contract exist with a maintenance and repair service provider? <service provider contract>, <training of subcontractor> • How does the company monitor the execution of the hired activities? • How does the company verify the effectiveness of the hired activities?
4.15	**Equipment**	
4.15.1	Equipment shall be suitably designed and defined for the intended use. Before commissioning, it shall be validated that the product and customer requirements are complied with. Consumables used for equipment should not affect the product safety and quality of the product.	• Is equipment suitably designed and were they checked before start up? <start up protocol> • What rules exist for the start up of new equipment?
4.15.2	Where relevant for product safety, evidence for conformity shall be in place to demonstrate that equipment, utensils and other materials in contact with the product are suitable for the intended use.	• Are conformity certificates or other certificates available for all equipment and tools which come into direct contact with products?
	Additional Information *In case no specific legal requirements are in place, evidence shall be available, such as:* • *certificate of conformity* • *technical specifications* • *manufacturer's self-declaration to demonstrate that they are suitable for the intended use.*	

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4.15.3	Equipment shall be located to allow effective cleaning, disinfection and maintenance operations.	• Does an equipment installation plan exist? <machinery installation plan> <start up protocol>, <machinery installation plan>
4.16	**Traceability**	
4.16.1*	**KO N° 4:** A traceability system shall be documented, implemented and maintained that enables the identification of product lots and their relation to batches of raw materials and packaging in direct contact with product and intended or expected to be in direct contact with product. The traceability system shall incorporate all relevant records of: • receipt, • processing at all steps, • use of rework, • distribution. Traceability shall be ensured at all stages and documented until delivery to the customer.	At all stages meaning work in progress, post treatment and rework. • How is the finished product batch identified? • Does the traceability system defined by the company include the relation between finished product batches, raw materials, production processes and controls? • How is traceability ensured? • What products come from which supplier? • Is there a list available with all current suppliers?
4.16.2	The company shall ensure that the used packaging and labelling correspond to the product being packaged and comply with agreed customer product specifications. This shall be regularly checked and documented.	<check of labels>
4.16.3	The traceability system shall be tested at least once within a 12-month period or whenever significant changes occur. The test samples shall verify the complexity of the company's product range. The test records shall demonstrate upstream and down-stream traceability (from delivered products to raw materials and vice versa). The tracea-bility of the finished products shall be performed within four (4) hours maximum.	• When was the last test to verify the traceability system carried out? • According to which criteria were the samples selected? • Did the test include verification of upstream and downstream traceability? • Are complete records for the test available? • What percentage of the total amount was traced? • How big is a batch? • How much time did the company take to trace the final products? • Are there customer requirements for the timeframe? • Have timeframes been respected during own traceability exercises?

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4.16.4	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.).	• Where has the equipment used for production been registered?
4.16.5	If required by customer and/or law, 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. For products which have no shelf life, the storing duration shall be justified, and this justification shall be documented.	Manufacturing batch refers to finished product • Does the customer request retained samples? • What is the purpose of the retained sample system? • Was the representative sampling of retained samples agreed with the manufacturer? If yes, where are the retained samples kept?; under which conditions? • Is a sample bank implemented? • How are these samples managed?
4.17	**Allergen risk mitigation**	
4.17.1	Information about allergens requiring declaration shall be available. The company shall have a continuously maintained system to demonstrate all raw materials containing allergens used at its premises are known and identifies all blends and formulas to which such raw materials containing allergens are added.	• Does the company have a list or other format containing all raw materials containing allergens? <allergen list>; <software where listed allergens> • Are the allergens identified in formulas / configurations, semi-finished products and finished products? • Are allergens identified in specifications? E.g: fragrances, preservaties, etc.
4.17.2*	Risk based measures shall be implemented and maintained from receipt to dispatch, to ensure that potential cross contamination of products by allergens is minimized. The potential cross contamination risks shall consider at a minimum: • environment, • transport and storage, • raw materials, • allergen precursors, • production process. Implemented measures shall be monitored.	• Is a procedure in place to avoid contamination of allergen free products? • Are legal and customer requirements related to the declaration of allergens in final products? • Are preventive and control measures in place to minimise potential cross-contamination risks? • How are preventive and control measures verified?
4.17.3	Finished products containing allergens requiring declarations, shall be declared in accordance with legal requirements and/or customer requirements.	• Has allergen status been documented in specifications? <finished product specifications>

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4.18	**Product Defence**	
4.18.1	A product defence procedure and plan shall be implemented in relation to assessed threats. This shall encompass at a minimum: • identification of critical areas and/or practices and policy of access by employees, visitors and contractors, • transport vehicles, • IT, • legal requirements, if applicable, • any other appropriate control measure. The product defence plan shall be well known and established within the company and shall be reviewed annually and upon changes.	• Are there any legal/customer product defence requirements applicable to the company? • How can the company demonstrate compliance with such requirements? • What is the process/procedure used to perform the hazard analysis and assessment of associated risks? • Is the hazard analysis in line with legal and/or customer needs and/or expectations? • How do the systems assist the company to identify critical or high risk areas? • How often is a review of the product defence program performed? • What criteria does the company consider in order to determine the frequency to perform the hazard analysis, if is not done annually? • How is the company alerted of any product defence breach? • How does the company evaluate the effectiveness of the product defence program? • How are transport vehicles checked? <product defence plan>, <risk assessment>, <meeting minutes>

	Additional Information
	• *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*	

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
4.18.2	The responsibilities for the product defence shall be defined. The responsible person(s) shall have full commitment from the senior management.	• Who is accountable for the product defence program? • What are the competence and qualifications demonstrated by the person(s) responsible for the product defence program? • What is the position of the person(s) responsible for the product defence program with respect to the management team? • How does senior management support the person(s) responsible for the product defence program? • Where are the responsibilities clearly defined? • Was this communicated to members of the company? How? <Job description>, <training records>
5	**Measurements, analyses and improvements**	
5.1	**Internal audits**	
5.1.1	An effective internal audit program shall be documented, implemented and maintained and shall ensure that all the requirements of the IFS Standard are assessed within a 12-month period and its execution shall not exceed 15 months. The company shall have a risk assessment in place where activities critical to product safety and quality shall be audited more frequently. It shall also apply to off-site storage locations owned or rented by the company.	• Does an up to date internal audit plan exist? <audit plan> • How often are internal audits performed? • Are all requirements of the standard assessed within a 12-month period and does the execution take place within 15 months? • Is audit plan based on risk assessment? <risk assessment> • Is a checklist available? Does it consider off-storage locations? <it is based on IFS HPC requirements>

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5.1.2	The auditors shall be competent and independent from the audited department.	• Who are the auditors? • How are auditors qualified for this job? • Do auditors have any connection with the audit area? <auditors list>, <continued education evidence>
	Additional Information *Some examples of alternatives to fulfil the independent criteria might comprise:* • *Allow the internal auditors to only audit those processes and departments in which they are not directly involved or for which they are not responsible.* • *Exchange internal auditors from other company sites to execute the internal audits.* • *Hire an IFS Consultant or an external professional with the relevant competencies to execute the internal audits.*	
5.1.3	Internal audits shall be documented and results communicated to the senior management and to the persons responsible for the concerned activities. Compliances, deviations and non-conformities shall be documented and communicated to the relevant persons.	• Are internal audits documented? • Are the results communicated to the senior management / responsible person? • How/when are the results communicated?
5.2	**Site inspections**	
5.2.1	Site inspections shall be planned and carried out for topics, for example: • constructional status of production and storage premises, • external areas, • product control during processing, • hygiene during processing and within the infrastructure, • foreign material hazards, • personal hygiene. The frequency of inspections shall be based on risks and on the history of previous results.	• How often are site inspections carried out and who makes them? • What is reviewed during site inspections? • For which areas do site inspections exist? • Are all required areas covered? <site inspections protocol>

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
5.3	**Process validation and control**	
5.3.1	The criteria for process validation and control shall be defined. Process parameters (temperature, time, pressure, chemical properties, etc.) which are essential to ensure the product safety and quality shall be monitored, recorded continuously and/or at defined intervals and secured against unauthorized access and/or change.	• Which are the criteria defined for validation? • Which are the criteria defined for the control of the process? • Which are the criteria defined for the control of the working environment? • Does the company have a procedure/ protocol regarding process validation? • When was the last process validation conducted (process, date, result)? • What kind of validation, verification and monitoring activities are considered by the company? • How are the monitoring and verification activities defined? • At what frequency are the monitoring and verification activities carried out?
	Additional Information *The working environment parameters refers to the conditions that shall be controlled for ensuring the production of conforming products.* *Depending on the impact on product compliance, some examples of parameters to be controlled are biological contaminants (e.g. pathogens, moulds or yeast that could cause spoilage), chemicals contaminants in surfaces, temperature, humidity, among others.*	
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 is the processing operation followed? • Where is information for production kept? • What kinds of monitoring exist? <fabrication order>, <job instruction>, <nomenclature product>

	HPC v3	Guidance for industry and auditors: What to check? / What could be asked?
5.3.3	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 to assure that product requirements are complied with. If relevant, customers shall be informed accordingly.	• How are the changes controlled? • Who is responsible to authorise the changes? • How are the process characteristics reviewed to assure that product requirements are fulfilled? • What kind of actions are taken to prevent adverse impacts? • Who is responsible for label review?
5.3.4	All rework operations shall be validated, monitored and documented. These operations shall not affect the product safety and quality.	• How is it assured that rework complies with specifications? • Where is rework documented? <model documentation for rework> • Who reviews rework results? • Who decides on the release of reworked products? • What kinds of rework is used in practice? <use of product in a following lot>, <adaptation 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?
5.3.5	Procedures shall be documented, implemented and maintained for prompt notification, recording and monitoring of equipment malfunction and process deviations.	• What happens when a failure occurs? • What happens when the cold chain is interrupted? <machinery stand still protocol>
5.3.6	If substantial process modifications occur a revalidation shall be carried out.	• When was the last modification? • Was re-validation performed after modification?

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5.4	**Calibration, adjustment and checking of measuring and monitoring devices**	
5.4.1	Measuring and monitoring devices required to ensure compliance with product safety and product quality shall be identified and recorded. Their calibration status shall be recorded. Measuring and monitoring devices shall be legally approved if required by current relevant legislation.	• What kinds of monitoring devices exist? • What is demanded of monitoring devices? • What monitoring device is adequate for which kind of measurement? • How are monitoring devices identified? • Do calibrated devices exist? • How is the calibration status of a measuring device identified? <monitoring devices list>, <identification stickers on monitoring devices>, <identification stickers>
5.4.2	All measuring devices shall be checked, monitored, adjusted and calibrated at defined, recognized standard/methods and within relevant limits of the process parameter values. The results shall be documented.	• How is the check of measuring devices organised? <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> • Does the company perform additional internal checks of measuring devices on a risk based frequency?

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5.4.3	All measuring devices shall be used exclusively for their defined purpose. Where the results of measurements or the status of the device indicate a malfunction, the device in question shall be immediately repaired or replaced. Where malfunction has been identified, the impact on processes and products shall be assessed to identify whether non-conforming products have been processed.	• What actions are taken when measurement results are uncertain? • How are device/equipment with malfunction/failure identified?
5.5	**Quantity control monitoring**	
5.5.1*	The frequency and methodology of quantity checking shall be implemented and maintained to meet legal requirements (including destination country/ies) and customer specifications.	• How is it ensured that legal requirements for amount control are met? • How is it ensured that customer requirements for amount control are met?
5.5.2	Compliance criteria to control lot quantity shall be defined.	<procedure for quantity checking (frequency)>, <compliance criteria>
5.5.3	Monitoring shall be implemented and recorded according to a sampling plan which ensures a proper representation of the manufacturing lot. Results of these checks shall be compliant with defined criteria for all products ready to be delivered.	• Is a sampling plan implemented? • How was the size of sampling and the frequency of checks determined?
5.6	**Product testing and environmental monitoring**	
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 done in house 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>
5.6.2	Suitable equipment and environment shall be available for all tests performed.	<site inspection>

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5.6.3	Analyses which are relevant for product safety, quality and legality shall preferably be performed by laboratories with appropriate accredited programs/methods (ISO/IEC 17025). If the analyses are performed internally or by a laboratory without the appropriate accredited programs/methods, the results shall be cross-checked by laboratories accredited to these programs/methods (ISO/IEC 17025) at least once within a 12-month period, or whenever significant changes occur. The company shall be able to demonstrate that the results are reliable.	• Is there an analytical laboratory on site? • Is it accredited to ISO 17025? • Are internal lab results verified by an accredited lab? • Which external laboratories are used? • Are these accredited under ISO 17025? <accreditation evidence>
	Additional Information *Scope 3, performance (resistance, thickness etc...)* *Reliability of the analysis could be proved if the lab uses published scientific methods which are validated (published in e.g. scientific journals, Chemical society journal, European pharmacopoeia etc.), and suitable and calibrated equipment*	
5.6.4	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?
5.6.5*	Testing and monitoring plans for internal and external analyses shall be riskbased to ensure that product safety, quality, legal and specific customer requirements are met. The plan shall cover at a minimum: • raw materials, • semi-finished products (if applicable), • finished products, • packaging materials, • contact surfaces of processing equipment (if appropriate), • relevant parameters for environmental monitoring. The testing plan shall include the frequency of the tests and the tolerance associated to the specification limits.	• Does an inspection plan exist? • Who organises the inspection plan? • Which products are encompassed in the inspection plan? (raw materials, semi-finished and finished products, wrapping materials, environmental tests?) • Is the inspection plan based on hazard analysis? • Where are test results documented? • Which chemical, physical or microbiological analyses are made or subcontracted? • Which analyses are performed by own laboratory and which by external?, and how frequently?

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5.6.6	The results shall be reviewed regularly and trends identified. Immediate corrections shall be implemented for any unsatisfactory results, or where such trends indicate unsatisfactory results. When unsatisfactory trends are identified, the impact on processes and products as well as the need for actions shall be assessed.	• Who reviews analytical results? • How are analytical results verified? • Are trends investigated? • Are corrective actions introduced when results are unsatisfactory? <corrective actions>
5.6.7	When relevant, sampling of raw materials and of bulk product shall be performed in an appropriate manner and by authorized personnel.	• Where is the sampling of raw materials performed? • Is an adequate sampling cabin available for microbiologically sensitive materials? • Who is responsible for performing this? <procedure>, <job instruction>
5.6.8	Where internal analyses or controls are undertaken, these shall be carried out in accordance with defined procedures by competent and approved personnel.	• Which tests are performed internally? • What qualifications does the lab technician have? <qualification evidence> • Is an internal lab available? • Is an incubator, sterilization equipment available? • How is product contamination by internal lab prevented? <qualification evidence>
5.6.9	Results of checks on finished products including rework material shall be reviewed by authorized personnel to verify the conformity of the finished and semi-finished products with the acceptance criteria. Appropriate corrective actions shall be undertaken for any unsatisfactory results.	• Are results of checks reviewed by authorized personnel? • Who is authorised to verify the results? • When was the last unsatisfactory result? Were effective corrective actions taken?
5.6.10	For monitoring of the quality of the finished product, organoleptic tests shall be carried out. These tests shall be in accordance with specifications and related to the impact on respective parameters of product characteristics. The results of these tests shall be documented.	• When and how are organoleptic tests performed? <inspection plan>, <documentation of organoleptic test results>

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5.6.11	The testing and monitoring plans shall be regularly reviewed and updated, based on results, changes to legislation or issues that may have an impact on product requirements.	• What was the last review of the testing plan? • How was the review executed? • How does the company update the plan in case of legislation changes? • Are product fraud topics included for the plan review?
5.6.12	In-process controls shall not compromise product requirements.	• What kind of in-process controls are carried out? <results during site inspection>
5.7	**Product release**	
5.7.1	A procedure for quarantine (blocking/ hold) shall be documented, implemented and maintained to ensure that only raw materials including packaging materials, semi-finished and finished products, and packaging materials complying with product and customer requirements, are processed and dispatched.	• Who quarantines or releases products? • How are quarantined products identified? <job description>
5.8	**Management of complaints from authorities and customers**	
5.8.1*	A procedure shall be documented, implemented and maintained for the management of product complaints (including any written notification from the competent authorities, if relevant), and shall take into account specific procedures (e.g. undesirable effects).	• How does the company handle complaints? • Is a prompt reaction to every complaint ensured? • Which complaints occurred recently? • How is a uniform procedure for complaint handling ensured? • What is the range or indicator of complaints raised by customers, consumers (if applicable), and authorities separately? <complaint handling procedure>
5.8.2	All complaints shall be recorded, readily available and assessed by competent staff. Where it is justified, actions shall be taken immediately.	• How are complaints received, and by whom? • Who evaluates complaint significance? • Who defines the actions to be taken? • Within what time frame shall actions be taken?

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5.8.3	Complaints shall be analysed with a view to implementing actions to avoid the recurrence of deviations and non-conformity.	• How are complaints analysed?, how often are they analysed? • Who manages complaint statistics? • Is there a breakdown for the different complaint reasons? • Does the company investigate the causes for complaints? • Are there examples of corrective actions resulting from complaints? • Were these corrective actions effective? • What actions are taken to avoid recurrence? • Who is responsible for the process? <complaint statistics>
5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons including the senior management.	• To whom are the complaint data statistics presented? <retailer/business partner complaint statistics data>
5.9	**Management of product recall, product withdrawal and incidents**	
5.9.1*	**KO N° 5:** An effective procedure shall be documented, implemented and maintained for the management of recalls, withdrawals, incidents and potential emergency situations with an impact on product safety, quality, and legality. It shall include at a minimum: • the assignment of responsibilities, • the training of the responsible persons, • the decision-making process, • the nomination of a person authorized by the company and permanently available to initiate the necessary process in a timely manner, • an up-to-date alert contact list including customer information, sources of legal advice (if necessary), and contacts availability, • a communication plan including customers, authorities, and where applicable consumers.	• Who belongs to the incident management staff? • Who is informed when an incident occurs? • How are incidents managed? • What is an incident? Is a pandemic considered? • What kind of incident management is implemented? • Has the company considered external resources (e.g. lawyer)? • Who is responsible for communication with customers, press/media and authorities? • Is a list of important telephone numbers available? • Who is informed when a crisis occurs? • When are media involved? <phone list>, <crisis management procedures>, <incident management procedures>, <emergency plan>, <alarm plan
	Additional Information *In regard to the management of incidents, the company should consider the impact for consumers, customers, and the impact on the relationship with other stakeholders, such as reputation, confidence gained, corporate image, and business continuity.*	

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5.9.2	The procedure shall be subject to internal testing for recall/withdrawal, by covering the end-to-end process, at least once within a 12-month period and its execution shall not exceed 15 months. The outcome of the test shall be reviewed for continuous improvement.	• Is the procedure tested? • When was the last test? • Is the frequency of testing the procedure being followed? • Was the result of test positive/improvement was implemented?
5.10	**Management of non-conforming products**	
5.10.1	A procedure shall be documented, implemented and maintained for the management of all non-conforming raw materials, semi-finished products, finished products, processing equipment and packaging materials. This shall include at a minimum: • defined responsibilities, • isolation/quarantine procedures, • risk assessment, • identification including labelling, • decision about the further usage like release, rework/reprocessing, blocking, quarantine, rejection/disposal.	• What procedures exist for the management of non-conforming products? • How are non-conforming products identified? • What rules exist for product quarantine procedures? <quarantine tickets>
5.10.2	The procedure for the management of non-conforming products shall be understood and applied by all relevant employees.	• Who is responsible for putting non-conforming products into quarantine? • Who may release quarantined products? • How is it ensured that only authorized persons release quarantined products? <quarantine tickets>
5.10.3	Where non-conforming products are identified, immediate actions shall be taken to ensure that product safety and product quality requirements are complied with.	• What procedures are implemented with nonconforming products? • Who decides about non-conforming products? <quarantine tickets>

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5.10.4	Finished products (including packaging) that are out of specification shall not be placed on the market under the corresponding label unless a written approval of the brand owner is available.	• How are out of specification products destroyed? Are records of this available? • If the customer allowed the release of products out of specification, is there written evidence of this approval? For example, evidence can be provided to show that products have not been placed on the market (e.g. contracts with external waste destroying service providers) Exceptions can be checked with examples (situations which already occurred), by checking the content of the contract.
5.11	**Management of deviations, non-conformities, corrections and corrective actions**	
5.11.1	A procedure for the management of corrections and corrective actions shall be documented, implemented and maintained for the recording analysis and communication to the relevant persons of deviations and non-conformities and non-conforming products, with the objective to close the non-compliances and avoid recurrences by corrections and/or corrective actions. This shall include a root cause analysis at least for deviations and non-conformities related to safety, legality and/or recurrence of deviations and non-conformities.	Corrective actions already include a root cause analysis which must be documented. • What are corrective action procedures? <corrective actions procedures>
5.11.2*	**KO N° 6:** Corrective actions shall be formulated, documented and implemented as soon as possible to avoid further occurrence of deviations and non-conformity. The responsibilities and the timescales for corrective actions shall be defined. The documentation shall be securely stored and easily accessible.	• Which corrective actions were implemented? • Where are corrective actions documented? • Who is responsible for corrective actions? • How long may it take to implement corrective actions? <model corrective action procedures>
5.11.3	The effectiveness of the implemented corrections and corrective actions shall be assessed, and the results of the assessment documented.	• Where are corrective actions documented? • How are corrective actions verified? When? <model corrective action procedures>, <model with verified corrective action procedures>

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