IFS HPC

IFS HPC version 2

# Checklist for IFS Split Assessment Protocol

FEBRUARY 2021

ENGLISH

# PREFACE

**This checklist was structured as aditional assessment tool based on IFS Split Assessment Protocol, document and respective IFS HPC version 2 Standard, Doctrine and Guidelines. Assessments shall be performed according to refered documents.**

**Considerations and explanations to each requirement assessment technique:**

**on-site:**
Those requirements shall be evaluated fully on-site. This includes physical and documentation check.

**remote:**
Can be completely remote, (but it could be assessed physically too depending on the situation)

**on-site and remote:**
Part of the check of the requirement is carried out on-site, the associated document review can be done remotely

**”cross-check”:**
The auditor collects on-site information for random samples that are to be cross-checked in the remote part at the latest.

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| **1** | **Senior Management Responsibility** | |
| **1.1** | **Corporate policy/ Corporate principles** | |
| 1.1.1 | The senior management shall draw up and implement a corporate policy. The corporate policy shall include as a minimum reference to:<br>• customer and consumer focus,<br>• environmental responsibility,<br>• occupational health,<br>• buildings,<br>• machines and equipment,<br>• product requirements (includes: product safety, quality, legality, process and specification).<br>The corporate policy shall be communicated to all employees. | remote |
| 1.1.2 | The content of the corporate policy shall have been broken down into specific objectives for the relevant departments. The responsibility and the time scale for achievement shall be defined for each department of the company. | remote |
| 1.1.3 | From the corporate policy, the quality and product safety objectives shall be communicated to the employees in the respective departments and shall be effectively implemented. The company shall ensure that all relevant information is communicated effectively and in a timely manner to the relevant personnel. | on-site/remote (cross-check) |
| 1.1.4 | The senior management shall ensure that the achievement of all objectives is regularly reviewed, as a minimum the objectives shall be reviewed annually. | remote |
| **1.2** | **Corporate structure** | |
| 1.2.1 | An organization chart shall be available showing the structure of the company. | remote |
| 1.2.2 | Competences and responsibilities, including deputation of responsibility shall be clearly specified. | remote |
| **1.2.3 KO** | **The senior management shall ensure that employees are aware of their responsibilities relating to product safety and quality. Senior management shall also ensure that mechanisms are in place to monitor the effectiveness of the operation of the employees. Such mechanisms shall be clearly identified and documented.** | on-site/remote |
| 1.2.4 | Employees with influence on product requirements shall be aware of their responsibilities, through job descriptions, and shall be able to demonstrate understanding of their responsibilities. | on-site/remote |
| 1.2.5 | The company shall have an IFS representative nominated by senior management. | remote |
| 1.2.6 | The senior management shall provide sufficient and relevant resources to meet the product requirements. | on-site/remote |
| 1.2.7 | The department responsible for quality and product safety management shall have a direct reporting relationship to the senior management. | remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 1.2.8 | The company shall ensure that all processes (documented and undocumented) are known by the relevant personnel and are applied consistently. | on-site/remote |
| **1.3** | **Customer focus** | |
| 1.3.1 | A documented process shall be in place to identify fundamental needs and expectations of customers. | remote |
| 1.3.2 | The results of this process shall be evaluated and considered to determine quality and product safety objectives. | remote |
| **1.4** | **Management Review** | |
| 1.4.1 | Senior management shall ensure that the quality and product safety management systems are reviewed at least annually, or more regularly, if changes occur. Such reviews shall contain at least:<br>• results of audits,<br>• customer feedback,<br>• process compliance and product conformity,<br>• status of preventive and corrective actions,<br>• follow up actions from previous management reviews,<br>• changes that could affect the product safety and quality management system,<br>• complaints from Authorities,<br>• recommendations for improvement. | on-site/remote (cross-check) |
| 1.4.2 | This review shall include the evaluation of measures for the control of the quality and product safety management system and for the continuous improvement process. | remote |
| 1.4.3 | The company shall identify and review regularly (e.g. by internal audits or factory inspection) the infrastructure needed to achieve conformity to product requirements. This shall include, for example, the following items:<br>• buildings,<br>• supply systems,<br>• machines and equipment,<br>• laboratory equipment,<br>• transport.<br>The results of the review shall be considered, with due consideration to risk, for investment planning. | remote |
| 1.4.4 | The company shall identify and review regularly (e.g. by internal audits or factory inspection) the work environment needed to achieve conformity to product requirements. This shall include for example, the following criteria:<br>• staff facilities,<br>• environmental conditions,<br>• hygienic conditions,<br>• workplace design,<br>• external influences (e.g. noise, vibration).<br>The results of the review shall be considered, with due consideration to risk for investment planning. | remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| **2** | **Quality and Product Safety Management System** | |
| **2.1** | **Quality Management** | |
| **2.1.1** | **Documentation requirements** | |
| 2.1.1.1 | The quality and product safety management system shall be documented and implemented, and shall be retained in one location (it can be an electronic documented system). | on-site/remote (cross-check) |
| 2.1.1.2 | A documented procedure shall exist for the control of documents and their amendments. | on-site/remote (cross-check) |
| 2.1.1.3 | All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times. | on-site/remote (cross-check) |
| 2.1.1.4 | All documents which are necessary for compliance with the product requirements shall be available in their latest version. | on-site/remote (cross-check) |
| 2.1.1.5 | The reason for any amendments to documents, critical for the product requirements shall be recorded and approved. | on-site/remote (cross-check) |
| 2.1.1.6 | Documents shall be removed from the job area and destroyed if they are outdated. | on-site |
| **2.1.2** | **Record keeping** | |
| 2.1.2.1 | All relevant records necessary for the product requirements shall be completed, detailed and securely maintained (e.g. with backup system) and shall be available on request. | on-site/remote (cross-check) |
| 2.1.2.2 | Records shall be legible and genuine. They shall be maintained in a way that subsequent manipulation of records is prohibited. | on-site/remote (cross-check) |
| 2.1.2.3 | All records, including records showing the effective control of process, product safety and quality shall be kept in accordance with legal requirements and customer specifications (this includes, for instance and where relevant, the cosmetic product information file). These records shall be kept for a minimum of one year after the end of shelf life period. For products which have no shelf life, the duration of record keeping shall be in line with customers' requirements. | on-site/remote (cross-check) |
| 2.1.2.4 | Any amendments to records shall only be carried out by authorized persons. | on-site/remote (cross-check) |
| **2.2** | **Product Safety Management** | |
| **2.2.1** | **Risk management system (Hazard analysis and Risk assessment)** | |
| 2.2.1.1 | Before developing a risk management system, the company shall have implemented all necessary Good Manufacturing Practices (GMP's) which are commonly used in its scope of activity. | on-site |
| 2.2.1.2 | The basis of the company's product safety control system shall be a fully implemented, systematic and comprehensive risk management system. It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The risk management system shall be implemented at each production site.<br>The risk management system shall cover all raw material groups, products or product groups, as well as every process (included outsourced process) from goods receipt to product dispatch, including product development and product packaging. | on-site/remote |

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|---|---|---|
| 2.2.1.3 | The company shall ensure that the risk management system is based upon scientific literature, or technical verified specifications relating to the manufactured products and procedures.<br>The risk management system shall be maintained in line with any new technical and scientific process development. | on-site/remote (cross-check) |
| 2.2.1.4 | Risk management system shall be reviewed and necessary changes shall be made when any modification is made in the product, process or any change that could affect product requirements. | on-site/remote (cross-check) |
| **2.2.2** | **Risk management team** | |
| 2.2.2.1 | The risk management team shall be multidisciplinary and include operational staff. Personnel appointed as risk management team members shall have specific knowledge of hazards and risks associated to products and processes.<br>Where competent knowledge is not available, external expert advice shall be obtained. | remote |
| 2.2.2.2 | Those responsible for the development and maintenance of risk management system shall have received adequate training in the application of the risk management principles based on the risk management tool (Risk matrix, FMEA, HACCP, RPN, etc.) which the company uses. | remote |
| 2.2.2.3 | The risk management team shall have senior management support and shall be well known and established within the company. | on-site/remote |
| **2.2.3** | **Hazard analysis and risk assessment** | |
| 2.2.3.1 | **Describe the product**<br>The assessment shall make reference to the full description of the product including all applicable relevant information on product safety and regulation such as:<br>• composition (raw materials, rework, reprocessing, etc.),<br>• physical, chemical and microbiological parameters,<br>• methods of treatment,<br>• packaging, labeling,<br>• durability (shelf life),<br>• conditions for storage,<br>• method of transport. | remote |
| 2.2.3.2 | **Identify intended use**<br>The intended use of the product shall be described in relation to the expected use of the product by the consumer, taking into account vulnerable groups of consumers. | remote |
| 2.2.3.3 | **Construct flow diagram**<br>A flow diagram shall exist for each product, product groups, raw material groups, etc., and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall be dated, and clearly identify each critical control point with the number assigned to it. In the event of any changes the flow diagram shall be revised. | remote |
| 2.2.3.4 | **On-site confirmation of the flow diagram**<br>The risk management team shall review the processes at all operation stages against the flow diagram. Where relevant, amendments of the diagram will be made. | remote |

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|---|---|---|
| **2.2.3.5** | **Conduct a hazard analysis and risk assessment for each step** | |
| 2.2.3.5.1 | A hazard analysis shall be available for all physical, chemical and biological hazards that may be reasonably expected.<br>A hazard analysis and a risk assessment shall be conducted for each step from raw materials to the finished products including development and packaging material validation. | on-site/remote (cross-check) |
| 2.2.3.5.2 | Based on the hazard analysis, the risk assessment shall demonstrate the actions required if a hazard is a risk, taking into account the probability of harm to the consumer and the severity of damage (effect, potential consequences). The methodology for assessing risk shall be documented. | on-site/remote (cross-check) |
| 2.2.3.6 | **Determine critical control points:**<br>Based on level of acceptability of risk, critical control points shall be identified and documented. | remote |
| 2.2.3.7 | **Establish critical limits for each critical control point:**<br>For each critical control point, the appropriate critical limits shall be defined and validated in order to clearly identify when a process is out of control. | on-site/remote |
| **2.2.3.8**<br>**KO** | **Establish a monitoring system for each critical control point:**<br>**Specific monitoring procedures shall be established for each critical control point to detect any loss of control. Records of monitoring shall be maintained for a relevant period. Each defined critical control point shall be under control at all times. Monitoring and control of each critical control point shall be demonstrated by records. The records shall specify the person responsible, as well as the date and result of the monitoring activities.** | on-site/remote |
| 2.2.3.9 | **Establish corrective actions:**<br>For each critical control point, corrective actions shall be established. In case the monitoring indicates that a particular critical control point is not under control, adequate corrective actions shall be taken and documented.<br>Such corrective actions shall also take into account any non-conforming products. | on-site/remote |
| 2.2.3.10 | **Establish verification procedures:**<br>Procedures of verification shall be established to confirm that the risk management system is effective.<br>Verification of the risk management system shall be performed at least once a year. Examples of verification activities include:<br>• internal audits,<br>• analyses,<br>• sampling,<br>• evaluations,<br>• complaints by authorities and customers.<br>The results of this verification shall be incorporated into the risk management system. | remote |
| **3** | **Resource Management** | |
| **3.1** | **Human resources management** | |
| 3.1.1 | All personnel performing work that affects product safety, legality and quality shall have the required competence (demonstrated by education, work experience and/ or training) based on hazard analysis and assessment of associated risk. | on-site/remote |

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|---|---|---|
| **3.2** | **Personnel hygiene management** | |
| **3.2.1** | **Personnel hygiene** | |
| 3.2.1.1 | There shall be documented requirements relating to personnel hygiene. These include, as a minimum the following criteria:<br>• protective clothing,<br>• hand washing and disinfection,<br>• eating and drinking,<br>• smoking,<br>• actions to be taken in case of cuts or skin abrasions,<br>• fingernails, jewelry and personal belongings,<br>• hair and beards.<br>The requirements shall be based on hazard analysis and assessment of associated risk in relation to product and process. | on-site |
| 3.2.1.2 | The requirements for personnel hygiene shall be in place and applied by all relevant personnel, contractors and visitors. Compliance with the requirements shall be checked regularly. | on-site |
| 3.2.1.3 | Visible jewelry (incl. piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated based on hazard analysis and assessment of associated risk. | on-site |
| 3.2.1.4 | Cuts and skin abrasions shall be covered by a colored plaster/ bandage (different from the product color). Any exceptions shall have been comprehensively evaluated based on on hazard analysis and assessment of associated risk. | on-site |
| 3.2.1.5 | Based on hazard analysis and assessment of associated risk, there shall be a program to control effectiveness of hand hygiene. | on-site |
| 3.2.2 | Protective clothing for personnel, contractors and visitors | |
| 3.2.2.1 | Company procedures shall exist to ensure that all personnel, contractors and visitors are aware of the rules regarding the management of wearing and changing protective clothing in specified areas in accordance with product requirements. | on-site |
| 3.2.2.2 | In work areas where wearing headgear and/or beard snood (covering) is required, the hair shall be covered completely, so that product contamination is prevented. | on-site |
| 3.2.2.3 | Clearly defined usage rules shall exist for work areas/ activities where it is required to wear gloves (colored differently from the product color). Compliance with these rules shall be checked on a regular basis. | on-site |
| 3.2.2.4 | Suitable protective clothing and devices to ensure personnel safety shall be available in sufficient quantity for each employee, when required. | on-site |
| 3.2.2.5 | When required, all protective clothing shall be thoroughly and regularly laundered. Based on hazard analysis and assessment of associated risk, taking into consideration the processes and products, the company shall determine if clothing shall be washed by a contract laundry, on-site laundry or by the employee. | on-site |
| 3.2.2.6 | Guidelines shall exist for laundering of protective clothing and a procedure shall be in place for checking its cleanliness, when required. | on-site |

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|---|---|---|
| 3.2.2.7 | The company shall review that implemented preventive measures to ensure personnel safety related to hazardous working conditions are effective. | on-site |
| **3.2.3** | **Procedures applicable to infectious diseases** | |
| 3.2.3.1 | There shall be written and communicated measures for personnel, contractors and visitors in case of any infectious disease which may have an impact on product safety. In case of declaration of infectious disease, actions shall be taken in order to minimize risk of contamination of products. | on-site |
| **3.3** | **Training and instruction** | |
| 3.3.1 | The company shall implement documented training and/or instruction programs with respect to the product requirements and the training needs of the employees based on their job which shall include:<br>• training contents,<br>• training frequency,<br>• employee's task,<br>• languages,<br>• qualified trainer/tutor,<br>• evaluation methodology. | remote |
| 3.3.2 | The documented training and/or instruction programs shall apply to all personnel, including temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained in accordance with the documented training /instruction programs. | on-site/remote (cross-check) |
| 3.3.3 | Records shall be available of all training/instruction events, stating:<br>• list of participants (this shall include their signature),<br>• date,<br>• duration,<br>• contents of training,<br>• name of trainer/tutor.<br>There shall be a procedure or program in place to prove the effectiveness of the training and/or instruction programs. | on-site/remote (cross-check) |
| 3.3.4 | The contents of training and/or instruction shall be reviewed and updated regularly and take into account company's specific issues, product safety, product related legal requirements and product/process modifications. | remote |
| **3.4** | **Staff facilities, sanitary facilities and equipment for personnel hygiene** | |
| 3.4.1 | The company shall provide staff facilities, which shall be proportional in size, equipped for the number of personnel and designed and operated so as to minimize product safety risk. Such facilities shall be kept clean and in good condition. | on-site |
| 3.4.2 | There shall be in place rules and facilities to ensure the correct management for personnel belongings and food and other materials brought to work by personnel and shall include, food from dining room and from vending machines. The food and other materials shall only be stored and/or consumed in designated areas. | on-site |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 3.4.3 | The company shall provide suitable changing rooms for personnel, contractors and visitors. Where necessary, outdoor clothing and protective clothing shall be stored separately. | on-site |
| 3.4.4 | Changing rooms shall be separated from production area and shall be sited so that they allow direct access to the areas where products are handled.<br>Based on hazard analysis and assessment of associated risk, exceptions shall be justified and managed. | on-site |
| 3.4.5 | Toilets shall not have direct access to an area where products are handled. The sanitary facilities shall be equipped with adequate hand washing facilities. Sanitary facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided. | on-site |
| 3.4.6 | Adequate hand hygiene facilities shall be provided near points of entry to and within production areas, as well as at staff facilities. Based on hazard analysis and assessment of associated risk, further areas shall be similarly equipped. | on-site |
| 3.4.7 | Hand washing facilities shall provide as a minimum:<br>• water,<br>• liquid soap,<br>• appropriate equipment for hand drying. | on-site |
| 3.4.8 | If necessary, following additional requirements regarding hand hygiene shall also be provided:<br>• hand contact-free fittings,<br>• hand disinfection,<br>• adequate hygiene equipment,<br>• signage highlighting hand hygiene requirements,<br>• waste container with hand contact free opening. | on-site |
| **4** | **Planning and production process** | |
| **4.1** | **Contract agreement** | |
| 4.1.1 | The requirements which are defined in the contract with the customer shall be established, agreed upon and reviewed concerning their acceptability before a supply agreement is concluded. All clauses related to quality and product safety shall be known and communicated to each relevant department. | remote |
| 4.1.2 | Changes of existing contractual agreements shall be documented, communicated and updated between the contract partners. | remote |
| **4.2** | **Specifications and formulas** | |
| **4.2.1** | **Raw Materials (including packaging materials), semi-finished products and rework specifications** | |
| 4.2.1.1 | Specifications shall be available and in place for all raw materials (raw materials/ingredients, additives, packaging materials, rework) and where relevant, for semi-finished product. The specifications shall be up to date, unambiguous, available and always in conformance with legal requirements. | on-site/remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 4.2.1.2 | Identification of raw materials including packaging materials shall contain the following information:<br>• name of the product,<br>• unique identification code,<br>• date or number of receipt (if relevant),<br>• supplier´s name,<br>• expiry date, if existing,<br>• batch reference given by the supplier and the one given at receipt, if different. | on-site/remote |
| 4.2.1.3 | A reevaluation of the suitability of raw materials shall be in place, in cases where raw materials are close to the best before date, or when they are returned to storage or other relevant parameters given by the supplier. | remote |
| 4.2.1.4 | When raw materials including packaging materials are repacked, the new label shall contain the relevant information as on the original label. | on-site/remote |
| 4.2.1.5 | Where relevant, raw material specifications identifying allergens requiring declaration shall be available. The company shall maintain a continuously up to date listing of all raw materials containing allergens used at its premises, which also identifies all blends and formulas to which such raw materials containing allergens are added. | remote |
| 4.2.2 | Finished product specifications | |
| 4.2.2.1 | Specifications shall be available for all final products and shall be agreed upon in writing with customers. The specifications shall be up to date, traceable, unambiguous, available to relevant personnel and always in conformance with legal and customer requirements. | remote |
| **4.2.2.2 KO** | **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.** | on-site/remote |
| 4.2.2.3 | Where customers specifically require that products are "free from" certain substances or ingredients, or that certain methods of treatment or production are excluded, verifiable procedures shall be in place. | on-site/remote (cross-check) |
| 4.2.2.4 | There shall be a procedure for the creation, the modification and approval of specifications for all parts of the process, which shall include the preliminary acceptance of the customer, if specifications have been agreed with customers. | remote |
| 4.2.2.5 | The specification control procedure shall include the update of finished product specification in case of any modification requested by the customer and/ or defined by the company, related to:<br>• raw material,<br>• formula/ recipe,<br>• process with influence on the final product,<br>• packaging with influence on the final product. | remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| **4.3** | **Legislative framework and R&D process** | |
| **4.3.1** | **Legislative framework** | |
| 4.3.1.1 | The company shall comply with the current applicable legislation and shall be able to demonstrate its own role in the supply chain. | remote |
| 4.3.1.2 | The company shall have a system in place to ensure that it is kept informed of all relevant legislation on product safety and quality issues, scientific and technical developments and industry codes of practice. Legislation shall be understood and applied. | remote |
| 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. | on-site/remote |
| 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. | remote |
| 4.3.1.5 | In accordance with the current legislation, the company shall mandate a qualified safety assessor to consider the general toxicological profile of the ingredients, their chemical structure and exposure level, and finally provide the company with a safety assessment of the finished product regarding human health. | remote |
| 4.3.1.6 | A process shall be in place to ensure that labelling complies with current legislation of destination country and customer requirements. | on-site/remote |
| 4.3.1.7 | The conformity of the product with its labeling shall be reviewed each time before a new label is issued for use. Such review shall take into account the product requirements and particular relevant legislation in the destination countries. | on-site/remote |
| **4.3.2** | **R & D process** | |
| 4.3.2.1 | The company shall have an implemented procedure for R&D that takes into account risks and patents and that demonstrates that all existing and new products are designed to meet legal requirements. | remote |
| 4.3.2.2 | The progress and the results of R&D shall be properly recorded. | remote |
| 4.3.2.3 | Without the authorization from the patent holder, the company shall not use raw materials, or composition and shall not process finished products that are already patented. | on-site/remote |
| 4.3.2.4 | Product formulation, manufacturing processes and the fulfilment of product requirements shall have been ensured by factory trials, performance tests, stability tests, organoleptic assessments where relevant and product testing. | on-site/remote |
| 4.3.2.5 | Where relevant, shelf life tests shall be carried out taking into account product formulation, packaging, manufacturing and storage conditions. The shelf life (e.g. best before date) of the labeled goods shall be calculated accordingly, from the original production date. Where relevant, for products with shelf lives, tests shall be done at the end of the product shelf life on retained samples. | on-site/remote |
| 4.3.2.6 | Where specific R&D tests are needed, equipment shall be available and pertinent (such as dosages for regulated ingredients, preservatives, biocides etc.). In case tests are not performed on-site, results of these external tests shall be available. | on-site/remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 4.3.2.7 | Claims shall be supported by scientific evidence (e.g. sun screen formulations, detergents, etc.) in order to ensure that the product meet the stated claim. | on-site/remote |
| 4.3.2.8 | Where relevant, pilot equipment(s) shall be available and used in order to warranty good formulation´s industrialization. | on-site |
| 4.3.2.9 | The consumer packaging shall be designed and labelled to prevent non intended use in order to protect the safety of the potential user. The risk assessment shall address this topic. | on-site/remote |
| 4.3.2.10 | If required by law and based on hazard analysis and assessment of associated risk, the company shall verify the capability of the packaging material for each relevant product (e.g. organoleptic tests, storage tests, chemical analysis). | on-site/remote |
| **4.4** | **Purchasing** | |
| 4.4.1 | The company shall control purchasing processes to ensure that all externally sourced materials (raw materials, including packaging materials) and services, which have an impact on product safety and quality, comply with requirements. Where a company chooses to outsource any process that may have an impact on product safety and quality, the company shall ensure control over such processes and fulfill requirements ref. 4.4.8 | remote |
| 4.4.2 | Purchased products and services shall conform to current specifications and contractual agreements. | on-site/remote |
| 4.4.3 | The schedule of these checks shall take into account the product requirements, supplier status and the impact of raw materials on the finished product. | remote |
| 4.4.4 | There shall be a procedure for approval and monitoring of suppliers (internal and external), outsourced production and sub-processes. In case of any kind of outsourced production, the customer shall always be informed. | remote |
| 4.4.5 | The approval and monitoring procedure shall contain clear assessment criteria such as: audits, certificates of analysis, supplier reliability and complaints, as well as required performance standards based on hazard analysis and assessment of associated risk. | remote |
| 4.4.6 | The results of supplier´s assessment shall be reviewed regularly. There shall be records of the reviews and of the actions taken as a consequence of assessment. | remote |
| 4.4.7 | There shall be records to identify which raw material including packaging and semi-finished products are sourced from each supplier. | on-site/remote |
| 4.4.8 | Outsourced production (if applicable) | |
| 4.4.8.1 | Control of outsourced processes shall be identified, risk assessed and documented within the product safety and quality management system. | remote |
| 4.4.8.2 | A contract shall exist between the company and its subcontractor. | remote |
| 4.4.8.3 | Based on hazard analysis and assessment of associated risk, the company shall regularly audit the subcontractor, by using an audit checklist covering IFS HPC requirements (including e.g. relevant documented risk management system, control plan, traceability system, crisis management, etc.). Documents of such checks shall be available. | remote |

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|---|---|---|
| 4.4.8.4 | The checks performed at the subcontractor shall be performed by a qualified auditor/ inspector. | remote |
| 4.4.8.5 | If relevant, the company shall check the products on receipt from its subcontractor. | on-site/remote |
| **4.5** | **Factory location** | |
| **4.5.1** | **Site security** | |
| 4.5.1.1 | Senior management shall ensure that hazards related to site security (fire, explosions, electrical devices, flooding) are identified and preventive measures are managed. | on-site |
| 4.5.1.2 | The production and storage areas of the site shall be secured effectively by controlled access in order to prevent unauthorized entry. | on-site |
| **4.5.2** | **Factory exterior** | |
| 4.5.2.1 | The company shall investigate to what extent the factory environment (e.g. ground, air) may have an adverse impact on product safety and product quality.<br>In each case, appropriate measures shall be established. The effectiveness of the established measures shall be periodically reviewed (examples: extremely dusty air, strong smells). | on-site |
| 4.5.2.2 | The factory exterior shall be sustainable maintained, clean and tidy. The external condition of the premises shall be considered within the internal audit process. | on-site |
| 4.5.2.3 | All grounds within the site shall be in good condition. Where natural drainage is inadequate, a suitable drainage equipment shall be installed. | on-site |
| **4.5.3** | **Plant layout and process flow** | |
| 4.5.3.1 | Plans clearly describing internal flows of finished products, raw materials including packaging materials, waste, personnel, water, etc. shall be in place. A site map covering all buildings of the facility shall be available. | on-site |
| 4.5.3.2 | The process flow, from receipt of goods to dispatch, shall be organized so that a contamination of raw materials including packaging materials, semi-processed, rework and finished products is avoided. The risk of cross-contamination shall be minimized through effective measures. | on-site |
| 4.5.3.3 | Where relevant, products shall not be produced, stored and filled on the same equipment as products with another intended use, unless evidence is available that there is no negative effect on the products. | on-site |
| 4.5.3.4 | If production areas are identified as microbiologically sensitive (e.g. clean room technology), a positive air pressure equipment shall be installed. Assessment of the level of the microorganisms shall be performed at risk based intervals. | on-site |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| **4.5.4** | **Buildings and facilities** | |
| **4.5.4.1** | **Building and internal structures** | |
| 4.5.4.1.1 | All buildings used in the manufacture or storage of products shall be designed and constructed in order to allow unobstructed installation, ease of maintenance, efficient pest control and easy cleaning of the equipment, as well as compliance with all relevant legislation. | on-site |
| 4.5.4.1.2 | Rooms where the products are prepared, treated, processed and stored shall be designed and constructed, so that product compliance and product safety is ensured. | on-site |
| 4.5.4.1.3 | Walls shall be constructed to prevent the accumulation of dirt, to reduce condensation and mold growth, and to facilitate cleaning. | on-site |
| 4.5.4.1.4 | Floors shall be in good condition and shall be designed to meet production requirements (e.g. mechanical loads, cleaning materials, etc.) and to facilitate cleaning and disinfection, where required. | on-site |
| 4.5.4.1.5 | Ceilings (or, where no ceilings are fitted, the undersides of roofs) and overhead fixtures (incl. piping, cables, lamps) shall be suitable for the process and shall be designed and constructed to minimize the accumulation of dirt, the detachment of paints or other coating materials, condensation and mold growth. Ceilings and overheads shall be designed to facilitate cleaning and prevent product contamination. | on-site |
| 4.5.4.1.6 | Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in good condition. | on-site |
| 4.5.4.1.7 | Doors and gates shall be in good condition and easy to clean. | on-site |
| 4.5.4.1.8 | Drainage equipment shall be designed to facilitate cleaning and to minimize the risk of product contamination (e.g. adverse impact, ingress of pests, environment impact etc.). The hygienic disposal of waste water shall be ensured. | on-site |
| 4.5.4.1.9 | Where relevant, for laboratories:<br>• location of laboratories at the factory shall not affect product safety<br>• microbiological laboratory shall be physically separated from chemical laboratory<br>• suitable equipment and environment shall be available for all tests performed. | on-site |
| **4.5.4.2** | **Lighting, air conditioning/ventilation** | |
| 4.5.4.2.1 | All working areas shall have adequate lighting. | on-site |
| 4.5.4.2.2 | Based on hazard analysis and assessment of associated risk, all lightning equipment and electric fly killer units shall be protected.<br>The factory areas where this clause shall apply:<br>• handling of unpackaged products,<br>• storage of raw materials, including packaging materials,<br>• handling of raw materials,<br>• changing rooms.<br>This does not preclude that other areas cannot have protected lighting equipment or electric fly killer units. | on-site/remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 4.5.4.2.3 | Adequate natural and/or artificial ventilation shall exist in all areas. | on-site |
| 4.5.4.2.4 | If ventilation equipment is installed, filters and other components which require cleaning or replacement shall be easily accessible. | on-site |
| 4.5.4.2.5 | The use of air in the production (e.g. compressed air supply) shall avoid contamination and be based on hazard analysis and assessment of associated risk. | on-site |
| 4.5.4.2.6 | Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated. | on-site |
| **4.5.4.3** | **Water quality** | |
| 4.5.4.3.1 | All process waters (including water used as an ingredient) shall be tested regularly for compliance with chemical, physical and microbiological specifications. Special attention shall be paid after periods of no water consumption (e.g. after a weekend or holiday period). The risk assessment shall address this topic.<br>The company shall demonstrate the effectiveness of its water treatment and usage. | on-site |
| 4.5.4.3.2 | A water monitoring program (especially in the case of cold mixing operations) shall verify that the water treatment is adequate and effective on a risk based plan. | on-site |
| 4.5.4.3.3 | Recycled water which is used in the process shall not pose a contamination risk. The water shall comply with applicable legal requirements for potable water; records of compliance testing shall be available. | on-site |
| **4.6** | **Cleaning and disinfection** | |
| 4.6.1 | Based on hazard analysis and assessment of associated risk, cleaning and disinfection schedules shall be available and implemented. These shall specify:<br>• objectives,<br>• responsibilities,<br>• the products used and their instructions for use,<br>• the areas to be cleaned and/or disinfected,<br>• cleaning frequency,<br>• documentation requirements,<br>• hazard symbols (if necessary).<br>These schedules shall be documented. | on-site/remote |
| 4.6.2 | Where relevant, only qualified personnel shall be allowed to undertake cleaning and disinfection.<br>The personnel shall be trained and retrained to carry out the cleaning schedules. | on-site/remote |
| 4.6.3 | Based on hazard analysis and assessment of associated risk, the effectiveness and safety of the cleaning and disinfection measures shall be verified, validated for equipment and documented according to a sampling schedule by using appropriate procedures. Resultant corrective actions shall be documented. | on-site/remote |
| 4.6.4 | Cleaning and disinfection measures shall be validated according to any changing circumstances (e.g. construction work, new products, new machines, changes of climate etc.). Where necessary, the cleaning and disinfection schedules shall be adapted. | on-site/remote (cross-check) |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 4.6.5 | Current safety data sheets (SDS) and instructions for use shall be always available on-site for chemicals and cleaning agents. Personnel responsible for cleaning shall be able to demonstrate their knowledge of such instructions. | on-site |
| 4.6.6 | Cleaning utensils and chemicals shall be clearly identified, used and stored appropriately, to avoid contamination or unintended use. | on-site |
| 4.6.7 | The cleaning of production tools shall, if relevant, be carried out at specific locations or specific time periods separated from the production process. If this is not possible, these operations shall be controlled as to not affect the product safety and quality. | on-site |
| 4.6.8 | Where a company hires a third-party service provider for cleaning and disinfection activities, all requirements specified within section 4.6 shall be clearly defined in the respective contract. | on-site/remote (cross-check) |
| **4.7** | **Waste Disposal** | |
| 4.7.1 | A waste management procedure shall exist and shall be implemented to avoid cross contamination. | on-site |
| 4.7.2 | All current legal requirements for waste disposal shall be met. | on-site |
| 4.7.3 | Waste collection containers and, where existing, compactors shall be clearly marked, suitably designed, in good state of repair, easy to clean, and disinfected where necessary. | on-site |
| 4.7.4 | Waste shall be collected in separate containers in accordance with the intended means of disposal. Such waste shall be disposed by authorized third parties only. Records of waste disposal shall be kept by the company.<br>Whenever possible, destruction of waste shall be intended to avoid re-use of unfit products. | on-site/remote (cross-check) |
| **4.8** | **Risk of foreign materials** | |
| 4.8.1 | Based on hazard analysis and assessment of associated risk, procedures shall be in place to avoid contamination with foreign material. | on-site |
| 4.8.2 | In all areas, i.e. handling of raw materials including packaging materials, processing and storage, where risk assessment has identified the potential for product contamination, the use of wood shall be excluded. Where the use of wood cannot be avoided, the risk shall be controlled. | on-site |
| 4.8.3 | Where metal and/or other foreign material detectors are required, they shall be installed to ensure efficiency of detection, in order to avoid subsequent contamination. | on-site |
| 4.8.4 | The accuracy of detectors shall be specified. Checks of proper function of detectors shall be carried out regularly. In case of malfunction or failure of foreign material detector, corrective actions shall be defined, implemented and documented. | on-site |
| 4.8.5 | Potentially contaminated products shall be isolated. Access and actions for further handling or checking for these isolated products shall be carried out only by authorized personnel according to defined procedures. If product's contamination is confirmed, those shall be treated as non-conforming products. | on-site |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 4.8.6 | A glass and brittle material management shall be implemented, taking into account preventive and corrective measures; the system shall include reference to procedures in the event of glass or brittle material breakage.<br>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. | on-site/remote |
| **4.9** | **Pest Monitoring/Pest Control** | |
| 4.9.1 | The company shall have a pest control system in place which is in compliance with local legal requirements, and as a minimum shall cover the following criteria:<br>• the factory environment (potential pests),<br>• site plan with area for application (bait map),<br>• identification of the baits on-site,<br>• responsibilities (in-house/external),<br>• used products/agents and their instructions for use and safety,<br>• the frequency of inspections.<br>The pest control system shall be based on hazard analysis and assessment of associated risk. | on-site/remote |
| 4.9.2 | The company shall have qualified and trained in-house staff and/ or employ the services of a qualified external provider.<br>Where an external provider is used, the activities required on-site shall be specified in a written contract. | on-site/remote |
| 4.9.3 | Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded. | on-site/remote |
| 4.9.4 | Baits, traps and insect exterminators shall be functioning, in sufficient number and placed in an appropriate position. They shall be constructed and positioned as not to cause any contamination. | on-site/remote |
| 4.9.5 | Incoming deliveries shall be checked on receipt for the presence of pests. Any infestation shall be documented and control measures taken. | on-site/remote |
| 4.9.6 | If windows pose a risk of a source of contamination such as the ingress of pests, windows and roof glazing shall remain closed and sealed during production.<br>If they are designed to be opened for ventilation purposes, they shall be sealed by easy removable pest screens or other measures in order to avoid any contamination. | on-site/remote |
| 4.9.7 | Based on hazard analysis and assessment of associated risk, external doors and gates shall be designed to prevent the ingress of pests; if possible, they shall be self-closing. | on-site/remote |
| **4.10** | **Receipt of goods and storage** | |
| 4.10.1 | All incoming goods, including packaging materials, shall be identified and checked for conformity against specifications/other legally required documentation and to a determined control plan. The control plan shall be risk based. Test results shall be documented. | on-site |
| 4.10.2 | The storage conditions and locations of raw materials including packaging materials, semi-processed and finished products as well as working materials shall in each case correspond to product requirements, shall not be detrimental to other products and shall minimize cross contamination. | on-site |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 4.10.3 | Where relevant, for semi-finished products, maximum duration for storage shall be defined. When this duration is reached, the semi-finished product shall be re-evaluated before use. | on-site |
| 4.10.4 | Outdoor storage shall be kept to a minimum. Where goods are stored outside, hazard analysis and assessment of associated risk shall be undertaken in order to ensure that there is no risk of contamination or adverse effect on quality and product safety. | on-site |
| 4.10.5 | When relevant, sampling of raw materials and of bulk product shall be performed in an appropriate manner and by authorized personnel. | on-site |
| 4.10.6 | Products shall be clearly identified on receipt and when stored. Use of products shall be undertaken in accordance with the principles of First In/First Out and/or First Expired/First Out, in accordance with relevant industry best practices. | on-site |
| 4.10.7 | Periodic inventory shall be performed to ensure stock reliability. Any significant discrepancy shall be investigated and corrective action taken. | on-site |
| 4.10.8 | Where a company hires a third-party storage service provider, the service provider shall be subject to IFS Logistics requirements. If the third party service provider is not certified to IFS Logistics, all relevant requirements equivalent to the company's own warehousing practices shall be fulfilled and this shall be clearly defined in the respective contract. | on-site/remote (cross-check) |
| **4.11** | **Transport** | |
| 4.11.1 | Before loading transport vehicles, their condition (e.g. absence of strange smells, high dust load, adverse humidity, absence of contamination, pests, mold) shall be checked and actions taken, if necessary. At the raw materials and packaging materials receipt, checks shall be made in order to assess that transportation has taken place under in good conditions. | on-site |
| 4.11.2 | In case of transport of dangerous goods, the company shall ensure that all the relevant legislative requirements are fulfilled. | on-site/remote |
| 4.11.3 | Adequate hygienic requirements for all transport vehicles and equipment used for loading / unloading (e.g. hoses of silo installations) shall exist. There shall be records of the actions taken. | on-site |
| 4.11.4 | Where relevant, loading and unloading areas shall have equipment in place to protect transported products from external influences. | on-site |
| 4.11.5 | Security of transport vehicles shall be appropriately maintained. | on-site/remote |
| 4.11.6 | Where a company hires a third-party transport service provider all the requirements specified within section 4.11 shall be clearly defined in the respective contract or the service provider shall be subject to IFS Logistics requirements. | on-site/remote (cross-check) |
| **4.12** | **Maintenance and repair** | |
| 4.12.1 | An adequate system of maintenance shall be in place. This system shall be maintained and documented, covering all critical equipment (incl. transport) for compliance with product requirements. This applies both for internal and external maintenance activities. | on-site/remote |
| 4.12.2 | Product requirements and prevention of contamination shall be ensured during and after maintenance and repair work. Records of maintenance and repair work and of corrective actions taken shall be kept. | on-site/remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 4.12.3 | All materials used for maintenance and repair shall be fit for the intended use. | on-site/remote |
| 4.12.4 | Failures of plant and equipment (incl. transport) covered by the maintenance system shall be documented and reviewed so as to adapt the maintenance system accordingly. | on-site/remote |
| 4.12.5 | Temporary repairs shall be carried out so that product requirements are not affected. Such work shall be documented and a short-term deadline set for eliminating the fault. | on-site/remote (cross-check) |
| 4.12.6 | Where a company hires a third-party maintenance and repair service provider, all the company specified requirements regarding material and equipment shall be clearly defined, documented and maintained. | on-site/remote (cross-check) |
| **4.13** | **Equipment** | |
| 4.13.1 | Equipment shall be suitably designed and specified for the intended use. Before commissioning, it shall be verified that the product requirements are complied with.<br>Consumables used for equipment should not affect the quality of the product. | on-site |
| 4.13.2 | Equipment shall be designed and locationed so that cleaning and maintenance operations can be effectively performed. | on-site |
| **4.14** | **Traceability** | |
| 4.14.1 | A traceability system shall be in place which enables the identification of product lots and their relation to batches of raw materials, packaging in direct contact with product and packaging intended or expected to be in direct contact with product. The traceability system shall incorporate all relevant processing and distribution records. Traceability shall be assured and documented until delivery to the customer. | on-site/remote |
| 4.14.2 | Downstream and upstream traceability records (from production sites to the customers) shall be available. The timeframe for producing these records for review shall be compliant with customer's requirements. | on-site/remote |
| 4.14.3 | Traceability shall be in place to identify the relationship between batches of final products and their labels. | on-site/remote |
| 4.14.4 | The traceability system shall be tested on a periodic basis at least annually, and each time the traceability system changes.<br>The test shall verify downstream and upstream traceability (from raw materials to delivered products and vice versa), including quantity checking. Test results shall be recorded. | remote |
| 4.14.5 | Based on hazard analysis and assessment of associated risk, on legal requirements and on customer specifications, traceability shall be ensured at all stages, including work in progress, post treatment and rework. | on-site/remote |
| 4.14.6 | Where relevant, it shall be possible to identify at all times all major equipment used for the production of finished product (containers of raw materials and of semi-finished products, mixers, filling lines, etc.). | on-site/remote |
| 4.14.7 | Identified samples representative of the manufacturing batch shall be stored appropriately and kept until expiration date of the finished product and, if necessary, for a determined period beyond this date ("sample bank"). | on-site/remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| **5** | **Measurements, analyses, corrective actions and management of incidents** | |
| **5.1** | **Internal audits** | |
| 5.1.1 | Effective internal audits shall be conducted according to a defined agreed audit program and shall cover at least all requirements of the IFS HPC Standard. Scope and frequency of internal audits shall be determined by risk assessment. This is also applicable for off-site storage locations owned or rented by the company. | on-site/remote (cross-check) |
| 5.1.2 | Internal audits shall be carried out at least once a year in all departments. | remote |
| 5.1.3 | The auditors shall be competent and independent from the audited department. | remote |
| 5.1.4 | Audit results shall be communicated to the senior management and to responsible persons of concerned department. Necessary corrective actions and a schedule for implementation shall be determined, documented and communicated to every relevant person. | remote |
| 5.1.5 | It shall be documented, how and when the corrective actions resulting from the internal audits shall be verified. | remote |
| **5.2** | **Factory inspections** | |
| 5.2.1 | Regular factory inspections shall be planned and carried out to assess criteria such as product control, hygiene, foreign material hazards, personal hygiene, and housekeeping.<br>Any deviation and the associated corrective actions shall be documented. | on-site/remote (cross-check) |
| **5.3** | **Manufacturing process validation and control** | |
| 5.3.1 | The criteria for process validation and control shall be clearly defined. All processes critical to product safety and product compliance shall be validated. | on-site/remote (cross-check) |
| 5.3.2 | Processing operations shall be carried out in accordance with processing control documentation, and shall include:<br>-suitable equipment,<br>-composition of the product,<br>-list of all raw materials identified according to relevant documents indicating batch numbers and quantities,<br>-detailed processing operations for each stage, such as addition of raw materials, temperatures, mixing times, sampling and semi-finished product transfer.<br>Where applicable, a batch number shall be assigned. | on-site/remote |
| 5.3.3 | In circumstances where the control of process and working environment parameters (temperature, time, pressure, chemical properties etc.) is essential to ensure the product requirements are met, such parameters shall be monitored and recorded continuously and/or at appropriate intervals. | on-site/remote |
| 5.3.4 | The company shall ensure that in the event of changes to processing methods, equipment and product formulation (including rework and packaging material), process characteristics are reviewed in order to assure that product requirements are complied with. If relevant, customers shall be informed accordingly. | on-site/remote (cross-check) |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 5.3.5 | Where relevant, all rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements. | on-site/remote |
| 5.3.6 | There shall be appropriate procedures for prompt notification, recording and monitoring of equipment malfunction and process deviations. | on-site/remote |
| 5.3.7 | Process validation shall be performed using the collected data that is relevant for product safety and the processes.<br>If substantial modifications occur, a revalidation shall be carried out. | on-site/remote (cross-check) |
| **5.4** | **Calibration, adjustment and checking of measuring and monitoring devices** | |
| 5.4.1 | The company shall identify the measuring and monitoring devices required to ensure compliance with product requirements. These devices shall be listed and clearly identified. | on-site/remote |
| 5.4.2 | All measuring devices shall be checked, adjusted and calibrated, under a monitoring system, at specified intervals and in accordance with defined recognized standard/methods.<br>The results of these checks, adjustments and calibrations shall be documented. Where necessary, corrective actions on devices and on processes and products shall be carried out. | on-site/remote |
| 5.4.3 | All measuring devices shall be used exclusively for their defined purpose. | on-site/remote |
| 5.4.4 | The calibration status of the measuring devices shall be clearly identified (labelling on the device or on a list of tested devices). | on-site/remote |
| **5.5** | **Quantity checking (quantity control/ filling quantities)** | |
| 5.5.1 | The frequency and methodology of quantity checking shall be determined so that the legal requirements and customer specifications, or if relevant, guidelines for nominal quantity are met. | on-site/remote |
| 5.5.2 | A procedure shall exist to define compliance criteria for lot quantity checking. | on-site/remote |
| 5.5.3 | Checks shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing lot. | on-site/remote |
| 5.5.4 | Results of these checks shall be compliant with defined criteria for all products ready to be delivered. | on-site/remote |
| 5.5.5 | If relevant, all equipment used for final checking shall be legally approved. | on-site/remote |
| **5.6** | **Product analysis (including quality checks)** | |
| 5.6.1 | There shall be procedures ensuring that all specified product requirements are met, including legal requirements, performance and specifications. Results of microbiological, physical and chemical analysis required for that purpose shall be available. | on-site/remote |
| 5.6.2 | Analyses, which are relevant for product safety and legality, shall preferably be performed by laboratories having appropriate accredited programs/methods (ISO 17025). If the analyses are performed by a factory internal or a laboratory not having appropriate accredited programs/methods, the company shall be able to demonstrate that the results are reliable. | remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 5.6.3 | Documented evidence shall exist, which ensure the reliability of the internal analysis results, on the basis of official and non-official recognized analytical methods. | remote |
| 5.6.4 | A control plan shall be drawn up for internal and external analysis, based on hazard analysis and assessment of associated risk and based on additional information regarding product quality (e.g. complaints). This plan shall cover raw materials, semi-processed and finished products and shall include the types of tests, their frequency and critical limits, which are linked to the specification limits. The test results shall be documented. | on-site/remote (cross-check) |
| 5.6.5 | The analytical results shall be reviewed regularly and trends identified. Appropriate measures shall be introduced promptly for any unsatisfactory results, or where such trends indicate unsatisfactory results. | on-site/remote |
| 5.6.6 | Where internal analysis is undertaken, qualified and trained personnel shall be in place, as well as appropriate equipment and premises. | on-site/remote |
| 5.6.7 | Results of checks on finished products including rework material shall be reviewed by authorized personnel in order to verify the conformity of the finished and semi-finished products with the acceptance criteria. | on-site/remote |
| 5.6.8 | Where relevant, for verification of finished product quality, organoleptic tests shall be carried out regularly. These tests shall be in accordance with specifications and related to the impact on respective parameters of product characteristic. The results of these tests shall be documented. | on-site/remote |
| 5.6.9 | Based on any internal or external information on product risk which may have an impact on product safety and/ or quality, the company shall update its control plan and/ or take any appropriate measure to control the compliance of the finished products. | on-site/remote |
| **5.7** | **Product quarantine (blocking/ hold) and product release** | |
| 5.7.1 | A procedure shall be in place for the quarantine and release of all raw materials including packaging materials, semi-processed and finished products, and processing equipment. The procedure shall ensure that only products and materials conforming to product requirements are processed and dispatched. | on-site/remote |
| **5.8** | **Management of complaints from authorities and customers** | |
| 5.8.1 | A system shall be in place for the management of product complaints and, when relevant, shall take into account specific procedures (e.g. undesirable effects). | remote |
| 5.8.2 | All complaints shall be assessed by competent staff. Where it is justified, appropriate actions shall be taken immediately. | remote |
| 5.8.3 | Complaints shall be analyzed with a view to implementing preventive and corrective actions which avoid the recurrence of the non-conformity. | remote |
| 5.8.4 | The results of complaint data analysis shall be made available to the relevant responsible persons and to the senior management. | remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| **5.9** | **Management of incidents, product withdrawal and product recall** | |
| 5.9.1 | A documented procedure shall be defined for management of incidents and of potential emergency situations that impact product safety, legality and quality. This procedure shall be implemented and maintained. This includes as a minimum: the nomination and training of a crisis team, an alert contact list, sources of legal advice (if necessary), contacts availability, customer information, and a communication plan, including information to consumers. | remote |
| 5.9.2 | Updated emergency contact details (such as names and phone numbers of suppliers, customers and competent authorities) shall be available. A person of the company, who has the authority to initiate the incident management process, shall be permanently available. | remote |
| 5.9.3 | The company shall assign the responsibility (ies) for the external communication (crisis management, authorities and communication with media) to specific personnel. | remote |
| 5.9.4 | There shall be an effective procedure for the withdrawal and recall of all products, which ensures that involved customers are informed, as soon as possible. This procedure shall include a clear assignment of responsibilities. | remote |
| 5.9.5 | The feasibility, effectiveness and timeliness of implementation of the withdrawal procedure shall be subject to regular internal testing, based on hazard analysis and assessment of associated risk, but carried out at least once a year. This shall be carried out in a manner to ensure the effective implementation and operation of the procedure. | remote |
| **5.10** | **Management of non-conformities and non-conforming products** | |
| 5.10.1 | A procedure shall exist for the management of all non-conforming raw materials including packaging materials, semi-finished and finished products and processing equipment. This procedure shall include always the following criteria, but may include other requirements:<br>• isolation/ quarantine procedures,<br>• risk assessment,<br>• identification (e.g. labeling),<br>• decision about the further use (e.g. release, destruction, rework/post-treatment, blocking, customer information, rejection/ disposal). | on-site/remote |
| 5.10.2 | The responsibilities for the management of non-conforming products shall be clearly identified. The procedure for the management of non-conforming products shall be understood by all relevant employees. | on-site |
| 5.10.3 | Where non-conformities are present, immediate corrections shall be taken to ensure that product requirements are complied with. | on-site/remote |
| 5.10.4 | Out of specification finished goods or finished goods that do not meet other legal and/ or customer requirements are not allowed to be placed on the market. In case of private labels, exceptions shall be agreed in writing with the contract partners. | on-site/remote |
| **5.11** | **Corrective actions** | |
| 5.11.1 | A procedure shall be in place for the recording and analysis of the non-conformities with the objective to avoid recurrences by the provision of preventive actions and/or corrective actions. | remote |

| No. | IFS HPC version 2 Requirements | Assessment technique |
|---|---|---|
| 5.11.2 | Corrective actions shall be clearly formulated, documented and undertaken, as soon as possible to avoid further occurrence of non-conformity. The responsibilities and the timescales for corrective actions shall be clearly defined. The documentation shall be securely stored and easily accessible. | on-site/remote |
| 5.11.3 | The effectiveness of the implemented corrective actions shall be documented and shall be validated. | on-site/remote |
| **6** | **Product Defense (optional)** | |
| **6.1** | **Senior Management Responsibility** | |
| 6.1.1 | The company shall have a documented product defense procedure in place to address product defense risk from products and establish, implement and maintain a system to reduce or eliminate the identified risk. | on-site/remote |
| 6.1.2 | A product defense assessment shall be conducted annually or upon changes that affect product integrity. | on-site/remote |
| 6.1.3 | Responsibilities for product defense shall be clearly defined. Those responsible shall be key staff or shall have access to the senior management team. | on-site/remote |
| 6.1.4 | Senior management shall have an internal communication system to inform and update staff about relevant security issues. | on-site/remote |
| **6.2** | **Site security** | |
| 6.2.1 | Based on the product defense procedure and legal requirements, the senior management should define and communicate the areas in which authorized personnel are allowed to access. | on-site/remote |
| **6.3** | **Visitor and Personnel Security** | |
| 6.3.1 | Visitor policy shall contain requirements relating to product defense. | remote |
| 6.3.2 | Employee hiring and employment termination practices shall consider security aspects as permitted by law. | remote |
| 6.3.3 | The company shall incorporate product security awareness, including information on how to prevent, detect and respond to tampering or other malicious, criminal, or terrorist actions or threats, into training programs for staff, including temporary, contract, and volunteer staff.<br>The training shall regularly take place and shall be documented. | remote |
| **6.4** | **Documentation requested by legislation** | |
| 6.4.1 | If legislation makes registration or on-site inspections necessary, these shall be carried out and evidence shall be provided. | remote |
| 6.4.2 | A documented procedure shall be in place for managing external inspections and regulatory visits (if applicable). Relevant personnel shall be trained to execute the procedure. | remote |

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