IFS PACsecure

IFS PACsecure version 2 and version 3 Checklists Comparison

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ENGLISH

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IFS PACsecure v3 checklist compared with IFS PACsecure v2 checklist
Words/texts in "italics" correspond to new content and/or relevant modifications in wording.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
1	**Governance and commitment**	**1**	**Governance and commitment**
1.1	**Policy**	**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. The corporate policy shall be communicated to all employees.	1.1.1*	The senior management shall develop, implement and maintain a clear corporate policy, which shall include, at a minimum: • customer focus • product safety culture • product requirements • sustainability The corporate policy shall be communicated to all employees.
1.1.2	The corporate policy shall be broken down into ***specific*** objectives for the relevant departments with defined responsibilities and timelines. These shall be known and shall be effectively implemented. ***Objectives about product safety culture shall include, at a minimum, communication about product safety policies and responsibilities, training, employee feedback on product safety related issues and performance measurement.***	1.1.2	The corporate policy shall be broken down into measurable objectives, with responsibilities and timelines defined. These shall be known by the relevant departments/parts and shall be effectively implemented.
1.1.3	All relevant information related to product requirements shall be communicated effectively ***and in a timely manner*** to the relevant personnel.	1.1.3	All relevant information related to product requirements shall be communicated effectively to the relevant personnel promptly.
1.2	**Corporate structure**	**1.2**	**Corporate structure**
1.2.1*	**KO No. 1: The senior management shall ensure that employees are aware of their responsibilities related to *product requirements*, the product safety and quality management system and that mechanisms are *implemented and maintained* to monitor the effectiveness of their operation. *Such mechanisms shall be identified and documented.***	**1.2.2***	**KO No. 1: The senior management shall ensure that employees are aware of their responsibilities related to the product safety and quality management system and product requirements. Clearly identified and documented mechanisms shall be in place to monitor the effectiveness of their operation.**

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
1.2.2	The senior management shall provide sufficient and ***appropriate*** resources to meet the product and process requirements, including those related to the product safety and quality management system.	1.2.3	The senior management shall provide sufficient and relevant resources to meet the product and process requirements, including those related to the product safety and quality management system.
1.2.3*	The personnel responsible for product safety and quality management shall have a direct reporting relationship to the senior management. ***An up-to-date organisational chart showing the company structure*** shall be documented, ***maintained***, and known by the relevant personnel.	1.2.1*	The structure of the company, hierarchy, and job positions shall be available, documented, and shall be known by the relevant personnel. The personnel responsible for the product safety and quality management shall have a direct reporting relationship to the senior management.
1.2.4	The senior management shall ensure that all processes (documented and undocumented) are known by the relevant personnel (including new/permanent personnel and temporary/seasonal workers) and are applied consistently.	1.2.4	The senior management shall ensure that all processes (documented and undocumented) are known by the relevant personnel (including new/permanent personnel and temporary/seasonal workers), and are applied consistently.
1.2.5*	The senior management shall ***implement and maintain*** a system to ensure that the company is kept informed of all relevant legal and regulatory requirements, scientific and technical developments, industry codes of practice, product safety and ***product*** quality issues, and that they are aware of factors that can influence product defence and product fraud risks.	1.2.5*	The senior management shall have a system in place to ensure that the company is kept informed of all relevant legal and regulatory requirements, scientific and technical developments, industry codes of practice, product safety and quality issues, and that they are aware of factors that can influence product defence and product fraud risks.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
1.2.6*	The senior management shall ensure that the certification body is informed of any changes that may affect the company's ability to conform to the certification requirements. This shall include, at a minimum: • any legal entity name change • any production site location change. For the following specific situations: • any product recall • any product recall and/or withdrawals ***decided by authorities*** for product safety and/or product fraud reasons • any visit from authorities which results in ***mandatory action connected to product safety, and/or product fraud*** which is related to the IFS PACsecure Standard scope the certification body shall be informed within three (3) working days.	1.2.6*	The senior management shall ensure that the certification body is informed of any changes that may affect the company's ability to conform to the certification requirements. This shall include, at a minimum: • any legal entity name change, • any production site location change. For the following specific situations: • any product recall, • any product recall and/or withdrawals by official order for product safety and/or product fraud reasons, • any visit from health authorities which results in notifications and/or penalties issued by authorities, which are related to the IFS PACsecure Standard scope the certification body shall be informed within three (3) working days.
1.3	***DELETED***	**1.3**	**Customer focus**
	MOVED ***See v3, chapter 4.1, requirement 4.1.1***	1.3.1	A process shall be in place to identify the fundamental needs and expectations of customers. The feedback from this process shall be taken as input for the company's continuous improvement.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
1.3	**Management review**	**1.4**	**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 its execution shall not exceed 15 months***. Such reviews shall include, at a minimum: • a review of objectives and policies, including elements of product safety culture • results of audits and site inspections • positive and negative customer feedback, including customer audit results • process compliance • ***product fraud assessment outcome*** • ***product defence assessment outcome*** • ***compliance*** issues • status of corrections and corrective actions • notifications from authorities.	1.4.1*	The senior management shall ensure that the product safety and quality management system is reviewed at least annually, or more frequently if significant changes occur. Such reviews shall include, at a minimum: • a review of objectives and policies, including elements of product safety culture • results of audits and site inspections • positive and negative customer feedback, including customer audit results • process compliance and changes/ improvements • authenticity and conformity issues • status of corrections and corrective actions • notifications from authorities.
1.3.2	Actions from the management review shall be 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.	1.4.2	Actions resulting 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 changes that could affect the product safety and quality management system. The management review shall be fully documented.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
1.3.3	The senior management shall identify and review (e.g. by internal audits or on-site inspections) the infrastructure and work environment needed to ***ensure*** product requirement ***compliance at least once within a 12- month period, or whenever significant changes occur***. This shall include, at a minimum: • buildings • supply system • 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.	1.4.3	The senior management shall identify and regularly review (e.g. by internal audits or on-site inspection) the infrastructure and work environment needed to conform to product requirements. This shall include, at a minimum: • buildings • supply system • machines and equipment • transport • staff facilities • environmental conditions • hygienic conditions • workplace design • external influences (e.g. noise, vibration). The results of the review shall be considered, with due consideration to risk, for investment planning.
2	**Product safety and quality management system**	**2**	**Product safety and quality management system**
2.1	**Quality management**	**2.1**	**Quality management**
2.1.1	**Document management**	**2.1.1**	**Document management**
2.1.1.1	A procedure shall ***be documented, implemented and maintained to*** control documents and their amendments. All documents which are necessary for compliance with product requirements ***and customer requirements*** shall be available in their latest version. The reason for any amendments to documents, critical to ***those*** requirements, shall be approved by authorised personnel and recorded.	2.1.1.2*	A documented procedure shall exist for the control of documents and their amendments. All documents which are necessary for compliance with the product requirements shall be available in their latest version. The reason for any amendments to documents, critical to the product and process requirements, shall be approved by authorised personnel, and recorded.
2.1.1.2	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.	2.1.1.1	The product safety and quality management system shall be documented and implemented, and shall be kept in one secure location. This is applicable for physical and/or digital documentation systems.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
2.1.1.3*	All documents shall be legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times.	2.1.1.3	All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times.
2.1.2	**Records and documented information**	**2.1.2**	**Records and documented information**
2.1.2.1	Records and documented information shall be legible, ***properly*** completed, genuine, and available on request. They shall be easily accessible; maintained in a way that subsequent manipulation or amendment ***by unauthorised persons*** is prohibited; securely stored and protected from loss, intentional adulteration and/or misuse.	2.1.2.1	Records and documented information shall be complete, legible, genuine, and available on request. They shall be easily accessible; maintained in a way that subsequent manipulation or amendment is prohibited; securely stored and protected from loss, intentional adulteration and/or misuse.
2.1.2.2*	All records and documented information 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 converting time. For products which have no converting time, the duration of record and documented information keeping shall be justified and this justification shall be documented.	2.1.2.2*	All records and documented information shall be kept in accordance with legal requirements and customer requirements. If no such requirements exist, records and documented information shall be kept for a minimum of one year after the specified converting time. For products which have no specified converting time, the duration of record and documented information keeping shall be justified and this justification shall be documented.
2.1.2.3	***A system shall be implemented and maintained to ensure that only authorised personnel have access to create or amend records and documented information (e.g. password protection for records documented electronically).***	2.1.2.3	Any amendments to records shall only be carried out by authorised persons.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
2.2	**Product safety and quality management**	**2.2**	**Product safety and quality management**
2.2.1	***Hazard and risk management system***	**2.2.1**	**Hazard analysis and risk assessment system**
	DELETED ***In v3, the content was merged in chapters 5.1 and 5.2, in requirement 2.2.1.1 and in other requirements related to chapters 3 and 4.***	2.2.1.1	Before developing a hazard analysis and risk assessment system, the company shall assess the implementation of legal and regulatory requirements, good manufacturing practices (GMP's), and industry guidelines when applicable to its scope of activity and relevant for product requirements.
2.2.1.1*	The basis of the company's product safety and quality management system shall be a fully implemented, systematic and comprehensive ***hazard and risk management*** system, based on the Codex Alimentarius principles or other applicable ***internationally***-recognised industry guidelines. It shall take into account ***good manufacturing practices, good hygiene practices and*** any legal and regulatory requirements of the production and destination countries which may go beyond such principles or guidelines. The ***hazard and risk management*** system shall be specific and implemented at ***the*** production site.	2.2.1.2	The basis of the company's product safety and quality management system shall be a fully implemented, systematic, comprehensive and documented hazard analysis and risk assessment system, based upon the Codex Alimentarius principles or on other applicable and recognised industry guidelines. It shall take into account any legal and regulatory requirements of the production and destination countries which may go beyond such principles or guidelines. The hazard analysis and risk assessment system shall be specific and implemented at each production site.
2.2.1.2*	The ***hazard and risk management*** system shall cover all raw materials, ***product contact*** wrapping materials, products or product groups as well as every production/conversion process from incoming goods up to the dispatch of finished products, including product development.	2.2.1.3	The hazard analysis and risk assessment system shall cover all raw materials, wrapping materials, products or product groups as well as every production/conversion process (including outsourced process) from incoming goods up to the dispatch of finished products, including product development.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
2.2.1.3	The ***hazard and risk management*** system ***shall be*** based upon scientific literature, or technical verified information related to the manufactured products and processes, or expert advice obtained from other sources, which may include: trade and industry associations, independent experts and authorities. This information shall be maintained in line with any new technical process development.	2.2.1.4	The company shall ensure that the hazard analysis and risk assessment system is based upon scientific literature, or technical verified information related to the manufactured products and processes, or expert advice obtained from other sources, which may include: • trade and industry associations, • independent experts, • and regulatory authorities. This information shall be maintained in line with any new technical and scientific process development.
2.2.1.4	In the event of changes to raw materials, wrapping materials, production/conversion processes, formulas/configurations, infrastructure and/or equipment, the ***hazard and risk management*** system shall be reviewed to ***ensure*** that product requirements are complied with.	2.2.1.5	The hazard analysis and risk assessment system shall be regularly reviewed, at least annually, and/or in the event of changes to raw materials, wrapping materials, production/conversion process, formulas/configuration, products, infrastructure and/or equipment, to assure that product requirements are complied with.
2.3	**Application of a hazard and risk management system**		
2.3.1	**Assemble a *hazard and risk management* team**	**2.2.2**	**Hazard analysis and risk assessment team**
2.3.1.1	The ***hazard and risk management*** team shall be multidisciplinary and include operational staff. Personnel appointed as team members shall have ***appropriate*** knowledge of hazards and risks associated to products and processes.	2.2.2.1	**Assemble hazard analysis and risk assessment team** The hazard analysis and risk assessment team shall be multidisciplinary and include operational staff. Personnel appointed as hazard analysis and risk assessment team members shall have specific knowledge of hazards and risks associated to products and processes.
2.3.1.2	Those responsible for the development and maintenance of the ***hazard and risk management*** system shall have received ***appropriate*** training in the ***development and*** application of the ***hazard and risk management system.*** An internal team leader shall be designated.	2.2.2.2	Those responsible for the development and maintenance of the hazard analysis and risk assessment system shall have received adequate training in the application of the hazard analysis and risk assessment principles. An internal team leader shall be designated.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
	DELETED	2.2.3	**Hazard analysis and risk assessment**
2.3.2	**Product description**		
2.3.2.1	A full description of the product ***shall be documented and maintained and shall contain*** all relevant information on product requirements, ***which includes, at a minimum:*** • composition (raw materials, rework, reprocessing, recycled materials, plant-based materials, functional additives, etc.) • physical, sensory, chemical, functional and microbiological characteristics • legal requirements in regard to product safety and quality • ***processing*** methods/***technologies*** • wrapping and labelling • durability (converting time) • conditions for storage, method of transport and distribution.	2.2.3.1	**Describe product** A full description of the product including all applicable relevant information on product requirements shall exist, such as: • composition (raw materials, rework, reprocessing, recycled materials, plant based materials, functional additives, etc.) • physical, sensory, chemical, functional and microbiological characteristics • legal requirements in regard to product safety and quality • methods of treatments • wrapping and labelling • durability (converting time) • conditions for storage, method of transport and distribution.
2.3.3	**Identify intended use and users of the product**		
2.3.3.1	The intended use of the product shall be described in relation to the expected use of the product by the customer, and also by ***the end*** consumer when: • products are intended to be sold to ***the end*** consumer • there is no subsequent transformation process that changes the characteristics and/or intended use of the product after it is sold to the customer. When ***the end*** consumer shall be considered, possible misuse and vulnerable groups shall be taken into account.	2.2.3.2	**Identify intended use** The intended use of the product shall be described in relation to the expected use of the product by the customer, and also by consumers when: • Products are intended to be sold to consumers • There is no subsequent transformation process that changes the characteristics and/or intended use of the product after it is sold to the customers. When consumers shall be considered, possible misuse and vulnerable groups shall be taken into account.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
2.3.4	**Construct flow diagram**		
2.3.4.1	A flow diagram shall ***be documented and maintained*** for each product, or product group, and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall identify ***every step and each control measure defined for a CCP*** and other control measures. It shall be dated, and in the event of any change, shall be updated.	2.2.3.3	**Construct flow diagram** A flow diagram shall exist for each product, or product group, and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall be dated, and after the determination of control measures, clearly identify each CCP and other control measures. In the event of any changes, the flow diagram shall be updated.
2.3.5	**On-site confirmation of the flow diagram**		
2.3.5.1	***Representatives of*** the ***hazard and risk management*** team shall verify the flow diagram ***through*** on-site verifications, at all operation stages and shifts. Where appropriate, amendments to the diagram shall be made.	2.2.3.4	**On-site confirmation of the flow diagram** The hazard analysis and risk assessment team, or their defined representatives, shall verify the flow diagram by on-site verifications at all operation stages and shifts. Where appropriate, amendments to the diagram shall be made.
2.3.6	**Conduct a hazard analysis and risk assessment for each step**	**2.2.3.5**	**Conduct a hazard analysis and risk assessment for each step**
2.3.6.1	A hazard analysis and risk assessment shall be conducted for all possible and expected physical, chemical (including radiological and allergens) and biological hazards. The hazard analysis and risk assessment shall include hazards linked to the materials in contact with the product, wrapping materials, work environment, and any other risk related to the product requirements.	2.2.3.5.1	A hazard analysis and risk assessment shall be conducted for all possible and reasonably expected physical, chemical (including radiological and allergens) and biological hazards. The hazard analysis and risk assessment shall include the hazards linked to the materials in contact with the product, wrapping materials, work environment, and also any other relevant risk related to product requirements.
2.3.6.2	The hazard analysis and risk assessment shall consider the likelihood of ***the occurrence of hazards and risks and the severity of their*** adverse effects. Consideration shall be given to control measures ***designed and*** applied for controlling each ***significant*** hazard ***or*** risk identified.	2.2.3.5.2	The hazard analysis and risk assessment shall consider the likelihood of adverse effects for the consumer and the potential severity of these adverse effects. Consideration shall be given to specific control measures applied which are relevant for controlling each hazard and risk identified.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
2.3.7	**Determining critical control points (CCP) and other control measures**	**2.2.3.6**	**Determine Critical Control Points (CCP) and other control measures**
2.3.7.1	***Determining whether the step at which a control measure is applied is a CCP in the hazard and risk management system shall be facilitated by using*** a decision tree or other tool(s) which demonstrates a logical reasoned approach. The determination of CCP's shall be justified and documented.	2.2.3.6.1	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. The determination of relevant CCP's and other control measures shall be justified and documented.
2.3.8	**Establish *validated critical* limits for each CCP**	**2.2.3.7**	**Establish limits for each CCP and other control measures**
2.3.8.1*	For each CCP, ***measurable or observable*** critical limits shall be defined and validated to identify when a process is out of control. Validation of ***critical*** limits ***established*** for each CCP shall be documented.	2.2.3.7.1*	For each CCP, the appropriate critical limits shall be defined and validated to clearly identify when a process is out of control. Validation of limits defined for each CCP shall be documented.
2.3.8.2	For control measures, ***other than those defined for CCPs***, appropriate limits shall be ***established***.	2.2.3.7.2	For other control measures defined, appropriate limits shall be determined.
2.3.9	**Establish a monitoring system for each CCP**	**2.2.3.8**	**Establish a monitoring system for each CCP and other control measures**
2.3.9.1*	**KO No. 2: 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.**	**2.2.3.8.1***	**KO No. 2: Specific monitoring procedures in terms of method, frequency of measurement or observation, and recording of results, shall be established for each CCP to detect any loss of control at that CCP. Each defined CCP shall remain under control. Monitoring and control of each CCP shall be demonstrated by records. The operative personnel in charge of the monitoring of CCP's shall have received specific training/ instruction. Records of CCP monitoring shall be verified by a responsible person within the company and maintained for a relevant period.**

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
2.3.9.2	***Records of CCP monitoring shall be verified by a responsible person within the company and maintained.***		***ADDED*** ***Content extracted from v2, requirement 2.2.3.8.1***
2.3.9.3	***The operative personnel in charge of the monitoring of control measures defined for CCPs and other control measures shall have received specific training/instruction.***		***ADDED*** ***Content extracted from v2, requirement 2.2.3.8.1***
2.3.9.4	Control measures, other than ***those defined for*** CCPs, shall be monitored, recorded and controlled by measurable or observable criteria.	2.2.3.8.2	Control measure other than CCP shall be monitored, recorded and controlled by measurable or observable criteria. Records of monitoring shall be maintained for a relevant period. The operative personnel in charge of the monitoring of these control measures shall have received specific training/instruction.
2.3.10	**Establish corrective actions**	**2.2.3.9**	**Establish corrective actions**
2.3.10.1	In the event that the monitoring indicates that a particular ***control measure defined for a CCP or any other*** control measure related to product safety is not under control, corrective actions shall be documented ***and implemented***. Such corrective actions shall also take any action relating to non-conforming products ***into account*** and identify the root cause for the loss of control ***of CCPs***.	2.2.3.9.1	In the event that the monitoring indicates that a particular CCP or a control measure other than CCP related to product safety is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any action taken relating to non-conforming products and identify the root cause for the loss of control.
2.3.11	***Validate the hazard and risk management system and*** **establish verification procedures**	**2.2.3.10**	**Establish verification procedures**
2.3.11.1	***Procedures of validation, including revalidation after any modification that can impact product safety, shall be documented, implemented and maintained to ensure that the hazard and risk management system is suitable to effectively control the identified hazards and risks.***		***NEW***

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
2.3.11.2*	Procedures of verification shall be ***documented, implemented and maintained*** to confirm that the ***hazard and risk management*** system is working correctly. Verification ***activities*** of the hazard and risk management system***, for example:*** • internal audits • ***testing*** • sampling • deviations ***and non-conformities*** • complaints ***shall be performed at least once within a 12-month period or whenever significant changes occur.*** The results of this verification shall be ***recorded and*** incorporated into the ***hazard and risk management*** system and shall be communicated to and reviewed by the senior management.	2.2.3.10.1*	Procedures of verification shall be established to confirm that the hazard analysis and risk assessment system is working correctly. Verification of the hazard analysis and risk assessment system shall be performed at least once per year. Examples of verification activities include: • results of internal audits and site factory inspections • analyses • sampling • complaints by authorities and customers • deviations The results of this verification shall be incorporated into the hazard analysis and risk assessment system and shall be communicated to and reviewed by the senior management.
2.3.12	**Establish documentation and record keeping**	**2.2.3.11**	**Establish documentation and record keeping**
2.3.12.1	Documentation ***and records*** related to the ***hazard and risk management*** system, ***for example:*** • hazard analysis and risk assessment • determination of ***control measures defined for*** CCPs and other control measures • determination of critical limits • processes • procedures • ***outcome of control measures defined for*** CCPs and other control measure monitoring activities • training records of the operative personnel in charge of the monitoring of CCPs and other control measures • observed deviations ***and non-conformities*** and implemented corrective actions ***shall be available***.	2.2.3.11.1	Documentation related to the hazard analysis and risk assessment system shall be in place. Examples of documentation include: • hazard analysis and risk assessment • determination of CCPs and other control measures • determination of critical limits • processes, procedures • results of hazard analysis and risk assessment system verification. Records examples: • outcome of CCPs and other control measures monitoring activities • training records of the operative personnel in charge of the monitoring of CCPs and other control measures • observed deviations and implemented corrective actions.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
3	**Resource management**	**3**	**Resource management**
3.1	**Human resources**	**3.1**	**Human resources**
3.1.1	All personnel performing work that affects ***product requirements*** shall have the required competence, appropriate to their role, as a result of education, work experience and/or training.	3.1.1	All personnel performing work that affects product safety, quality and legality shall have the required competence, appropriate to their role, as a result of education, work experience and/or training.
3.1.2	The responsibilities, competencies ***and job descriptions***, including deputies in case of absences, for ***all*** job ***titles with*** an impact on product requirements shall be documented, ***implemented and maintained***. Assignment of key roles shall be defined.	3.1.2	The responsibilities, competencies, including deputation of responsibility, for each job position that has an impact on product requirements shall be clearly defined, documented and in place. Assignment of key roles shall be defined. Employees shall be able to demonstrate that they understand their responsibilities.
3.2	**Personal hygiene**	**3.2**	**Personal hygiene**
3.2.1*	***Risk-based*** requirements ***relating to*** personal hygiene shall be documented, ***implemented and maintained*** and shall ***include***, at a minimum, the following topics: • coverage of hair and beards • protective clothing (including their condition of use in ***production*** areas and staff facilities) • hand washing, disinfection and hygiene • eating, drinking, ***smoking/vaping or other use of tobacco*** • actions to be taken in case of cuts or skin abrasions • fingernails, ***false nails/eyelashes***, personal belongings (including medicines), ***use of scented products***, and prohibited use of jewellery • ***identification and*** notification of infectious diseases and conditions impacting product safety via a medical screening procedure, subject to legal restrictions in the country of operation.	3.2.1*	Based on hazard analysis and assessment of associated risks, the requirements for personal hygiene shall consider, at a minimum, the following topics: • coverage of hair and beards • protective clothing (including their condition of use in productive areas and staff facilities) • hand washing, disinfection and hygiene • eating, drinking and smoking • actions to be taken in case of cuts or skin abrasions • fingernails, personal belongings (including medicines), and prohibition to use jewellery • notification of infectious diseases and conditions impacting product safety via a medical screening procedure, subject to legal restrictions in the country of operation. The requirements relating to personal hygiene shall be documented and in place.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
3.2.2*	**KO No. 3: The requirements for personal hygiene shall be *understood* and applied by all relevant personnel, contractors and visitors.**	**3.2.2***	**KO No. 3: The requirements for personal hygiene shall be in place and applied by all relevant personnel, contractors and visitors.**
3.2.3	Compliance with personal hygiene requirements shall be ***monitored on a risk-based frequency***.	3.2.3	Compliance with personal hygiene requirements shall be checked regularly.
3.2.4	***A risk-based program shall be implemented and maintained*** to control the effectiveness of hand hygiene.	3.4.8	Based on hazard analysis and assessment of associated risks, a program shall be in place to control effectiveness of hand hygiene.
3.2.5	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 differently from*** the product colour. Where appropriate: • plasters/bandages shall contain a metal strip • single use gloves shall be worn.	3.2.4	Cuts and skin abrasions shall be covered by a colored plaster/bandage which contrasts with the product color. Where appropriate: • plasters/bandages shall contain a metal strip • single use gloves shall be worn.
3.2.6	***Adequate*** protective clothing shall be ***provided*** in sufficient quantity for each employee.	3.2.5*	Suitable protective clothing shall be available and in sufficient quantity for each employee.
3.2.7	When required, all protective clothing shall be thoroughly laundered ***in-house by approved contractors or by employees. This decision, including frequency of laundry, shall be documented and based on risks. Requirements related to laundry*** shall ensure a minimum ***of the following***: • sufficient segregation of dirty and clean clothing at all times • avoidance of contamination until use. The effectiveness of laundering shall be monitored.	3.2.6	When required, all protective clothing shall be thoroughly and regularly laundered. The company shall determine if clothing shall be washed by a contract laundry, on-site laundry or by the employee, and the decision shall be justified by risk assessment. Defined requirements shall ensure, at a minimum: • sufficient segregation between dirty and clean clothing at all times • avoidance of contamination until use The effectiveness of the laundering conditions defined shall be appropriately monitored.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
3.2.8	In case the personnel, contractors and/or visitors ***have any health issues***, infectious diseases or conditions that may have an impact on product safety, ***these shall be immediately reported, and*** actions shall be taken to minimise contamination risks.	3.2.7	In case the personnel, contractors and/or visitors have infectious diseases and/or conditions that may have an impact on product safety, actions shall be taken to minimise contamination risks.
3.3	**Training and instruction**	**3.3**	**Training and instruction**
3.3.1*	***Documented training and/or instruction programs shall be implemented and maintained*** with respect to the product and process requirements and the training needs of the employees, based on their job, and shall include: • training objectives • training contents • training frequency • employee tasks • languages • ***competent*** trainer/tutor A procedure or program shall be ***documented, implemented and maintained*** to prove the effectiveness of the training and/or instruction programs.	3.3.1*	The company shall implement documented training and/or instruction programs with respect to the product and process requirements and the training needs of the employees based on their job and shall include: • training objectives • training contents • training frequency • employee's task • languages • qualified trainer/tutor There shall be a procedure or program in place to prove the effectiveness of the training and/or instruction programs, in relation to the accomplishment of the training objectives.
3.3.2*	The documented training and/or instruction ***programs*** shall apply to all personnel, including seasonal and temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained/instructed in accordance with the documented training/instruction programs.	3.3.2*	The documented training and/or instruction shall apply to all personnel, including seasonal and temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained/instructed in accordance with the documented training/instruction programs.
3.3.3	Records of all training/instruction events shall be available, stating: • list of participants (including their signature) • date • duration • contents of training • name of trainer/tutor.	3.3.3	Records shall be available of all training/instruction events, stating: • list of participants (this shall include their signature) • date • duration • contents of training • name of trainer/tutor.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
3.3.4	The contents of training and/or instruction shall be reviewed and updated when necessary. Special consideration shall be given to these specific topics, ***at minimum***: • product safety culture • ***product requirements*** • product fraud • product defence • product/process modifications • complaints and non-conformities related to product compliance and its impact on customers (and consumers, if applicable) • feedback from the previous documented training/instruction program.	3.3.4	The contents of training and/or instruction shall be regularly reviewed and updated when necessary. Special considerations shall be given as a minimum to these specific topics: • product safety culture • product safety, quality and legal requirements • product fraud, • product defence, • product/process modifications, • complaints and non-conformities related to product compliance and its impact on customers (and consumers, if applicable) • feedback from the previous documented training/instruction program.
3.4	**Staff facilities**	**3.4**	**Staff facilities**
3.4.1*	***Adequate*** staff facilities shall be provided and shall be proportional in size, equipped for the number of personnel, and designed and ***controlled*** to minimise product safety risks. Such facilities shall be ***maintained in a way to prevent contamination***.	3.4.1*	The company shall provide suitable staff facilities, which shall be proportional in size, equipped for the number of personnel and designed and operated so as to minimise product safety risks. Such facilities shall be kept in a clean and good condition.
3.4.2	Product contamination risks by food and drink and/or foreign materials shall be minimised. Consideration shall be given to food and drink from vending machines, canteen and/or brought to work by personnel.	3.4.2	The risk of product contamination by food, drink and/or foreign material from staff facilities shall be evaluated and minimised. Consideration shall be given to food and drink from vending machines, canteen and/or brought to work by personnel.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
3.4.3	Changing rooms shall be located to allow direct access to the areas where ***exposed*** products ***(e.g. not covered or protected by wrapping)*** are handled. ***When infrastructure does not allow it, alternative measures shall be implemented and maintained*** to minimise product contamination risks. Outdoor clothing and protective clothing shall be stored separately ***unless alternative measures are implemented and maintained to prevent contamination risks.***	3.4.3	Changing rooms shall be located to allow direct access to the areas where products are handled. If this is not possible, control activities justified by risk assessment shall be in place to minimise product contamination risks. Where necessary, outdoor clothing and protective clothing shall be stored separately.
3.4.4	Toilets shall neither have direct access nor pose contamination risk to areas where products are handled. The toilets shall be equipped with hand washing facilities. ***The*** facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.	3.4.4	Toilets shall neither have direct access nor pose a contamination risk to an area where products are handled. The toilets shall be equipped with 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.
3.4.5*	Hand hygiene facilities shall be provided and shall address, at a minimum: • ***adequate*** number of wash basins • suitably located at access points to and/or within production areas • ***designated*** for cleaning hands only. ***The necessity of*** similar equipment in further areas (e.g. storage area), shall be ***based on risks***.	3.4.5*	Hand hygiene facilities shall be provided and shall address, at a minimum: • sufficient number of wash basins, • suitably located at access points to and/or within production areas, • sole use for cleaning hands only. Where similar equipment is needed in further areas (e.g. storage area), these shall be based on hazard analysis and assessment of associated risks.
3.4.6	Hand hygiene facilities shall provide: • running potable water at an ***adequate*** temperature • ***adequate*** cleaning and disinfection equipment • ***adequate*** means for hand drying.	3.4.6	Hand hygiene facilities shall provide: • running potable water at an appropriate temperature, • appropriate cleaning and disinfection equipment, • appropriate means for hand drying.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
3.4.7	Where the processes require a higher ***hygiene control***, the hand washing equipment shall provide in addition: • hand contact-free fittings • hand disinfection • waste container with hand contact-free opening.	3.4.7	Where the processes require a higher standard of hygiene, the hand washing equipment shall provide in addition: • hand contact-free fittings, • hand disinfection, • waste container with hand contact-free opening.
	MOVED ***See v3, chapter 3.2, requirement 3.2.4***	3.4.8	Based on hazard analysis and assessment of associated risks, a program shall be in place to control effectiveness of hand hygiene.
3.4.8	***The necessity of*** cleaning and disinfection facilities for boots, shoes and further protective clothing ***shall be based on risks***.	3.4.9	Where it is justified by risk assessment, cleaning and disinfection facilities shall be available and used for boots, shoes and further protective clothing.
4	**Operational processes**	**4**	**Operational processes**
4.1	***Customer focus and*** **contract agreement**	**4.1**	**Contract agreement**
4.1.1	A ***procedure*** shall be ***implemented and maintained*** to identify the fundamental needs and expectations of customers. The feedback from this process shall be ***used*** as input for the company's continuous improvement.	1.3.1	A process shall be in place to identify the fundamental needs and expectations of customers. The feedback from this process shall be taken as input for the company's continuous improvement.
4.1.2	The requirements between the company and its customers shall be ***defined***, agreed upon and reviewed concerning their acceptability before the supply agreement is concluded. All requirements related to product safety and quality within ***the customer agreement***, and any revision of these clauses, shall be communicated to, and implemented by each relevant department.	4.1.1	The requirements defined between the company and its customers shall be established, agreed upon and reviewed concerning their acceptability before the supply agreement is concluded. All requirements related to product safety and quality within defined agreement with customers, and any revision of these clauses, shall be communicated to and implemented by each relevant department.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.1.3*	**KO No. 4: Where there are customer agreements related to:** • **product *formula*/configuration *(including raw material characteristics)*** • **process** • **technological requirements** • ***testing and monitoring plan*** • **wrapping** • **labelling** ***these* shall be complied with.**	**4.2.2.1***	**KO No. 5: Where there are customer agreements related to:** • **product formulation/ configuration** • **process and technological requirements** • **labelling** • **wrapping** **they shall be complied with.**
4.1.4	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-conformities identified by competent authorities.	4.1.2	In accordance with customer requirements, the senior management shall inform their affected customers as soon as possible of any issue related to product safety or legality, including non-conformity/ies identified by competent authorities.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.2	**Specifications and formulas/ configurations**	**4.2**	**Specifications and formulas/ configurations**
4.2.1	**Specifications**	**4.2.1**	**Specifications**

4.2.1.1	A procedure to control the creation, approval and amendment of specifications and formulas/configurations shall be ***documented, implemented and maintained*** and shall include, where required, the acceptance of the customer(s). ***The*** procedure shall include:
	• ***the management of customers' specifications and the protection of its information, if existing***
	• ***the formal agreement of specifications, formulas/configurations, where required by customers***
	• the update of ***finished product*** specifications in case of ***any modification*** related to:
	  ◦ raw materials
	  ◦ formula/configuration
	  ◦ processes ***which impact the finished products***
	  ◦ wrapping materials ***which impact the finished products***
	• how to communicate the information and its changes inside the company and, when applicable, to the customer.
		4.2.1.1	A procedure to control the creation, approval and amendment of specifications and formulas/configurations shall be in place and shall include, where required, the acceptance of the customer(s). Where required by customers, specifications, formulas/ configurations shall be formally agreed.
			This procedure shall include:
			• the review and update of specifications in case of changes related to raw materials, formulas/configurations process, wrapping material, legal and/or customer requirements, when applicable.
			• how to communicate the information and its changes inside the company and, when applicable, to the customer.
			• the management of customers' specifications and the protection of its information, when existing.

4.2.1.2*	Specifications shall be ***documented, implemented and maintained*** for all finished products. They shall be up to date, unambiguous and in compliance with legal and customer requirements.	4.2.1.3*	Specifications shall be available and in place for all finished products. They shall be up to date, unambiguous and be in compliance with legal and customer requirements.
4.2.1.3*	**KO No. 5: Specifications shall be *documented, implemented and maintained* for all raw materials. Specifications shall be up to date, unambiguous and in compliance with legal requirements and, if *defined*, with customer requirements.**	**4.2.1.2***	**KO No. 4: Specifications shall be available and in place for all raw materials. Specifications shall be up to date, unambiguous and be in compliance with legal requirements and, if existing, with customer requirements.**

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.2.1.4	Specifications and/or their components shall be available on-site for all relevant personnel.	4.2.1.4	Specifications and/or their components shall be available on-site for all relevant personnel.
4.2.1.5*	***Where products are requested to be labelled and/or promoted with a claim or where certain methods of treatment or production are excluded, control measures shall be implemented and maintained to verify and ensure compliance with such a statement.***	4.2.1.5*	A procedure shall be in place to verify and ensure, when applicable: • the fulfilment of specific customer requirements related to the exclusion of certain methods of treatment or production (e.g. GMOs), or the absence of specific components or ingredients (e.g. free-from Bisphenol A, phthalates, allergens, etc.) • the clearness, accuracy and truthfulness of claims according to the intended use of products, by means of scientific evidence and the relevant tests/analysis.
	DELETED	**4.2.2**	**Formula/configuration**
	MOVED ***See v3, chapter 4.1, requirement 4.1.3***	**4.2.2.1***	**KO No. 5: Where there are customer agreements related to:** • **product formulation/ configuration** • **process and technological requirements** • **labelling** • **wrapping** **they shall be complied with.**
4.3	**Product development, product modification, and/or modification of production/conversion processes**	**4.3**	**Product development, product modification, and/or modification of production/conversion processes**
4.3.1	For the development of products ***and/or processes***, a hazard analysis and ***risk assessment*** shall be conducted. In the case of modification of products and/or processes, the hazard analysis and risk assessment shall be reviewed ***and***, when applicable, necessary changes shall be made.	4.3.1	For each new development of products, a hazard analysis and assessment of associated risks shall be conducted. In the case of modification of products, of production/ conversion processes and/or formulas/configuration, the company shall review the hazard analysis and risk assessment to ensure the fulfilment of product requirements. When applicable, necessary changes shall be made.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.3.2*	A procedure shall be ***documented, implemented and maintained*** to ensure that the finished product complies with current legislation of the destination country/ies, and customer requirements.	4.3.5*	A procedure shall be in place to ensure that the finished product complies with current legislation of the production and destination countries, and customer requirements.
4.3.3*	The development ***or modification of*** products ***and/or*** processes shall result in specifications about formula/ configuration, ***rework***, wrapping ***materials***, ***manufacturing*** processes (including printing) and process parameters ***which comply with*** product and ***customer*** requirements. ***This includes*** factory trials, product testing/analysis and ***process monitoring***. The progress and results of the development/modification of products ***and/or*** processes shall be recorded.	4.3.2*	The product development, product modification and modification of production/conversion process shall result in specifications about formulation/configuration, wrapping requirements, production/conversion processes (including printing) and process parameters related to the fulfilment of product requirements. Factory trials and product test/ analysis shall be established to ensure product requirements are complied with. The progress and results of the product development/modification and modification of production/ conversion process shall be recorded.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.3.4	When the company has printing processes, a system to manage the development, modification and usage of artwork shall be implemented and maintained. This system shall comprise the following elements, at a minimum: • responsibilities and activities related to the management of artwork and customer-approved reference material between the company and customer • approval of final artwork, product concepts, printing specifications and the identification of critical information, by the customer, when applicable • usage and storage conditions of approved artwork master, customer-approved reference material and printing materials, in order to avoid degradation, misuse and loss • management of renewal, changes and obsolescence of artwork masters, customer-approved reference material and printing materials, including their disposal.	4.3.3*	When the company has printing processes, a system to manage the development, modification and usage of artwork shall be implemented and maintained. This system shall comprise the following elements, at a minimum: • responsibilities and activities related to the management of artwork and customer-approved reference material between the company and customer. • approval of final artwork, of product concepts, of printing specifications and the identification of critical information, by the customer, when applicable. • usage and storage conditions of approved artwork master, customer-approved reference material and printing materials, in order to avoid their degradation, misuse and loss. • management of renewal, changes and obsolescence of artwork masters, customer-approved reference material and printing materials, including their disposal.
4.3.5	Converting time tests or ***appropriate*** validation through physical, sensory, chemical, functional and microbiological evaluation shall be carried out and consideration shall be given to product formula/configuration, wrapping material, manufacturing, declared conditions ***and intended use***. The converting time shall be ***defined*** in accordance with this evaluation.	4.3.4	Conversion time tests or validation through physical, sensory, chemical, functional and microbiological evaluation shall be carried out and consideration shall be given to product formulation/configuration, wrapping material, manufacturing, and declared conditions. In accordance with this evaluation, the conversion time shall be established.
4.3.6	Recommendations for handling and/or use of products ***related to product safety and/or quality*** shall be ***validated and documented*** where appropriate.	4.3.6	Recommendations for handling (e.g. storage conditions) and/or use of products (e.g. conversion time, intended use, etc.) shall be established, where appropriate.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
	DELETED ***In v3, the content was merged in requirement 4.3.3***	4.3.7	In the event of changes to process characteristics or product formulation/configuration, including rework and/or wrapping materials, the company shall ensure that the product requirements are complied with. Labelling shall be reviewed and adapted when necessary.
4.4	**Purchasing**	**4.4**	**Purchasing**
	DELETED ***In v3, the content was merged in requirements 4.4.1, 4.4.2 and 4.4.3***	4.4.1*	The company shall control purchasing processes to ensure that all externally sourced raw materials, semi-finished products, wrapping materials and services, which have an impact on product safety and quality, conform to defined requirements.
4.4.1*	A procedure for ***the sourcing of raw materials, semi-finished products and wrapping materials and*** the approval and monitoring of suppliers shall be ***documented, implemented and maintained. This procedure shall include, at a minimum:*** • ***raw materials and/or suppliers' risks*** • required performance standards ***(e.g. certification, origin, etc.)*** • ***exceptional situations (e.g. emergency purchase)*** ***and, based on risks, additional criteria shall be included, for example:*** • audits performed by an experienced and competent person • ***analyses/testing results*** • supplier reliability • complaints • ***supplier questionnaire.***	4.4.2*	A procedure for the approval and monitoring of suppliers shall be in place. The approval and monitoring procedure shall contain clear assessment criteria, such as: • audits performed by an experienced and competent person • certificates of analyses • supplier reliability • complaints • required performance standards.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.4.2	The purchased ***materials*** shall be ***assessed, based on risks and suppliers' status, for product safety, product quality, legality, and authenticity. The results shall be the basis for the testing and monitoring plans.***	4.4.4	The purchased raw materials, semi-finished products and wrapping materials shall be checked in accordance with the existing specifications and justified by risk assessment for their authenticity. The schedule of these checks shall take at a minimum, defined product safety and quality risks. The frequency and scope of sampling shall be based on: • the impact of the raw materials, semi-finished product and wrapping materials on the finished product • the supplier's status
4.4.3*	The ***purchasing*** services ***which, based on risks, have an impact on product requirements***, shall be ***evaluated to ensure they comply with defined requirements***. ***This shall consider***, at a minimum: • the service requirements • the supplier's status (according to its assessment) • the impact of the service on the finished products.	4.4.5	The purchased services shall be checked in accordance with the existing specifications. The schedule of these checks shall take into account, at a minimum: • the defined service requirements, • the supplier status according to its assessment • the impact of the service on the finished product.
4.4.4*	Where ***a part of production/conversion process (including wrapping and labelling) is outsourced***, ***this shall be*** documented in the product safety and quality management system and such processes shall be ***controlled*** to guarantee that ***product requirements*** are not compromised. Control of such outsourced processes shall be identified and documented. ***When required by the customer***, there shall be evidence that ***they*** have been informed and have agreed to such outsourced process.	4.4.6	Where a company outsources a part of product processing/conversion (including wrapping and/or labelling), the company shall have it documented in the product safety and quality management system and ensure control over such processes to guarantee that product safety and quality are not compromised. Control of such outsourced processes shall be identified and documented. There shall be evidence that, when required, the customer has been informed and has agreed to such outsourced process.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.4.5	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***.	4.4.7	A written agreement shall be in place, covering the outsourced processes and describing any arrangements made in connection with it, including in-process controls, sampling and analyses.
4.4.6	***Suppliers*** of the outsourced processes ***shall be approved*** through: • certification to IFS PACsecure or other GFSI recognised production of food packaging certification standard, or • documented supplier audit, performed by an experienced and competent person, ***which shall include, at a minimum***, requirements ***for*** product safety, product quality, legality and authenticity.	4.4.8	The company shall approve the supplier of the outsourced processes through: • certification to IFS PACsecure or other GFSI recognised production of food packaging certification standard, or • documented supplier audit, performed by an experienced and competent person, and shall cover at least the requirements related to product safety, quality, legality and authenticity.
4.4.7	The ***sourcing of materials*** and supplier assessments 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 assessment shall be documented.	4.4.3*	The results from the supplier assessments shall be reviewed regularly and this review shall be justified by risk assessment. There shall be records of the reviews and the consequential actions of the assessment shall be documented.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.5	**Product wrapping**	**4.5**	**Product wrapping**
4.5.1*	***Based on risks*** and intended use, key parameters for the wrapping materials ***shall be defined*** in detailed specifications complying with the current relevant legislation and other relevant hazards or risks. The suitability of the wrapping materials ***in contact with*** products shall be ***validated and monitored*** by means of the relevant test/analysis, ***for example***: • sensory tests • functional test • storage and distribution tests • chemical analysis • migration test results.	4.5.1*	Based on hazard analysis, assessment of associated risks and intended use, the company shall define the key parameters for the wrapping materials in detailed specifications complying with the current relevant legislation and other relevant hazards or risks. The company shall check and verify the suitability of the wrapping material used on products by means of the relevant test/analysis, such as: • sensory tests • chemical analysis • functional test • storage and distribution tests • migration test results.
4.5.2	For all wrapping material which could have an impact on products, ***declarations of compliance***, which attest conformance with legal requirements shall ***be documented and maintained***. In the event that no specific legal requirements are applicable, evidence shall be ***documented and maintained*** to ***ensure*** that wrapping materials are suitable for ***the intended*** use. This applies for wrapping material which could have an influence on raw materials, semi-finished and finished products.	4.5.2	For all wrapping material which could have an impact on products, certificates of conformity shall exist which attest conformance with legal requirements. In the event that no specific legal requirements are applicable, evidence shall be available to demonstrate that wrapping materials are suitable for use. This applies for wrapping material which could have an influence on raw materials, semi-finished and finished products.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.5.3	***Used*** wrapping material and labelling ***shall*** correspond to the product being wrapped and ***shall*** comply with agreed customer product specifications. ***Labelling information shall be legible and indelible***. When applicable, special consideration shall be given to these specific issues: • label reprints • label and/or wrapping rework activities • suitability of reused containers or wrapping materials • information to be added on labels when special transport or storage conditions for products are used. This shall be ***monitored*** and documented ***at least at the start and end of a production run as well as at every product changeover***.	4.5.3	The company shall ensure that the wrapping and labelling in use corresponds to the product being wrapped and complies with agreed customer product specifications. When applicable, special consideration shall be given to these specific issues: • label reprints • label and/or wrapping rework activities • suitability of reused containers or wrapping materials • Information to be added on labels when special transport or storage conditions for products are used. This shall be regularly checked and documented.
4.6	**Factory location**	**4.6**	**Factory location**
4.6.1*	***Potential adverse impact on product safety and/or product quality from the factory environment (e.g. ground, air) shall be investigated. Where risks have been identified (e.g. extremely dusty air, strong smells), control measures shall be implemented, maintained and reviewed for effectiveness at least once within a 12-month period or whenever significant changes occur.***	4.6.1*	The company shall investigate the extent to which the factory environment (e.g. ground, air) may have an adverse impact on product safety and product quality. Where it is established that product safety and/or product quality is at risk of being compromised, appropriate control activities shall be implemented. The effectiveness of the implemented control activities shall be periodically reviewed (examples: extremely dusty air, strong smells).
4.7	**Factory exterior**	**4.7**	**Factory exterior**
4.7.1	All external areas of the factory shall be clean, tidy, ***designed*** and maintained ***in a way to prevent contamination***. Where natural drainage is not effective, an ***adequate*** drainage system shall be installed.	4.7.1	All external areas of the factory shall be clean, tidy, and maintained in good condition. Where natural drainage is not effective, a suitable drainage system shall be installed.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.7.2	Outdoor storage shall be kept to a minimum. Where goods are stored outside, it shall be ***ensured*** that there are no contamination risks or adverse effects on product safety and quality.	4.7.2	Outdoor storage shall be kept to a minimum. Where goods are stored outside, it shall be justified by risk assessment to ensure that there is no risk of contamination or adverse effects on product safety and quality.
4.8	**Plant layout and process flow**	**4.8**	**Plant layout and process flow**
4.8.1	A site ***plan*** covering all buildings of the production site shall be ***documented, implemented and maintained, and shall*** describe, ***at a minimum***, the process flow of: • finished products • ***semi-finished products, including rework*** • wrapping materials • raw materials • personnel • waste • water.	4.8.1	A site map covering all buildings of the production site shall be available. Plans shall be in place that clearly describe the process flow of: • finished products • raw materials • wrapping materials • personnel • waste • water.
4.8.2	The process flow, from receipt of goods to dispatch, shall be ***defined, implemented, maintained***, reviewed and where necessary, modified to ensure that microbiological, chemical and physical contamination risks of raw materials, wrapping ***materials***, semi-finished and finished products are avoided. The risk of cross-contamination, mix-ups and mixing, shall be minimised through effective ***control measures***.	4.8.2*	The process flow from receipt of goods to dispatch, shall be established, reviewed and where necessary, modified to ensure that microbiological, chemical and physical contamination risks of raw materials, wrapping, semi-finished and finished products are avoided. The risk of cross-contamination, mix-ups and mixing, shall be minimised through effective control activities.
4.8.3	In the case ***where*** areas sensitive to microbiological, chemical and physical risk(s) ***have been identified***, they shall be designed, operated and monitored to ensure product safety is not compromised.	4.8.3	In the case of areas sensitive to microbiological, chemical and physical risk(s) which is/are justified by risk assessment, they shall be designed, operated and monitored to ensure product safety is not compromised.
4.8.4	Laboratory facilities and in-process controls shall not affect product safety.	4.8.4	Laboratory facilities and in-process controls shall not affect product safety.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.9	**Production and storage premises**	**4.9**	**Production and storage premises**
4.9.1	**Constructional requirements**	**4.9.1**	**Constructional requirements**
4.9.1.1*	Premises where products are prepared, treated, processed and stored, shall be designed, constructed ***and maintained*** to ensure product safety.	4.9.1.1*	Premises, where products are prepared, treated, processed and/or converted, wrapped and stored, shall be designed and constructed to ensure product safety.
4.9.2	**Walls**	**4.9.2**	**Walls**
4.9.2.1	Walls shall be designed and constructed to ***meet production requirements in a way to*** prevent ***contamination***, reduce condensation and mould growth, facilitate cleaning ***and if necessary, disinfection***.	4.9.2.1	Walls shall be designed and constructed to prevent the accumulation of dirt, to reduce condensation and mould growth, and to facilitate cleaning. Walls shall be impervious, wear-resistant, and their surfaces shall be clean and in good condition, to minimise product contamination risks.
4.9.2.2	***The surfaces of walls shall be maintained in a way to prevent contamination and be easy to clean; they shall be impervious and wear-resistant to minimise product contamination risks.***		***ADDED*** ***Content extracted from v2, requirement 4.9.2.1***
4.9.2.3	The junctions between walls, floors, and ceilings shall be ***designed to facilitate cleaning and if necessary, disinfection.***	4.9.2.2	The junctions between walls, floors, and ceilings shall be clean, in good condition, and shall not pose contamination risks.
4.9.3	**Floors**	**4.9.3**	**Floors**
4.9.3.1	Floor coverings shall be designed ***and constructed*** to meet production requirements ***and be maintained in a way to prevent contamination*** and facilitate cleaning ***and if necessary, disinfection. Surfaces*** shall be impervious ***and*** wear-resistant to minimise product contamination risks.	4.9.3.1	Floor coverings shall be designed to meet production requirements, and to facilitate cleaning. Floors shall be impervious, wear-resistant, and their surfaces shall be clean and in good condition, to minimise product contamination risks.
4.9.3.2	The hygienic disposal of water and other liquids shall be ensured. Drainage systems shall be designed, ***constructed and maintained in a way*** to minimise product contamination risks (e.g. entry of pests, transmission of odours, among others) ***and shall be easy to clean.***	4.9.3.2	The hygienic disposal of water and other liquids shall be ensured. Drainage systems shall be easy to clean and designed to minimise the product contamination risks (e.g. entry of pests, transmission of odours, among others).

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.9.3.3	***In product handling areas, machinery and piping shall be arranged to allow waste water, if possible, to flow directly into a drain.*** Water or other liquids shall reach drainage without difficulty to minimise product contamination risks. ***Stagnation of*** puddles shall be avoided.	4.9.3.3	Water or other liquids shall reach drainage without difficulties to minimise product contamination risks. Puddles shall be avoided.
	DELETED ***In v3, the content was merged in requirement 4.9.3.3***	4.9.3.4	In product handling areas, machinery and piping shall be arranged to allow waste water, if possible, to flow directly into a drain.
4.9.4	**Ceilings/Overheads**	**4.9.4**	**Ceilings/Overheads**
4.9.4.1	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 minimise the accumulation of dirt and condensation, and shall not pose any physical and/or microbiological contamination risks.	4.9.4.1	Ceilings (or, where no ceilings exist, the inside of roofs) and overhead fixtures (including piping, cableway, lamps, etc.) shall be constructed to minimise the accumulation of dirt and condensation, and shall not pose any physical and/or microbiological contamination risks.
4.9.4.2	Where false ceilings are used, access to the vacant area shall be provided to facilitate cleaning, maintenance and inspections for pest control.	4.9.4.2	Where false ceilings are used, access to the vacant area shall be provided to facilitate cleaning, maintenance and inspections for pest control.
4.9.5	**Windows and other openings**	**4.9.5**	**Windows and other openings**
4.9.5.1	Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in ***a way to prevent contamination and shall be easy to clean***.	4.9.5.1	Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in a clean and good condition.
4.9.5.2	Where there are contamination risks, windows and roof glazing shall remain closed and fixed during production.	4.9.5.2	Where there are contamination risks, windows and roof glazing shall remain closed and fixed during production.
4.9.5.3	Where windows and roof glazing are designed to be opened for ventilation purposes, they shall be fitted with ***easy to clean*** protective barriers ***to prevent any*** contamination.	4.9.5.3	Where windows and roof glazing are designed to be opened for ventilation purposes, they shall be fitted with protective barriers to minimise the product contamination risk. If pest screens are utilised, they shall be maintained in good condition and clean.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.9.5.4	In areas where exposed products are handled (e.g. not covered or protected by wrapping), windows shall be protected against breakage.	4.9.5.4	In areas where exposed products are handled (e.g. not covered or protected by wrapping), windows shall be protected against breakage.
4.9.6	**Doors and gates**	**4.9.6**	**Doors and gates**
4.9.6.1	Doors and gates shall be maintained in ***a way to prevent contamination and be easy to clean***. They shall be ***designed and*** constructed with materials which avoid: • splintering parts • flaking paint • corrosion.	4.9.6.1	Doors and gates shall be maintained in a clean and good condition. They shall be constructed with materials which avoid: • splintering parts • flaking paint • corrosion.
4.9.6.2	External doors and gates shall be constructed to prevent the access of pests.	4.9.6.2	External doors and gates shall be constructed to prevent the access of pests; if possible, they shall be self-closing.
4.9.6.3	Plastic strip curtains separating areas shall be ***maintained in a way to prevent contamination and be easy to clean***.	4.9.6.3	Plastic strip curtains separating the internal areas shall be clean and in good condition.
4.9.7	**Lighting**	**4.9.7**	**Lighting**
4.9.7.1	All production/conversion, storage, receipt and dispatch areas shall have ***adequate*** levels of light according to the activities carried out.	4.9.7.1	All production/conversion, storage, receipt and dispatch areas shall have the levels of light according to the activities carried out.
4.9.8	**Air conditioning/Ventilation**	**4.9.8**	**Air conditioning/Ventilation**
4.9.8.1	***Adequate*** natural and/or artificial ventilation shall be ***designed, constructed and maintained*** in all areas.	4.9.8.1	Natural and/or artificial ventilation covering process/product needs shall be in place in all areas.
4.9.8.2	If ventilation equipment is installed, filters and other components shall be easily accessible and ***monitored***, cleaned or replaced as necessary.	4.9.8.2	If ventilation equipment is installed, filters and other components shall be easily accessible and checked, cleaned or replaced as necessary.
4.9.8.3	Air conditioning equipment and artificially generated airflow shall not compromise product safety and quality.	4.9.8.3	Air conditioning equipment and artificially generated airflow shall not compromise product safety and quality.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.9.8.4	Dust extraction equipment shall be ***designed, constructed and maintained*** in areas where considerable amounts of dust are generated.	4.9.8.4	Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated.
4.9.9	**Water**	**4.9.9**	**Water**
4.9.9.1*	Water which is used ***for hand washing, cleaning and disinfection***, or as material in the process shall be of potable quality at the point of use and supplied in sufficient quantity.	4.9.9.1*	Water which is used as an ingredient in the production/conversion process or for cleaning shall be of potable quality at the point of use and supplied in sufficient quantity; this also applies to steam and ice used within the production/conversion area.
4.9.9.2	The quality of water (including recycled water), steam or ice shall be monitored following a ***risk-based*** sampling plan.	4.9.9.3	The quality of water (including recycled water), steam or ice shall be monitored following a sampling plan based on hazard analysis and assessment of associated risks.
4.9.9.3	Recycled water, which is used in the process, shall not pose contamination risk.	4.9.9.2	Recycled water, which is used in the process, shall not pose contamination risk.
4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall neither be connected to the ***potable*** water system nor allow the possibility of reflux to ***prevent*** contamination of potable water sources or the factory environment.	4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall neither be connected to the drinking water system nor allow the possibility of reflux to avoid contamination of potable water sources or the factory environment.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.9.10	**Compressed air and gases**	**4.9.10**	**Compressed air and gases**
4.9.10.1*	The quality of ***compressed*** air that comes in direct contact with products, ***or wrapping materials in contact with products***, shall be monitored ***based on risks. Compressed air shall not pose contamination risks.***	4.9.10.1*	The quality of air (including compressed air) that comes in direct contact with products or surfaces in direct contact with products, shall be monitored based on hazard analysis and assessment of associated risks. If gases are used, their safety and quality shall be demonstrated through a declaration of compliance and shall be suitable for the intended use.
	DELETED ***In v3, the content was merged in requirement 4.9.10.1***	4.9.10.2	Compressed air shall not pose a risk of contamination.
4.9.10.2	***If gases are used in direct contact with products, or with wrapping materials in contact with products, evidence shall be documented and maintained to ensure their safety and quality for the intended use.***		***ADDED*** ***Content extracted from v2, requirement 4.9.10.1***
4.10	**Cleaning and disinfection**	**4.10**	**Cleaning and disinfection**
4.10.1*	***Risk-based*** cleaning and disinfection schedules shall be ***validated, documented,*** implemented ***and maintained***. These shall ***include***: • objectives • responsibilities • the products used and their instructions for use • dosage of cleaning and disinfection chemicals • the areas ***and timeslots for cleaning and disinfection activities*** • cleaning and disinfection frequency • ***Cleaning In Place (CIP) criteria, if applicable*** • documentation requirements • hazard symbols (if necessary).	4.10.1*	Based on hazard analysis and assessment of associated risks, cleaning and disinfection schedules shall be available and implemented. These shall specify: • objectives • responsibilities • the products used and their instructions for use • dosage of cleaning and disinfection chemicals • the areas to be cleaned and/or disinfected • cleaning and disinfection frequency • documentation requirements • hazard symbols (if necessary).

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.10.2	Cleaning and disinfection ***activities*** shall be implemented and shall result in effectively cleaned premises, facilities and equipment.	4.10.2	Defined cleaning and disinfection methods shall be implemented, documented, monitored, and shall result in effectively cleaned premises, facilities and equipment.
4.10.3	***Cleaning and disinfection activities shall be documented and such records shall be verified by a responsible designated person in the company.***	4.10.3	Monitoring records for cleaning and disinfection shall be available.
4.10.4*	Only ***competent*** personnel shall ***perform*** cleaning and disinfection ***activities***. The personnel shall be trained and retrained to carry out the cleaning and disinfection schedules.	4.10.4	Only qualified personnel shall be allowed to undertake cleaning and disinfection. The personnel shall be trained and retrained to carry out the cleaning and disinfection schedules.
4.10.5*	Cleaning and disinfection ***equipment*** shall be ***suitably designed and defined for the*** intended use***, identified***, used ***and stored*** in a way that avoids contamination.	4.10.7	The intended use of cleaning and disinfection utensils shall be clearly identified. Cleaning and disinfection utensils shall be used in a way that avoids contamination.
4.10.6	Safety Data Sheets and instructions for use shall be available ***on-site*** for cleaning and disinfection ***chemicals***. Personnel responsible for cleaning and disinfection ***activities*** shall be able to demonstrate their knowledge of such instructions.	4.10.8*	Safety Data Sheets and instructions for use shall be available for chemicals and cleaning and disinfection agents. Personnel responsible for cleaning and disinfection shall be able to demonstrate their knowledge of such instructions, which shall be always available on-site.
4.10.7	The effectiveness of the cleaning and disinfection activities shall be verified. The verification ***shall rely on a risk-based*** sampling schedule and shall consider ***one or several actions, for example***: • visual inspection • rapid testing • analytical testing methods. Resultant actions shall be documented.	4.10.5	The effectiveness and safety of the cleaning and disinfection activities shall be verified and justified by risk assessment. The verification shall be based on an appropriate sampling schedule and shall consider: • visual inspection • rapid testing • analytical testing methods Resultant corrective actions shall be documented.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.10.8	Cleaning and disinfection schedules shall be reviewed and modified in the event that changes occur to products, processes or cleaning and disinfection equipment, if necessary.	4.10.6	Cleaning and disinfection schedules shall be reviewed and modified in the event of a change to products, processes, cleaning and disinfection activities and/or equipment, if necessary.
4.10.9	Cleaning and disinfection chemicals shall be labelled, used and stored ***in a way that avoids*** contamination. Access to cleaning and disinfection chemicals shall be limited to authorised personnel.	4.10.9*	Cleaning and disinfection chemicals shall be clearly labelled, used and stored appropriately, to avoid contamination. The access to cleaning and disinfection chemicals shall be limited to authorised personnel.
	DELETED ***In v3, the content was merged in requirement 4.10.1***	4.10.10	Cleaning and disinfection activities shall be carried out in periods of non-production. If this is not possible, these operations shall be controlled in order not to affect the products.
4.10.10	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.	4.10.11*	Where a company hires a third-party service provider for cleaning and disinfection activities, all requirements specified within section 4.10 shall be clearly defined in the service contract.
4.11	**Waste management**	**4.11**	**Waste management**
4.11.1*	A waste management procedure shall be ***documented, implemented and maintained*** to ***prevent*** cross contamination.	4.11.1*	A waste management procedure shall be in place to avoid cross contamination.
4.11.2	All local legal requirements for waste disposal shall be met.	4.11.2	All local legal requirements for waste disposal shall be met.
4.11.3	Product waste and other waste shall be removed as quickly as possible from areas where the product is handled. The accumulation of waste shall be avoided.	4.11.3	Product waste and other waste shall be removed as quickly as possible from areas where the product is handled. The accumulation of waste shall be avoided.
4.11.4	Waste collection containers shall be marked, suitably designed ***and maintained***, easy to clean, and where necessary, disinfected.	4.11.4	Waste collection containers shall be clearly marked, suitably designed, in a good state of repair, easy to clean, and where necessary disinfected.
	DELETED ***In v3, the content was merged in requirement 4.11.4 and in chapter 4.13***	4.11.5	Waste collection rooms and containers (including compactors) shall be maintained tidy, clean and in good condition to minimise pest attraction.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.11.5	Waste shall be collected in separate containers in accordance with the intended means of disposal. Such waste shall be disposed of by authorised third-parties only. Records of waste disposal shall be kept by the company.	4.11.6	Waste shall be collected in separate containers in accordance with the intended means of disposal. Such waste shall be disposed of by authorised third-parties only. Records of waste disposal shall be kept by the company.
4.11.6*	A procedure to manage and control the disposal and/or destruction of trademark materials/products shall be ***documented, implemented and maintained***. The procedure shall comply with legal requirements and customer agreements, when applicable. The disposal and/or destruction of trademark materials/products shall be recorded and shall be included in the traceability system of the company.	4.11.7*	A procedure to manage and control the disposal and/or destruction of trademark materials/products shall be in place. The procedure shall comply with legal requirements and customer agreements, when applicable. The disposal and/or destruction of trademark materials/products shall be recorded, and shall be included in the traceability system of the company
4.12	**Foreign material *and chemical* risk mitigation**	**4.12**	**Foreign material risk mitigation**
4.12.1*	**KO No. 6: *Based on risks*, procedure(s) shall be *documented, implemented and maintained* to *prevent* contamination with foreign materials. Contaminated products shall be treated as non-conforming products.**	**4.12.2***	**KO No. 6: Based on hazard analysis and assessment of associated risks, procedures shall be in place to avoid contamination with foreign materials. Contaminated products shall be treated as non-conforming products.**

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.12.2	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 • pipes • walkways • platforms • ladders. ***If, for*** technological characteristics and/or ***needs***, ***it is not possible to protect the products***, appropriate ***control measures*** shall be ***implemented and maintained***.	4.12.1	The products being processed shall be protected against physical contamination, which includes but is not limited to: • environmental contaminants • oils or dripping liquids from machinery • dust spills. Special consideration shall be given to product contamination caused by: • equipment and utensils, • pipes, • walkways, • platforms, • ladders. In the event that this is not possible due to technological characteristics and/or requirements, appropriate controls shall be defined and applied.
4.12.3	***All chemicals within the facility shall be fit for purpose, labelled, stored and handled in a way not to pose any contamination risk. Safety Data Sheets and instructions for use shall be available on-site.***		***NEW***
4.12.4	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.***	4.12.3	Where metal and/or other foreign material detectors are required, they shall be installed to ensure maximum efficiency of detection, in order to avoid subsequent contamination. Detectors shall be subjected to regular maintenance to avoid malfunction.
4.12.5	The accuracy of all equipment and methods designed to detect and/or eliminate foreign materials shall be ***defined***. Functionality ***tests*** of such equipment and methods shall be carried out ***on a risk-based frequency***. In case of malfunction or failure, ***the impact on products and processes shall be assessed***.	4.12.4	The accuracy of all equipment and methods designed to detect and/or eliminate foreign materials shall be specified. Functionality checks of such equipment and methods shall be carried out regularly. In case of malfunction or failure, corrective actions shall be defined, implemented and documented.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.12.6	Potentially contaminated products shall be isolated. Access and actions for the further handling ***or testing*** of these isolated products shall only be carried out by authorised personnel.	4.12.5	Potentially contaminated products shall be isolated. Access and actions for the further handling or checking of these isolated products shall only be carried out by authorised personnel according to defined procedures. After this check, contaminated products shall be treated as non-conforming products.
4.12.7	In areas where raw materials, wrapping materials, semi-finished and finished products are handled, the use of glass and/or brittle materials shall be excluded; however, where the presence of glass and/or brittle materials cannot be avoided, the risks shall be controlled and the glass and/or brittle materials shall be clean and pose no risks to product safety.	4.12.6	In areas where raw materials, wrapping materials, semi-finished and finished products are handled, the use of glass and/or brittle materials shall be excluded; however where the presence of glass and/or brittle materials cannot be avoided, the risks shall be controlled and the glass and/or brittle materials shall be clean and pose no risks to product safety.
4.12.8	***Risks-based control measures*** shall be ***implemented and maintained*** for the handling of all kinds of containers used in production/conversion processes (including wrapping materials) which are made of glass or brittle material. After this process step, there shall be no further contamination risks.	4.12.7	Based on hazard analysis and assessment of associated risks, preventive measures shall be in place for the handling of all kinds of containers used in production/conversion processes (including wrapping materials) which are made of glass or brittle material. After this process step there shall be no further contamination risks.
4.12.9	Procedure(s) shall be ***documented, implemented and maintained*** describing the ***control measures*** to be taken in case of glass breakage and/or brittle materials. Such ***control*** measures shall include identifying the scope of goods to be isolated, ***designation of*** authorised personnel, cleaning ***and if necessary, disinfection of*** the production environment and releasing the production line for continued production.	4.12.8	Procedures shall be in place describing the measures to be taken in case of glass breakage and/or brittle material. Such measures shall include identifying the scope of goods to be isolated, specifying authorised personnel, cleaning the production environment and releasing the production line for continued production.
4.12.10	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.	4.12.9	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.12.11	Where visual inspection is used to detect foreign materials, ***these shall be carried out in accordance with defined procedures, and by competent and trained personnel***. Operative changes shall be performed at ***a risk-based*** frequency to maximise the effectiveness of the process.	4.12.11*	Where visual inspection is used to detect foreign materials, the employees shall be trained and operative changes shall be performed at an appropriate frequency to maximise the effectiveness of the process.
4.12.12	In areas where raw materials, wrapping materials, semi-finished and finished products are handled, the use of wood shall be excluded; however, where the presence of wood cannot be avoided, the risks shall be controlled, and the wood shall be clean and pose no risk to product safety.	4.12.10	In areas where raw materials, wrapping materials, semi-finished and finished products are handled, the use of wood shall be excluded; however, where the presence of wood cannot be avoided, the risks shall be controlled and the wood shall be clean and pose no risk to product safety.
4.13	**Pest monitoring and control**	**4.13**	**Pest monitoring and control**
4.13.1	Site ***premises*** and ***equipment*** shall be designed, built ***and maintained*** to prevent pest infestation.	4.13.1	Site infrastructure and operations shall be designed and built to prevent pest infestation.
4.13.2*	***Risks-based*** pest control ***measures*** shall be ***documented, implemented and maintained***. ***They shall comply*** with local legal requirements and ***consider***, 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.	4.13.2*	Based on hazard analysis and assessment of associated risks, the company shall have adequate pest control activities in place which shall be in compliance with local legal requirements and shall take into account, at a minimum: • factory environment (potential pests) • type of raw material/finished products • site plan with area for application (bait map) • constructional designs susceptible for pest activity, such as ceilings, cellars, pipes, corners • identification of the baits on-site • responsibilities, in-house/external • agents used and their instructions for use and safety • frequency of inspections • rented storage if applicable.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.13.3	Where a company hires a third-party service provider for pest control, all ***above-mentioned*** requirements shall be ***documented*** in the service contract. A ***competent*** person at the company shall be appointed to monitor the pest control ***measures***. Even if the pest control service is outsourced, responsibilities for the necessary actions (including ongoing supervision of pest control ***measures***) shall remain within the company.	4.13.3	Where a company hires a third- party service provider for pest control, all requirements specified above shall be clearly defined in the service contract, to prevent any negative impact on products. A person at the company shall be appointed and trained to monitor the pest control activities. Even if the pest control service is outsourced, responsibilities of the necessary actions (including ongoing supervision of pest control activities) shall remain within the company.
4.13.4	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded. Any infestation shall be documented, and control ***measures*** shall be taken.	4.13.4	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded. Any infestation shall be documented and control activities taken promptly.
4.13.5	Baits, traps and insect exterminators shall be fully functioning, sufficient in number, designed for purpose, placed in appropriate positions and used in a way to avoid contamination.	4.13.5	Baits, traps and insect exterminators shall be fully functioning, sufficient in number, designed for purpose, placed in appropriate positions and used in a way that avoids any contamination risks.
4.13.6	Incoming deliveries shall be inspected on arrival for the presence of pests. Any findings ***and actions taken*** shall be recorded.	4.13.6	Incoming deliveries shall be inspected on arrival for the presence of pests. Any findings shall be recorded and control activities taken.
4.13.7	The effectiveness of pest control ***measures*** shall be monitored, including trend analysis, ***to allow timely appropriate actions***. Records of monitoring shall be available.	4.13.7	The effectiveness of the pest control activities shall be monitored, including trend analysis, to take actions as soon as possible. Records of this monitoring shall be available.
4.14	**Receipt and storage of goods**	**4.14**	**Receipt and storage of goods**
4.14.1*	All incoming goods, including wrapping materials, shall be checked for ***compliance with*** specifications and a determined ***risk-based monitoring plan***. Records of those inspections shall be available.	4.14.1*	All incoming goods, including wrapping materials, shall be checked for conformity against specifications and to a determined inspection plan. The inspection plan shall be justified by risk assessment. Records of those inspections shall be available.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.14.2*	A system shall be implemented and maintained to manage the storage of raw materials, semi-finished and finished products. It shall consider, at a minimum: • identification of all products • control ***measures*** to ensure the storage conditions correspond to product specification ***and minimise contamination risks or any other negative impact*** • usage of products in accordance with the principles of First In/First Out and/or First Expired/First Out • how to proceed when ***the defined*** converting time or expiry date of products is exceeded • how to manage incoming goods, including wrapping materials, which have no established converting time or expiry date.	4.14.4*	A system shall be implemented and maintained to manage the storage of raw materials, semi-finished, finished products and wrapping materials. It shall consider, at a minimum: • clear identification of all products • control activities to ensure the storage conditions correspond to product specification and shall not have any negative impact on other products • usage of products in accordance with the principles of First In/First Out and/or First Expired/First Out • how to proceed when converting time established or expiry date of products is exceeded • how to manage incoming goods, including wrapping materials, which have no converting time established or expiry date.
	DELETED ***In v3, the content was merged in requirement 4.14.2 and in chapter 4.9***	4.14.2	The storage areas of raw materials, wrapping materials, semi-finished and finished products, including loading/unloading areas to store and dispatch bulk goods, shall: • be clearly identified, • allow cleaning and inspection, • be clean and in good conditions to minimise the contamination risks or other negative impact (e.g. cross-contamination, mixing issues).
4.14.3	***Adequate*** storage facilities shall be available for the management and storage of working materials, equipment, tools, process aids and additives. The personnel responsible for the management of storage facilities shall be trained.	4.14.3	Appropriate storage facilities shall be available for the management and storage of working materials, equipment, tools, process aids, and additives. The personnel responsible for the management of storage facilities shall be trained.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.14.4	Where a company hires a third-party storage service provider, the service provider shall be certified to IFS Logistics or any other GFSI recognised certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own storage practices shall be fulfilled and this shall be defined in the respective contract.	4.14.5	Where a company hires a third-party storage service provider, the service provider shall be certified to IFS Logistics or any other GFSI recognised product safety certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own storage practices shall be fulfilled and this shall be clearly defined in the respective contract, to prevent any negative impact on products.
4.15	**Transport**	**4.15**	**Transport**
4.15.1*	The ***containers and vehicles*** used to transport goods shall be ***suitably designed and defined for the intended use, maintained in a way to prevent contamination***, and shall protect the products from adverse weather conditions and external influences. The conditions ***inside the containers and vehicles related to the absence of, for example***: • strange ***smells*** • ***adverse humidity*** • pests • foreign materials (e.g. wood splinters, stones, organic contaminants, etc.) • ***mould*** • surfaces shall be checked before loading and documented to ensure compliance with the ***defined*** conditions. ***The actions taken shall be recorded.***	4.15.1*	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 of transport vehicles, such as: • cleanliness • pests • foreign materials (e.g. wood splinters, stones, organic contaminants, etc.) • strange odours • surfaces shall be checked before loading, and these checks shall be documented to ensure compliance with the specified conditions. When applicable, actions shall be taken to avoid any negative impact on products and to ensure compliance with the specified conditions.
4.15.2	Where goods shall be transported at certain conditions, these shall be ***ensured*** and documented before loading ***and*** during transport.	4.15.3	Where goods shall be transported at certain conditions, these shall be checked and documented inside the vehicle before loading. The maintenance of these conditions during transport shall be ensured and documented.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.15.3	Procedures to prevent contamination during transport, including loading and unloading, shall be ***documented, implemented and maintained***. Different categories of goods (e.g. products, wrapping materials, etc.) ***shall be considered, if applicable.***	4.15.2	Procedures to prevent contamination during transport, including loading and unloading, shall be in place. This shall consider different categories of goods (e.g. products, wrapping materials, etc.)
4.15.4	***Risk-based*** hygiene requirements for transport vehicles and equipment used for loading/unloading (e.g. hoses of silo installations) covering product and process needs shall ***be documented, implemented and maintained. Compliance with these requirements shall be monitored, and actions taken shall be recorded***.	4.15.4	Hygienic requirements for all transport vehicles and equipment used for loading/unloading (e.g. hoses of silo installations) covering product and process needs shall exist. There shall be records of the control activities and actions taken.
4.15.5	The loading/unloading area shall be appropriate for their intended use. They shall be constructed in a way that: • the risks of pest ***intake*** are mitigated • products are protected from adverse weather conditions • accumulation of waste is avoided • condensation and growth of mould are prevented • cleaning ***and if necessary, disinfection*** can be easily undertaken.	4.15.5	The loading/unloading area shall be appropriate for its intended use. They shall be constructed in a way that: • the risks of pest ingress are mitigated • products are protected from adverse weather conditions and external influences • accumulation of waste is avoided • condensation and growth of mould are prevented • cleaning can be easily undertaken.
4.15.6	Where a company hires a third-party transport service provider, the service provider shall be certified to IFS Logistics or any other GFSI recognised certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own transportation practices shall be fulfilled and this shall be defined in the respective contract.	4.15.6	Where a company hires a third-party transport service provider, the service provider shall be certified to IFS Logistics or any other GFSI recognised product safety certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own transportation practices shall be fulfilled and this shall be clearly defined in the respective contract, to prevent any negative impact on products.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.16	**Maintenance and repair**	**4.16**	**Maintenance and repair**
4.16.1*	A maintenance plan shall be documented, ***implemented*** and maintained, that covers all critical equipment (including transport, ***production and storage premises***) ***to ensure*** product requirements. This applies both to internal maintenance activities and service providers. The plan shall include responsibilities, priorities and due dates.	4.16.1*	An adequate maintenance plan shall be in place, maintained and documented, that covers all critical equipment (including transport) for compliance with product requirements. This applies both to internal maintenance activities and service providers. The plan shall include responsibilities, priorities and due dates.
4.16.2	Product requirements and prevention of contamination shall be ensured during and after maintenance and repair work. Records of maintenance and repair work shall be kept.	4.16.2	Product requirements and prevention of contamination shall be ensured during and after maintenance and repair work. Records of maintenance and repair work and of corrective actions taken shall be kept.
4.16.3	All materials used for maintenance and repair shall be fit for the intended use and shall not pose contamination risks.	4.16.3	All materials used for maintenance and repair shall be fit for the intended use and shall not pose contamination risks.
4.16.4	Failures and malfunctions of ***premises*** and equipment (including transport), that are essential for product safety and quality shall be ***identified***, documented and reviewed to ***enable*** prompt actions and to improve the maintenance plan.	4.16.4	Failures and malfunctions of plant and equipment (including transport) essential for product safety and quality shall be notified, documented and reviewed to carry out prompt actions and to improve the maintenance plan.
4.16.5	Temporary repairs shall be carried out ***to avoid compromising product safety and quality***. Such work shall be identified, documented and a short-term deadline set for eliminating the ***issue***.	4.16.5	Temporary repairs shall be carried out so that product requirements are not affected. Such work shall be identified, documented and a short-term deadline set for eliminating the fault.
4.16.6	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 or agreement, to prevent any ***product contamination***.	4.16.6	Where a company hires a third-party maintenance and repair service provider, all the company specified requirements regarding material, equipment and operational rules shall be clearly defined, documented and maintained in the service contract or agreement, to prevent any negative impact on products.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.17	**Equipment**	**4.17**	**Equipment**
4.17.1*	Equipment shall be suitably designed and ***defined*** for the intended use. Before commissioning ***new equipment, compliance with product requirement and customer requirements shall be validated***.	4.17.1*	Equipment shall be suitably designed and specified for the intended use. Before commissioning, it shall be verified that the product requirements are complied with.
4.17.2	For all equipment and tools ***which could have an impact on the product, evidence shall be documented and maintained to demonstrate*** compliance with legal requirements. In ***the event that*** no specific legal requirements are ***applicable***, evidence shall be ***documented and maintained, for example***: • certificate of conformity • technical specifications • manufacturer's self-declaration to demonstrate that they are suitable for the intended use.	4.17.2	For all equipment and tools in direct contact with products, a certificate of conformity shall be in place, which confirms compliance with legal requirements. In case no specific legal requirements are in place, evidence shall be available, such as: • certificate of conformity • technical specifications • manufacturer's self-declaration to demonstrate that they are suitable for the intended use.
4.17.3	Equipment shall be located to allow effective cleaning, disinfection and maintenance operations.	4.17.3	All equipment shall be located to allow effective cleaning, disinfection and maintenance operations. The company shall ensure that all product equipment and its related tools are identified, controlled, maintained in good condition without any negative influence on products, stored and transported in a way that does not compromise product safety and product quality (e.g. damage, mixing, printing errors).
4.17.4	***All product equipment and related tools shall be identified, controlled, maintained, stored and transported in a way that does not compromise product safety and product quality (e.g. damage, mixing, printing errors).***		***ADDED*** ***Content extracted from v2, requirement 4.17.3***

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.17.5	In the event of changes to equipment, the process characteristics ***shall be*** reviewed to ***ensure*** that product requirements ***and customer requirements***, are complied with.	4.17.4	The company shall ensure that in the event of changes to processing methods and equipment, process characteristics are reviewed in order to assure that product requirements, as agreed with customers, are complied with.
4.18	**Traceability**	**4.18**	**Traceability**
4.18.1*	**KO No. 7: 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 wrapping materials *in contact with products and/or materials carrying legal and/or relevant product safety information*. The traceability system shall incorporate all relevant records of:** • **receipt** • **production/conversion processes *at all steps*** • **use of rework** • **distribution.** **Traceability shall be ensured and documented until delivery to the customer.**	**4.18.1***	**KO No. 7: A traceability system shall be in place which enables the identification of product batches and their relation to batches of raw materials and wrapping materials. The traceability system shall incorporate all relevant records of:** • **receipt** • **production/conversion processes** • **use of rework** • **distribution** **Traceability shall be ensured and documented until delivery to the customer.**
4.18.2*	The traceability system, ***including mass balance***, shall be tested ***at least once within a 12-month period or whenever significant changes occur***. The test samples shall ***reflect*** the complexity of the company's product range. The test records shall demonstrate upstream and downstream traceability (from delivered products to raw materials, and vice versa).	4.18.2*	The traceability system shall be tested on a periodic basis, at least annually and each time the traceability system changes. The test samples shall represent the complexity of the company's product range. The test records shall verify upstream and downstream traceability (from delivered products to raw materials, and vice versa). The traceability of the finished products shall be performed within four (4) hours maximum.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.18.3	***The traceability from the finished products to the raw materials and to the customers shall be performed within four (4) hours maximum.*** Test results, including the timeframe for obtaining the information, shall be recorded and where necessary actions shall be taken. Timeframe objectives shall be in compliance with customer requirements, ***if less than four (4) hours are required.***	4.18.3	Test results, including the timeframe for obtaining the information, shall be recorded and where necessary appropriate actions shall be taken. Timeframe objectives shall be defined and be in compliance with customer requirements.
	DELETED ***In v3, the content was merged in requirement 4.18.1***	4.18.4	Traceability shall be in place to identify the relationship between batches of final products and their labels.
	DELETED ***In v3, the content was merged in requirement 4.18.1***	4.18.5	Traceability shall be ensured at all stages, including work in progress, post treatment and rework.
4.18.4	Labelling of semi-finished or finished product ***lots*** shall be made at the time when they are directly wrapped to ensure their traceability. Where they are labelled at a later time, the temporarily stored semi-finished or finished products shall have a specific ***lot*** labelling.	4.18.6	Labelling of semi-finished or finished product batches shall be made at the time when they are directly wrapped to ensure their clear traceability. Where they are labelled at a later time, the temporarily stored of semi-finished or finished products shall have a specific batch labelling.
4.18.5	If required by the customer, identified representative samples of the manufacturing ***lot or*** batch number shall be stored appropriately and kept until expiration of the recommended converting time of the finished product and, if necessary, for a determined period beyond this date.	4.18.7	If required by the customer, identified samples representative for the manufacturing batch number shall be stored appropriately and kept until expiration of the recommended converting time of the finished product and if necessary for a determined period beyond this date.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.19	**Allergen risk mitigation**	**4.19**	**Allergen risk mitigation**
4.19.1	The company shall identify and maintain a continuously up to date listing of all raw materials containing or potentially containing allergens (e.g. traces, due to the adventitious or technically unavoidable presence) used at its premises. The formulas/ configurations, semi-finished products and finished products, in which such raw materials are utilised shall also be identified.	4.19.1*	The company shall identify and maintain a continuously up to date listing of all raw materials containing or potentially containing allergens (e.g. traces, due to the adventitious or technically unavoidable presence) used at its premises. The formulas/configurations, semi-finished products and finished products, in which such raw materials are utilised shall be also identified.
4.19.2*	***Risks-based control measures*** shall be implemented ***and maintained*** to ensure that: • all allergen entry routes are identified • potential cross-contamination of products by allergens is minimised. The potential cross-contamination risks related to the environment, transport, storage, raw materials, equipment, personnel (including contractors and visitors), cleaning and disinfection activities, process flow (from receipt of goods to dispatch) and rework shall be considered • the declaration of allergens are in accordance with legal and customer requirements, if existing. ***Implemented control measures shall be monitored.***	4.19.2*	Based on hazard analysis and assessment of associated risks, a documented allergen management plan shall be developed and implemented to ensure that: • all allergens entry are identified • potential cross-contamination of products by allergens is minimised. The potential cross-contamination risks related to the environment, transport, storage, raw materials, equipment, personnel (including contractors and visitors), cleaning and disinfection activities, process flow (from receipt of goods to dispatch) and rework shall be considered. • the declaration of allergens are in accordance with legal and customer requirement, if existing. The preventive and control measures, methods of control and monitoring shall be defined, implemented, and controls shall be verified.
4.19.3	The ***control measures*** shall be reviewed ***at least once within a 12-month period or whenever significant changes occur***. If necessary, the control measures shall be revised/ updated accordingly.	4.19.3	The allergen management plan shall be regularly reviewed, at least annually, and/or in the event of increased risks, or in case of changes in legal and/or customer requirements. If necessary, the allergen management plan and the related preventive and control measures shall be revised/updated accordingly.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.20	**Product fraud**	**4.20**	**Product fraud**
4.20.1	The responsibilities for a product fraud vulnerability assessment and mitigation plan shall be defined. The responsible person(s) shall have the appropriate specific knowledge.	4.20.1	The responsibilities for a product fraud vulnerability assessment and mitigation plan shall be clearly defined. The responsible person(s) shall have the appropriate specific knowledge and full commitment from the senior management.
4.20.2*	A product fraud vulnerability assessment, ***including assessment criteria***, shall be ***documented, implemented and maintained. The scope of the assessment shall cover*** all raw materials, wrapping materials and ***outsourced*** processes, to determine the risks of fraudulent activity in relation to substitution, mislabelling, adulteration or counterfeiting.	4.20.2*	A documented product fraud vulnerability assessment shall be undertaken on all raw materials, wrapping materials and processes (including outsourced), to determine the risks of fraudulent activity in relation to substitution, mislabelling, adulteration or counterfeiting. Criteria considered within the vulnerability assessment shall be defined.
4.20.3	A product fraud mitigation plan shall be ***documented, implemented and maintained***, with reference to the vulnerability assessment, ***and shall include the testing and monitoring methods***.	4.20.3*	A documented product fraud mitigation plan shall be developed, with reference to the vulnerability assessment, and implemented to control any identified risk. The methods of control and monitoring shall be defined and implemented.
4.20.4*	The product fraud vulnerability assessment shall be reviewed ***at least once within a 12-month period or whenever significant changes occur***. If necessary, the product fraud mitigation plan shall be revised/updated accordingly.	4.20.4*	The product fraud vulnerability assessment shall be regularly reviewed, at least annually, and/or in the event of increased risks. If necessary, the product fraud mitigation plan shall be revised/updated accordingly.
4.21	**Product defence**	**6**	**Product defence plan**
4.21.1	The responsibilities for product defence shall be defined. ***The responsible person(s)*** shall have the appropriate specific knowledge.	6.1	The responsibilities for the product defence plan shall be clearly defined. Those responsible shall have the appropriate specific knowledge and training, and have full commitment from the senior management.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
4.21.2*	A product defence assessment, ***including assessment criteria***, shall be ***documented, implemented and maintained to identify potential threats and define product defence measures***. This shall include, at a minimum: • legal requirements • customer requirements • site security conditions • identification of critical areas ***and/or practices and policy of access by employees*** • ***visitors and contractors*** • ***how to manage external inspections and regulatory visits*** • any other appropriate control ***measures***.	6.2	A documented product defence assessment shall be undertaken to determine the risks of malicious and ideologically motivated threats. This shall include, at a minimum: • legal requirements • customer requirements • site security conditions • identification of critical or high-risk areas of the site • practices and policy of access by employees, visitors and contractors • any other appropriate control activities The criteria considered within the vulnerability assessment shall be defined.
4.21.3	A product defence plan shall be documented, ***implemented and maintained***, with reference to the product defence assessment, ***and shall include the testing and monitoring methods***.	6.3	A documented product defence plan shall be developed, with reference to the product defence assessment, and implemented in place to effectively mitigate the identified risks. The methods of control and monitoring shall be defined and implemented.
4.21.4	The product defence plan shall be ***tested for effectiveness*** and reviewed ***at least once within a 12-month period or whenever significant changes occur. If necessary, the product defence plan shall be revised/updated accordingly.***	6.4*	The product defence plan shall be reviewed at least annually, and updated when appropriate. The test on the effectiveness of the product defence plan and the related control activities shall be included in the internal audit and the inspection plan.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5	**Measurements, analyses, improvements**	**5**	**Measurements, analyses, improvements**
5.1	**Internal audits**	**5.1**	**Internal audits**
5.1.1*	**KO No. 8: An effective internal audit program *shall be documented, implemented and maintained and shall ensure, at a minimum, that all* the requirements of the IFS Standard *are audited. This activity shall be planned within a 12-month period and its execution shall not exceed 15 months. The company shall have a risk assessment in place where activities, which are 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.**	**5.1.1***	**KO No. 8: The company shall have an effective internal audit program in place which shall cover, at least, all the requirements of the IFS PACsecure Standard. Scope and frequency of internal audits shall be determined and justified by risk assessment.** **The internal audit program shall also apply to off-site storage locations owned or rented by the company.**
	DELETED ***In v3, the content was merged in requirement 5.1.1***	5.1.2*	Internal audits of activities which are critical to product safety and quality shall be carried out at least once a year.
5.1.2	The auditors shall be competent and independent from the audited department.	5.1.3	The auditors shall be competent and independent from the audited department.
5.1.3	Internal audits shall be ***documented and results*** communicated to the senior management and to persons responsible for the concerned activities. ***Compliances, deviations and non-conformities*** shall be documented and communicated to the relevant persons.	5.1.4	Internal audit results shall be communicated to the senior management and to persons responsible for the concerned activities. Necessary corrections, corrective actions and a schedule for implementation shall be determined, documented and communicated to the relevant persons. All corrections and corrective actions resulting from the internal audits shall be verified.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5.2	**Site factory inspections**	**5.2**	**Site and factory inspections**
5.2.1*	Site factory inspections shall be planned and carried out for ***certain*** topics, ***like for example:*** • constructional status of production and storage premises • external areas • product control during processing • hygiene during ***production/conversion processes*** 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. ***Inspections and resulting actions*** shall be documented.	5.2.1*	Site and factory inspections shall be planned and carried out for topics, such as: • constructional status of production and storage premises • external areas • product control during processing • hygiene during processing and within the infrastructure • foreign material hazards • personal hygiene • product defence The frequency of inspections shall be justified by risk assessment and be based on the history of previous experience. Any deviation and the associated actions shall be documented.
5.3	***Process validation and control***	**5.3**	**Validation and control of the process and working environment**
5.3.1	The criteria for the validation and control of the process shall be defined. The validation of the process parameters shall be performed using the collected data that is ***essential*** for product safety and quality. If substantial modifications occur, a revalidation shall be carried out.	5.3.1*	The criteria for the validation and control of the process and working environment shall be clearly defined. The validation of the process and working environment parameters shall be performed using the collected data that is relevant for product safety and quality. If substantial modifications occur, a revalidation shall be carried out.
5.3.2	Process parameters which are essential to ensure the capability of consistently producing conforming products shall be monitored, recorded continuously and/or at appropriate intervals ***and secured against unauthorised access and/or change***.	5.3.2	Where the control of process and working environment parameters are essential to ensure the capability of consistently producing conforming products, such controls and parameters shall be validated, monitored and recorded continuously and/or at appropriate intervals. Procedures shall be in place for prompt notification, recording and monitoring of the deviations on the process and/or parameters. Where necessary appropriate actions shall be taken and these shall be recorded.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5.3.3*	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.	5.3.4*	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.
5.3.4	***Procedures shall be documented, implemented and maintained for prompt notification, recording and monitoring of process deviations. Where necessary, appropriate actions shall be taken, and these shall be recorded.***		***ADDED*** ***Content extracted from v2, requirement 5.3.2***

5.3.5	When applicable, the control of processes shall take the following aspects into account:
	• Handling of products in print trials, testing activities, start-up processes and production samplings.
	• Clearance activities among the production of different products and processes.
	• Control ***measures*** to ensure the artwork approved, printing equipment, and print specifications are traceable to the final product and correspond with the product being printed.
	• In case critical information on the product is being printed, control ***measures*** shall be implemented to:
	  • ensure the information is legible and correctly reproduced;
	  • prevent, identify and handle any issue related to misprinting, loss of information, cross-contamination and mixing in all stages where these issues can occur, including rework.
	The effectiveness of control measures shall be monitored. Records of ***this*** monitoring shall be ***documented***.
		5.3.3	When applicable, the control of process shall take into account the following aspects:
			• Handling of products in print trials, testing activities, start-up processes and production samplings.
			• Clearance activities among the production of different products and processes.
			• Control activities to ensure the artwork approved, printing equipment, and print specifications are traceable up to the final product and correspond to the product to be printed.
			• In case the product has critical information printed, control activities shall be implemented to:
			  • ensure the information is legible and correctly reproduced;
			  • prevent, identify and handle any issue related to misprinting, loss of information, cross-contamination and mixing in all stages where these issues can occur, including rework.
			The company shall verify the control activities and monitor their effectiveness. Records of the verification and monitoring shall be available.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5.4	**Calibration, adjustment and checking of measuring and monitoring devices and inspection equipment**	**5.4**	**Calibration, adjustment and checking of measuring, monitoring devices and inspection equipment**
5.4.1*	Measuring and monitoring devices required to ensure compliance with product requirements shall be identified and recorded. Their calibration status shall be recorded. Measuring and monitoring devices shall be agreed with the customer, or conform to accepted industry standards (e.g. spectrophotometers, lighting in print inspection cabinets, pantone patterns), and legally approved, if required by ***current relevant*** legislation.	5.4.1*	The company shall identify and record the measuring and monitoring devices required to ensure compliance with product requirements. Their calibration status shall be recorded, and when possible, visible on the device (e.g. labelled). Measuring and monitoring devices shall be agreed with the customer, or conform to accepted industry standards (e.g. spectrophotometers, lighting in print inspection cabinets, pantone patterns), and legally approved, if required by legislation.
5.4.2*	All measuring devices shall be checked, ***monitored***, adjusted and calibrated at ***defined*** intervals in accordance with recognised standard/methods and within relevant limits of the process parameter values. The results shall be documented. When inspection equipment is used to control parameters relevant for compliance with product requirement, the method and accuracy to control the parameter values and its limits ***shall be defined***. The continuous operation and efficiency of the inspection equipment to control the parameters under the values and limits defined shall be monitored.	5.4.2*	All measuring devices shall be checked, adjusted and calibrated at specified intervals under a monitoring system in accordance with defined, recognised national or international standard/methods and within relevant limits of the process parameter values. The results of the checks, adjustments and calibrations shall be documented. When inspection equipments are used to control parameters relevant for the compliance with product requirement, the company shall specify the method and accuracy to control the parameter values and its limits. The continuous operation and efficiency of the inspection equipments to control the parameters under the values and limits defined shall be monitored on a regular basis.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5.4.3	All measuring and monitoring devices and inspection equipment shall be used exclusively for their defined purpose. Where the results of measurements or the status of the device/ equipment indicate a malfunction or failure, the device in question shall be immediately repaired or replaced. ***Where a malfunction has been identified, the impact on processes and products shall be assessed to identify whether non-conforming products have been processed.***	5.4.3	All measuring, monitoring devices and inspection equipment shall be used exclusively for their defined purpose. Where the results of measurements or the status of the device/ equipment indicate a malfunction or failure, the device in question shall be immediately repaired or replaced. Where necessary, corrections and corrective actions on processes and products shall be carried out.
5.5	**Quantity control monitoring**	**5.5**	**Quantity control monitoring**
5.5.1*	Compliance criteria to control ***lot*** quantity shall be defined. ***A system on frequency and methodology*** for quantity control shall be ***implemented and maintained*** to meet legal requirements of the destination country/ies, and customer specifications.	5.5.1*	The company shall define compliance criteria to control batch quantity. A frequent and methodological approach for quantity control shall be in place to meet legal requirements of the production and destination countries, and customer specifications.
5.5.2	***Quantity control monitoring*** shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing ***lot***. The results ***from this monitoring*** shall be compliant with defined criteria for all products ready to be delivered.	5.5.2	Checks shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing batch. Results of these checks shall be compliant with defined criteria for all products ready to be delivered.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5.6	**Product *testing and environmental monitoring***	**5.6**	**Product and process analyses**
5.6.1*	***Risk-based*** testing ***and monitoring*** plans for internal and external analyses shall be ***documented, implemented and maintained*** to ensure that ***product requirements*** and specific customer requirements are met. The plans shall cover ***a minimum of***: • raw materials • semi-finished products ***(if applicable)*** • finished products • wrapping materials • contact surfaces of processing equipment • relevant parameters for the control of the process and environmental monitoring. All test results shall be recorded.	5.6.1*	Testing plans for internal and external analyses shall be justified by risk assessment to ensure that product safety, quality, legal and specific customer requirements are met. The plans shall cover topics, such as: • raw materials • semi-finished products • finished products • wrapping materials • contact surfaces of processing equipment • relevant parameters for the control of the process and environmental monitoring. All test results shall be recorded.
5.6.2*	***Based on risks, the criteria for environmental monitoring program shall be documented, implemented and maintained.***		***NEW***
5.6.3*	Analyses, which are relevant for product safety, shall preferably be performed by laboratories with appropriate accredited programs/methods (ISO/IEC 17025). If the analyses are performed internally or by a laboratory without appropriate accredited programs/methods, the results shall be ***cross-checked with test results from*** laboratories accredited to these programs/methods (ISO/IEC 17025) ***at least once within a 12-month period, or whenever significant changes occur.***	5.6.2*	Analyses, which are relevant for product safety, shall preferably be performed by laboratories with appropriate accredited programs/methods (ISO/IEC 17025). If the analyses are performed internally by the factory or a laboratory without appropriate accredited programs/methods, the results shall be verified on a regular basis by laboratories accredited to these programs/methods (ISO/IEC 17025).
5.6.4	Procedures shall be ***documented, implemented and maintained to*** ensure the reliability of the results from internal analyses, based on officially recognised analysis methods. This shall be demonstrated by ring tests or other proficiency tests.	5.6.3	Procedures shall exist which ensure the reliability of the internal analyses results, based on officially recognised analysis methods. This shall be demonstrated by ring tests or other proficiency tests.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5.6.5	Results of analyses shall be evaluated ***in a timely manner*** by competent personnel. ***Immediate corrections*** shall be ***implemented*** for any unsatisfactory results. ***Based on risks and legal requirements, the frequency for review of the testing and monitoring plan results shall be defined in order to identify trends. When unsatisfactory trends are identified, the impact on processes and products as well as the need for actions shall be assessed.***	5.6.4	Results of analyses shall be evaluated promptly by competent personnel. Appropriate corrective actions shall be undertaken for any unsatisfactory results. The analytical results shall be reviewed regularly to identify trends and, where necessary, corrective actions shall be taken.
5.6.6	Where internal analyses or controls are undertaken, these shall be carried out in accordance with defined procedures, ***performed by competent*** and approved personnel, in defined areas or laboratories using appropriate equipment.	5.6.5	Where internal analyses or controls are undertaken, these shall be carried out in accordance with defined procedures, by trained and approved personnel, in defined areas or laboratories using appropriate equipment.
5.6.7	When it is relevant for the ***monitoring*** of products requirements and/or ***required*** by the customer, internal sensory 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.	5.6.6	When it is relevant for the verification of products requirements and/or is specified by the customer, internal sensory tests shall be carried out regularly. These tests shall be in accordance with specifications and related to the impact on respective parameters of product characteristics. The results of these tests shall be documented.
5.6.8	The testing ***and monitoring plans/ programs*** shall be reviewed and updated, based on results, changes to legislation or issues that may have an impact on ***product requirements***.	5.6.7	The testing plan shall be regularly reviewed and updated, based on results, changes to legislation or issues that may have an impact on product safety, quality or legality.
5.7	**Product release**	**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, semi-finished, finished products and wrapping materials ***complying with*** product requirements ***and customer requirements***, are processed/converted and ***delivered***.	5.7.1*	A procedure for quarantine (blocking/ hold) and release shall be in place that is justified by risk assessment. The procedure shall ensure that only raw materials, semi-finished, finished products and wrapping materials conforming to product requirements, are processed/converted and dispatched.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5.8	**Management of complaints**	**5.8**	**Management of complaints**
5.8.1*	A procedure shall be ***documented, implemented and maintained*** for the management of complaints. The procedure shall consider, at a minimum: • product complaints by customers, and when applicable, by consumers • any written notification from the competent authorities – within the framework of official controls –, any ordering action or measure to be taken when non-compliance is identified • raw materials complaints by the company to its suppliers.	5.8.1*	A procedure shall be in place for the management of complaints. The procedure shall consider, at a minimum: • Product complaints by customers, and when applicable, by consumers • Any written notification from the competent authorities – within the framework of official controls –, any ordering action or measure to be taken when non-compliance in products is identified. • Raw materials complaints by the company to its suppliers
5.8.2*	All complaints shall be ***recorded***, ***be*** readily available and assessed by competent staff. Where it is justified, actions shall be taken immediately.	5.8.2*	All complaints shall be registered, readily available and assessed by competent staff. Where it is justified, appropriate actions shall be taken immediately.
5.8.3	Complaints shall be analysed with a view to implementing actions to avoid the recurrence of the ***deviations and/or*** non-conformities.	5.8.3	Complaints shall be analysed with a view to implementing appropriate actions to avoid the recurrence of the non-conformity.
5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons.	5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons and to the senior management.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5.9	**Management *of product recalls, product withdrawals and incidents***	**5.9**	**Management of incidents, product withdrawal, product recall**
	DELETED ***In v3, the content was merged in requirement 5.9.1***	**5.9.1***	A procedure shall be implemented and maintained for the management of incidents and of potential emergency situations with an impact on product safety, legality and quality. It shall include, at a minimum: • the decision-making process • the nomination of a person, authorised by the company and permanently available, to initiate the incident management process promptly • the nomination and training of an incident management team • an up-to-date alert contact list including customer information, sources of legal advice, contacts availability • a communication plan including authorities.
5.9.1*	**KO No. 9: 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 requirements. 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, authorised 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, available contacts*** • ***a communication plan including customers, authorities, and where applicable, consumers.***	**5.9.2***	**KO No. 9: An effective procedure for the withdrawal and/or the recall of all products shall be in place. This procedure shall include a clear assignment of responsibilities and a comprehensive information policy for customers, including consumers and competent authorities when applicable.**

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5.9.2*	***The procedure shall be subject to internal testing for recall/withdrawal, by covering the end-to-end process. This activity shall be planned within a 12-month period and its execution shall not exceed 15 months. The outcome of the test shall be documented, reviewed for continuous improvement, and where necessary actions shall be taken.***	5.9.3	The procedures for the management of incidents and withdrawal/recall shall be regularly tested for effectiveness, at least annually. The tests shall be carried out to ensure the effective implementation and operation of both procedures and shall include the verification of the updated contact data.
5.10	**Management of non-conforming products**	**5.10**	**Management of non-conformities and 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 wrapping 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.	5.10.1*	A procedure shall be in place for the management of all non-conforming raw materials, semi-finished products, finished products, converting/ processing equipment and wrapping materials. This shall include, at a minimum: • defined responsibilities • isolation/quarantine procedures • risk assessment • identification including labelling • decision about the further use (e.g. release, rework, blocking, quarantine, rejection/disposal).
5.10.2	The procedure for the management of non-conforming products shall be understood and applied by all relevant employees.	5.10.2	The procedure for the management of non-conforming products shall be understood and applied by all relevant employees.
5.10.3	Where ***non-conforming products*** are identified, immediate actions shall be taken to ensure that product requirements are complied with.	5.10.3	Where non-conformities are identified, immediate actions shall be taken to ensure that product requirements are complied with.
5.10.4	Finished products that are out of specification shall not be placed on the market unless written approval of the customer is available. ***When*** out of specification products shall be destroyed, records of this shall be maintained.	5.10.4	Finished products (including wrapping) that are out of specification shall not be placed on the market, unless written approval from the customer is available. The out of specification products shall be destroyed appropriately and records of this shall be maintained.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
5.11	***Management of deviations, non-conformities, corrections and*** **corrective actions**	**5.11**	**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,*** non-conformities and non-conforming products, ***with the objective to close the deviations and/or non-conformities and avoid recurrences via corrective actions. This shall include a root cause analysis, at least for deviations and non-conformities related to safety, legality, authenticity and/or recurrence of deviations and non-conformities.***	5.11.1*	A procedure shall be in place for the recording and analysis of non-conformities and non-conforming products, by preventive actions, corrections and/or corrective actions. The root cause analysis for corrective actions related to product safety shall be documented; in any other case, the need to document the root cause analysis shall be defined and justified by risk assessment.
5.11.2	***Where deviations and non-conformities are identified, corrections shall be implemented.***		***NEW***
5.11.3*	**KO No. 10: Corrective actions shall be formulated, documented and *implemented* as soon as possible *to avoid the further occurrence of deviations and non-conformities*. The responsibilities and the timescales for corrective actions shall be defined.**	5.11.2*	**KO No. 10: Corrective actions shall be clearly formulated, documented and undertaken as soon as possible. The actions defined shall be focused on avoiding the recurrences of non-conformities. The responsibilities and the timescales for corrective actions shall be clearly defined.**
5.11.4	The effectiveness of the implemented ***corrections and*** corrective actions shall be assessed, and the results of the assessment documented.	5.11.3	The effectiveness of the implemented corrective actions shall be assessed and the results of the assessment documented.
	MOVED ***See v3, chapter 4.21***	**6**	**Product defence plan**
	MOVED ***See v3, chapter 4.21.1***	6.1	The responsibilities for the product defence plan shall be clearly defined. Those responsible shall have the appropriate specific knowledge and training, and have full commitment from the senior management.

V3 chapter	Requirements in v3	V2 chapter	Requirements in v2 and type of changes
	MOVED ***See v3, chapter 4.21.2***	6.2	A documented product defence assessment shall be undertaken to determine the risks of malicious and ideologically motivated threats. This shall include, at a minimum: • legal requirements • customer requirements • site security conditions • identification of critical or high-risk areas of the site • practices and policy of access by employees, visitors and contractors • any other appropriate control activities The criteria considered within the vulnerability assessment shall be defined.
	MOVED ***See v3, chapter 4.21.3***	6.3	A documented product defence plan shall be developed, with reference to the product defence assessment, and implemented in place to effectively mitigate the identified risks. The methods of control and monitoring shall be defined and implemented.
	MOVED ***See v3, chapter 4.21.4***	6.4*	The product defence plan shall be reviewed at least annually, and updated when appropriate. The test on the effectiveness of the product defence plan and the related control activities shall be included in the internal audit and the inspection plan.
	DELETED ***In v3, the content was merged in requirement 4.21.2***	6.5	A documented procedure shall exist for managing external inspections and regulatory visits. Relevant personnel shall be trained to execute the procedure.

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