IFS Global Markets PACsecure checklist compared with IFS PACsecure V2 checklist

Note: The IFS Global Markets PACsecure requirements are based on the IFS PACsecure V2 requirements. When the content of an IFS Global Markets PACsecure requirement is different than the one in the IFS PACsecure, the text is highlighted in red color.

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
1	Governance & commitment		1	Governance & commitment
1.1	Policy		1.1	Policy
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.	Intermediate	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 measurable objectives, with responsibilities and timelines defined. These shall be known by the relevant departments / parts and shall be effectively implemented	Intermediate	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 to the relevant personnel promptly.
1.2	Corporate structure		1.2	Corporate structure

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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.	Intermediate	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.
1.2.2	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.	Intermediate	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.
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.	Basic	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.
1.2.4	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.	Intermediate	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.

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1.2.5	The senior management shall **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.	Intermediate	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.
1.2.6	The senior management shall ensure that the certification body **(or assessment service provider)** 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 Global Markets - PACsecure scope,** the certification body **(or assessment service provider)** shall be informed within three (3) working days.	Basic	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	**Customer focus**

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			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.
1.4	**Management review**		**1.4**	**Management review**
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 policies**, including elements of product safety culture – results of audits and site inspections – customer audit results – process compliance and changes / improvements – authenticity and conformity issues – status of corrections and corrective actions – notifications from authorities.	Intermediate	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.
			1.4.2	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.

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			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 systems – machines and equipment – transport – staff facilities – environmental conditions – hygienic conditions – workplace design – external influences (e.g. noise, vibration). The results of the review shall be considered, with due consideration to 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	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.

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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.	Intermediate	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.
			2.1.1.3	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 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.	Basic	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 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.	Basic	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.

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2.1.2.2	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.	Intermediate		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	Any amendments to records shall only be carried out by authorised persons.
2.2 2.2.1	**Product Safety and Quality Management Hazard analysis and risk assessment system**		**2.2 2.2.1**	**Product safety and quality management Hazard analysis and risk assessment system**
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.	Basic	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.

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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.	Intermediate	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.
2.2.1.3	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.	Intermediate	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.

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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.	Intermediate	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.
2.2.1.5	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.	Intermediate	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.
2.2.2	**Hazard analysis and risk assessment team**		**2.2.2**	**Hazard analysis and risk assessment team**
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.	Basic	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.

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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.	Basic	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.
2.2.3	**Hazard analysis and risk assessment**		**2.2.3**	**Hazard analysis and risk assessment**
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	Basic	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

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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.	Basic	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.
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.	Basic	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.
2.2.3.4	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.	Basic	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.

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2.2.3.5	**Conduct a hazard analysis and risk assessment for each step**		**2.2.3.5**	**Conduct a hazard analysis and risk assessment for each step**
2.2.3.5.1	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.	Intermediate	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.
2.2.3.5.2	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.	Intermediate	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.
2.2.3.6	**Determine Critical Control Points (CCP) and other control measures**		**2.2.3.6**	**Determine Critical Control Points (CCP) and other control measures**
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.	Intermediate	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.

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2.2.3.7	**Establish limits for each CCP and other control measures**		**2.2.3.7**	**Establish limits for each CCP and other control measures**
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.	Intermediate	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.
2.2.3.7.2	For other control measures defined, appropriate limits shall be determined.	Intermediate	2.2.3.7.2	For other control measures defined, appropriate limits shall be determined.
2.2.3.8	**Establish a monitoring system for each CCP and other control measures**		**2.2.3.8**	**Establish a monitoring system for each CCP and other control measures**
2.2.3.8.1	Specific monitoring procedures in terms of method, frequency of measurement or observation, and recording of results, shall be established for each CCP to detect any loss of control at that CCP. Each defined CCP shall **be** under control. Monitoring and control of each CCP shall be demonstrated by records. 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.	Intermediate	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.

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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.	Intermediate	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.
2.2.3.9	**Establish corrective actions**		**2.2.3.9**	**Establish corrective actions**
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.	Intermediate	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.
2.2.3.10	**Establish verification procedures**		**2.2.3.10**	**Establish verification procedures**

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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.	Intermediate	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.
2.2.3.11	**Establish documentation and record keeping**		**2.2.3.11**	**Establish documentation and record keeping**

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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.	Intermediate	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.
3	**Resource Management**		**3** **3.1**	**Resource management** **Human resources**
			3.1.1	All personnel performing work that affects product safety, quality and legality shall have the required competence, appropriate to their role, as a result of education, work experience and / or training.

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			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	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.	Basic	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.

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3.2.1	The requirements relating to personnel hygiene shall be based on hazard analysis and assessment of associated risks.	Intermediate		The requirements relating to personal hygiene shall be documented and in place.
3.2.2	The requirements for personal hygiene shall be in place and applied by all relevant personnel, contractors and visitors.	Basic	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 checked regularly.	Basic	3.2.3	Compliance with personal hygiene requirements shall be checked regularly.
			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.
3.2.5	Suitable protective clothing shall be available and in sufficient quantity for each employee.	Basic	3.2.5	Suitable protective clothing shall be available and in sufficient quantity for each employee.

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			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.
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.	Basic	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	The company shall ensure that all personnel are adequately trained in product safety, quality and practices according to their job responsibilities.	Basic	3.3.1	The company shall implement documented training and / or instruction programs with respect to the product and process requirements and the training

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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 jobs.	Intermediate		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 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 **to their jobs.**	Basic	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 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.	Intermediate	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.

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			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	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.	Intermediate	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	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.

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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 shall be in place to minimise product contamination risks. Where necessary, outdoor clothing and protective clothing shall be stored separately.	Basic	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.
3.4.3	Control activities implemented in relation to changing rooms shall be justified by risk assessment.	Intermediate		
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.	Basic	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: – 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.	Intermediate	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.

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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.	Basic	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.
			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.
3.4.8	Based on hazard analysis and assessment of associated risks, a program shall be in place to control effectiveness of hand hygiene.	Intermediate	3.4.8	Based on hazard analysis and assessment of associated risks, a program shall be in place to control effectiveness of hand hygiene.
3.4.9	Where it is justified by risk assessment, cleaning and disinfection facilities shall be available and used for boots, shoes and further protective clothing.	Intermediate	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 **4.1**	**Operational processes** **Contract agreement**		**4** **4.1**	**Operational processes** **Contract agreement**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Basic	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.
			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.
4.2 **4.2.1**	**Specifications and formulas / configurations** **Specifications**		**4.2** **4.2.1**	**Specifications and formulas / configurations** **Specifications**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Intermediate	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 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.	Basic	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.
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.	Basic	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.
4.2.1.4	Specifications and / or their components shall be available on-site for all relevant personnel.	Basic	4.2.1.4	Specifications and / or their components shall be available on-site for all relevant personnel.

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Intermediate	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.
4.2.2	**Formula / configuration**		**4.2.2**	**Formula / configuration**
4.2.2.1	Where there are customer agreements related to: – product formulation / configuration – process and technological requirements – labelling – wrapping they shall be complied with.	Basic	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**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
			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.
			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.

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
			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.

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
			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.
			4.3.5	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.
			4.3.6	Recommendations for handling (e.g. storage conditions) and / or use of products (e.g. conversion time, intended use, etc.) shall be established, where appropriate.
			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**
4.4.1	The company shall control purchasing processes to ensure that all externally sourced raw materials, semi-finished products, wrapping materials, which have an impact on product safety and quality, conform to defined requirements.	Basic	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.

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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.	Intermediate	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.
			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.
			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

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
			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.
4.4.6	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.	Intermediate	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.
			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.

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			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 require- ments related to product safety, quality, legality and authenticity.
4.5	**Product wrapping**		**4.5**	**Product wrapping**
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.	Intermediate	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.

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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.	Basic	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.
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.	Basic	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**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Basic	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).
4.6.1	The effectiveness of the implemented control activities shall be periodically reviewed (examples: extremely dusty air, strong smells).	Intermediate		
4.7	**Factory Exterior**		**4.7**	**Factory exterior**
4.7.1	All external areas of the factory shall be clean, tidy, and maintained in good condition. Where natural drainage is not effective, a suitable drainage system shall be installed.	Basic	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.
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.	Intermediate	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 flows**		**4.8**	**Plant layout and process flows**

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			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 established, reviewed and where necessary, modified to ensure that microbiological, chemical and physical contamina- tion risks of raw materials, wrapping, semi-finished and finished products are avoided.	Basic	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.
4.8.2	The risk of cross-contamination, mix-ups and mixing, shall be minimised through effective control activities.	Intermediate		
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.	Intermediate	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.

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4.8.4	Laboratory facilities and in-process controls shall not affect product safety.	Intermediate	4.8.4	Laboratory facilities and in-process controls shall not affect product safety.
4.9 **4.9.1**	**Production and storage premises** **Constructional requirements**		**4.9** **4.9.1**	**Production and storage premises** **Constructional requirements**
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.	Basic	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 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.	Basic	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 junctions between walls, floors, and ceilings shall be clean, in good condition, and shall not pose contamination risks.	Basic	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 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.	Basic	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.

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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).	Basic	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).
4.9.3.3	Water or other liquids shall reach drainage without difficulties to minimise product contamination risks. Puddles shall be avoided.	Basic	4.9.3.3	Water or other liquids shall reach drainage without difficulties to minimise product contamination risks. Puddles shall be avoided.
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.	Basic	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 constructed to minimise the accumulation of dirt and condensation, and shall not pose any physical and / or microbiological contamination risks.	Basic	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.	Basic	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 clean and good condition.	Basic	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.

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
4.9.5.2	Where there are contamination risks, windows and roof glazing shall remain closed and fixed during production.	Basic	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 protective barriers to minimise the product contamination risk. If pest screens are utilised, they shall be maintained in good condition and clean.	Basic	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.
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.	Basic	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 clean and good condition. They shall be constructed with materials which avoid: – splintering parts – flaking paint – corrosion.	Basic	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; if possible, they shall be self-closing.	Intermediate	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 the internal areas shall be clean and in good condition.	Basi	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**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
4.9.7.1	All production / conversion, storage, receipt and dispatch areas shall have the levels of light according to the activities carried out.	Basic	~~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	Natural and / or artificial ventilation covering process / product needs shall be in place in all areas.	Basic	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 checked, cleaned or replaced as necessary.	Basic	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.	Basic	4.9.8.3	Air conditioning equipment and artificially generated airflow shall not compromise product safety and quality.
4.9.8.4	Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated.	Basic	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 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.	Basic	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	Recycled water, which is used in the process, shall not pose contamination risk.	Basic	4.9.9.2	Recycled water, which is used in the process, shall not pose contamination risk.

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
4.9.9.3	The quality of water (including recycled water), steam or ice shall be monitored following a sampling plan.	Basic	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	The sampling plan shall be based on hazard analysis and assessment of associated risks.	Intermediate		
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.	Basic	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.
4.9.10	**Compressed air and gases**		**4.9.10**	**Compressed air and gases**
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.	Intermediate	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.
4.9.10.2	Compressed air shall not pose a risk of contamination.	Basic	4.9.10.2	Compressed air shall not pose a risk of contamination.
4.10	**Cleaning and disinfection**		**4.10**	**Cleaning and disinfection**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
4.10.1	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).	Basic	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).
4.10.1	Cleaning and disinfection schedules shall be based on hazard analysis and assessment of associated risks.	Intermediate		
4.10.2	Defined cleaning and disinfection methods shall be implemented, documented, monitored, and shall result in effectively cleaned premises, facilities and equipment.	Basic	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	Monitoring records for cleaning and disinfection shall be available.	Basic	4.10.3	Monitoring records for cleaning and disinfection shall be available.
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.	Basic	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.

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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.	Intermediate	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.
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.	Intermediate	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.
4.10.7	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.	Basic	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.
4.10.8	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.	Basic	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.

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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.	Basic	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.
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.	Basic	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.
			4.10.11	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 in place to avoid cross contamination.	Intermediate	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.	Basic	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.	Basic	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.

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			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.
4.11.5	Waste collection rooms and containers (including compactors) shall be maintained tidy, clean and in good condition to minimise pest attraction.	Basic	4.11.5	Waste collection rooms and containers (including compactors) shall be maintained tidy, clean and in good condition to minimise pest attraction.
			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.
4.11.7	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.	Intermediate	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 risk mitigation**		**4.12**	**Foreign material risk mitigation**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Basic	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.
4.12.2	Procedures shall be in place to avoid contamination with foreign materials. Contaminated products shall be treated as non-conforming products.	Basic	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.
4.12.2	The procedures shall be based on hazard analysis and assessment of associated risks.	Intermediate		

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Intermediate	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.
4.12.4	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.	Intermediate	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.
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.	Basic	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.
			4.12.6	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.

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			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.
4.12.8	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.	Intermediate	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.
4.12.9	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.	Basic	4.12.9	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.
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.	Intermediate	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.
4.12.11	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.	Intermediate	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.

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4.13	Pest monitoring and control		4.13	Pest monitoring and control
4.13.1	Site infrastructure and operations shall be designed and built to prevent pest infestation.	Basic	4.13.1	Site infrastructure and operations shall be designed and built to prevent pest infestation.
4.13.2	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.	Basic	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.
4.13.2	The pest control activities shall be based on hazard analysis and assessment of associated risks.	Intermediate		

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Basic	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 activities taken promptly.	Basic	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 that avoids any contamination risks.	Basic	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 shall be recorded and control activities taken.	Basic	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 the pest control activities shall be monitored, including trend analysis, to take actions as soon as possible. Records of this monitoring shall be available.	Intermediate	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**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
4.14.1	All incoming goods, including wrapping materials, shall be checked for conformity against specifications and to a determined inspection plan. Records of those inspections shall be available.	Basic	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.
4.14.1	The inspection plan shall be justified by risk assessment.	Intermediate		
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).	Basic	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	Appropriate storage facilities shall be available for the management and storage of working materials, equipments, tools, process aids, and additives. The personnel responsible for the management of storage facilities shall be trained.	Basic	4.14.3	Appropriate storage facilities shall be available for the management and storage of working materials, equipments, tools, process aids, and additives. The personnel responsible for the management of storage facilities shall be trained.

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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.	Intermediate	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.
			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**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Basic	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	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.).	Intermediate	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.).
4.15.3	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.	Basic	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.

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Intermediate	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 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.	Intermediate	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 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.
4.16	**Maintenance and repair**		**4.16**	**Maintenance and repair**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Intermediate	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 and of corrective actions taken shall be kept.	Intermediate	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.	Basic	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 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.	Intermediate	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 so that product requirements are not affected. Such work shall be identified, documented and a short-term deadline set for eliminating the fault.

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			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.
4.17	**Equipment**		**4.17**	**Equipment**
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.	Basic	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 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.

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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).	Intermediate	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	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	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.	Basic	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.

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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.	Intermediate	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.
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.	Intermediate	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.
4.18.4	Traceability shall be in place to identify the relationship between batches of final products and their labels.	Basic	4.18.4	Traceability shall be in place to identify the relationship between batches of final products and their labels.
4.18.5	Traceability shall be ensured at all stages, including work in progress, post treatment and rework.	Basic	4.18.5	Traceability shall be ensured at all stages, including work in progress, post treatment and rework.
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.	Intermediate	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.

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			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.
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 be also identified.	Basic	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.

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4.19.2	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.	Basic	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 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.	Intermediate	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.
4.20	**Product fraud**		**4.20**	**Product fraud**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Intermediate	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 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.	Intermediate	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 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.	Intermediate	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 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.
5	**Measurements, Analysis, Improvements**		**5**	**Measurements, Analysis, Improvements**
5.1	**Internal audits**		**5.1**	**Internal audits**

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5.1.1	The company shall have an effective internal audit program in place which shall cover, at least, all the requirements of the **IFS Global Markets - PACsecure.** 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.	Intermediate	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.
			5.1.2	Internal audits of activities which are critical to product safety and quality shall be carried out at least once a year.
			5.1.3	The auditors shall be competent and independent from the audited department.
			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.
5.2	**Site and factory inspections**		**5.2**	**Site and factory inspections**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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 Any deviation and the associated actions shall be documented.	Basic	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.
5.2.1	The frequency of inspections shall be justified by risk assessment and be based on the history of previous experience.	Intermediate		
			5.3	**Validation and control of the process and working environment**
			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.

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			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.

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			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.
			5.3.4	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.
5.4	**Calibration, adjustment and checking of measuring, monitoring devices and inspection equipment**		**5.4**	**Calibration, adjustment and checking of measuring, monitoring devices and inspection equipment**

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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.	Basic	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, 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.	Intermediate	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.

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Intermediate	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**
			5.5.1	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	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.
5.6	**Product and process analyses**		**5.6**	**Product and process analyses**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
5.6.1	Testing plans for internal and external analyses shall exist 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 environmental monitoring. All test results shall be recorded.	Basic	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.
5.6.1	Testing plans for internal and external analyses shall be justified by risk assessment.	Intermediate		
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).	Intermediate	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).

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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.	Intermediate	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.
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.	Basic	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.
			5.6.5	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.
			5.6.6	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.
			5.6.7	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**

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
5.7.1	A procedure for quarantine (blocking / hold) and release shall be in place. The procedure shall ensure that only raw materials, semi-finished, finished products and wrapping materials conforming to product requirements, are processed / converted and dispatched.	Basic	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.
5.7.1	The procedure for quarantine (blocking / hold) and release shall be justified by risk assessment.	Intermediate		
5.8	**Management of complaints**		**5.8**	**Management of complaints**
			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 registered, readily available and assessed by competent staff. Where it is justified, appropriate actions shall be taken immediately.	Basic	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.

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
5.8.3	Complaints shall be analysed with a view to implementing appropriate actions to avoid the recurrence of the non-conformity.	Intermediate	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 and to the senior management.	Intermediate	5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons and to the senior management.
5.9	**Management of incidents, product withdrawal, product recall**		**5.9**	**Management of incidents, product withdrawal, product recall**
5.9.1	The company shall demonstrate the ability to withdraw and recall affected products, contact relevant customers and maintain records of these incidents.	Basic	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

Req. No.	IFS Global Markets PACsecure Version 1	Level	Req. No.	IFS PACsecure Version 2
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.	Intermediate		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.
5.9.2	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.	Intermediate	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.
5.9.3	The procedures for the management of incidents and withdrawal / recall shall be regularly tested, 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.	Intermediate	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.

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5.10	**Management of non-conformities and non conforming products**		**5.10**	**Management of non-conformities and non conforming products**
5.10.1	A procedure shall be in place for the management of all non-conforming raw materials, semi-finished products, finished products, converting / processing equipment and wrapping materials. This shall include, at a minimum: – defined responsibilities – isolation / quarantine procedures – identification including labelling – decision about the further use (e.g. release, rework, blocking, quarantine, rejection/disposal).	Basic	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).
5.10.1	The procedure shall be based on hazard analysis and assessment of associated risks.	Intermediate		
5.10.2	The procedure for the management of non-conforming products shall be understood and applied by all relevant employees.	Basic	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-conformities are identified, immediate actions shall be taken to ensure that product requirements are complied with.	Basic	5.10.3	Where non-conformities are identified, immediate actions shall be taken to ensure that product requirements are complied with.

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			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.
5.11	**Corrective actions**		**5.11**	**Corrective actions**
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.	Basic	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.
5.11.1	For corrective actions not related to product safety, the need to document the root cause analysis shall be defined and justified by risk assessment.	Intermediate		
5.11.2	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.	Basic	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.

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5.11.3	The effectiveness of the implemented corrective actions shall be assessed and the results of the assessment documented.	Intermediate	5.11.3	The effectiveness of the implemented corrective actions shall be assessed and the results of the assessment documented.
6	**Product defence plan**		**6**	**Product defence plan**
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.	Intermediate	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.
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.	Intermediate	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.

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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.	Intermediate	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.
			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
			6.5	A documented procedure shall exist for managing external inspections and regulatory visits. Relevant personnel shall be trained to execute the procedure.