



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
<b>1</b>	<b>Senior Management Responsibility</b>	Modification	<b>1</b>	<b>Governance &amp; commitment</b>
<b>1.1</b>	<b>Corporate policy/Corporate principles</b>	Modification	<b>1.1</b>	<b>Policy</b>
1.1.1	The senior management shall <del>draw up and</del> implement a clear corporate policy. This shall consider as a minimum: <ul style="list-style-type: none"> <li>– customer focus</li> <li>– environmental responsibility</li> <li>– sustainability</li> <li>– ethics and personnel responsibility</li> <li>– product requirements (includes: product safety, quality, legality, process and specification).</li> </ul> The corporate policy shall be communicated to all employees.	Modification	1.1.1	The senior management shall <b>develop</b> , implement <b>and maintain</b> a clear corporate policy, <b>which shall include</b> , at a minimum: <ul style="list-style-type: none"> <li>– customer focus</li> <li>– <b>product safety culture</b></li> <li>– product requirements</li> <li>– sustainability</li> </ul> The corporate policy shall be communicated to all employees.
1.1.2	The corporate policy shall have objectives specifying responsibilities and timelines appropriate for the size and complexity of the organization.	Modification	1.1.2	The corporate policy shall <b>be broken down into measurable objectives, with</b> responsibilities and timelines <b>defined. These shall be known by the relevant departments / parts and shall be effectively implemented</b>
1.1.3	<del>From the corporate policy, the quality and packaging material safety objectives shall be communicated to the employees in the respective departments and shall be effectively implemented.</del>	Deletion		<b>Merged in IFS PACsecure version 2, in the requirement 1.1.2</b>
1.1.4	<del>The senior management shall ensure that the achievement of all objectives is regularly reviewed, as a minimum at least once a year.</del>	Deletion		<b>Merged in IFS PACsecure version 2, in the requirement 1.4.1</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.1.5	All relevant information related to packaging material safety and quality shall be communicated effectively and in a timely manner to the relevant personnel.	Modification	1.1.3	All relevant information related to <b>product requirements</b> shall be communicated effectively to the relevant personnel <b>promptly</b> .
<b>1.2</b>	<b>Corporate structure</b>	None	<b>1.2</b>	<b>Corporate structure</b>
1.2.1	<del>An organisation chart shall be available showing the structure of the company.</del>	Modification	1.2.1	The structure of the company, <b>hierarchy, and job positions</b> 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.
4.2.2	<del>Competences and responsibilities, including deputation of responsibility shall be clearly laid down.</del>	Deletion		Competencies were included in IFS PACsecure version 2, chapter 3, req. 3.1.2 (Human Resources)
4.2.3	<del>Job descriptions with clearly defined responsibilities shall exist and shall be applicable for employees whose work has an effect on product requirements.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirements 1.2.2, 1.2.4 and 3.1.2
<del>4.2.4</del> <b>KO no. 4</b>	<b>The senior management shall ensure that employees are aware of their responsibilities related to packaging material safety and quality and that mechanisms are in place to monitor the effectiveness of their operation. Such mechanisms shall be clearly identified and documented.</b>	Modification	1.2.2 KO No. 1	The senior management shall ensure that employees are aware of their responsibilities related to <b>the product safety and quality management system and product requirements</b> . Clearly identified and documented mechanisms shall be in place to monitor the effectiveness of their operation.
4.2.5	<del>Employees with influence on product requirements shall be aware of their responsibilities, and shall be able to demonstrate their understanding of their responsibilities.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirements 1.2.2 and 1.2.4



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.2.6	<del>The company shall have an IFS PACsecure representative nominated by senior management.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirements 1.2.2 and 1.2.4
4.2.7	The senior management shall provide sufficient and relevant resources to meet the product requirements.	Modification	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.
4.2.8	<del>The department responsible for quality and packaging material safety management shall have a direct reporting relationship to the senior management.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 1.2.1
4.2.9	The company shall ensure that all processes (documented and undocumented) are known by the relevant personnel and are applied consistently.	Modification	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.
4.2.10	The company shall have a system in place to ensure that it is kept informed of all relevant legislation on packaging material safety and quality issues, scientific and technical developments and industry codes of practice.	Modification	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.2.11	<del>The company shall inform its customers, as soon as possible, of any issue related to product specifications or other legally required documentation in particular of all non-conformity(ies) identified by competent authorities related to products which could have, has or has had a defined impact on safety and/or legality of respective products. This could include, but are not limited to cautionary issues.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 4.1.2
		Inclusion	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: <ul style="list-style-type: none"> <li>– any legal entity name change,</li> <li>– any production site location change.</li> </ul> For the following specific situations: <ul style="list-style-type: none"> <li>– any product recall,</li> <li>– any product recall and / or withdrawals by official order for product safety and / or product fraud reasons,</li> <li>– any visit from health authorities which results in notifications and / or penalties issued by authorities, which are related to the IFS PACsecure Standard scope</li> </ul> the certification body shall be informed within three (3) working days.
1.3	<b>Customer focus</b>	None	1.3	<b>Customer focus</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
1.3.1	A documented procedure shall be in place to identify fundamental needs and expectations of customers.	Modification	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.
1.3.2	<del>The results of this procedure shall be evaluated and considered to determine quality and packaging material safety objectives.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 1.3.1
<b>1.4</b>	<b>Management review</b>	None	<b>1.4</b>	<b>Management review</b>
1.4.1	<del>Senior management shall ensure that the quality and packaging material safety management systems are reviewed at least annually or more frequently if changes occur. Such reviews shall contain, at least, results of audits, customer feedbacks, process compliance and product conformity, status of preventive and corrective actions, quality and product safety policy and objectives, follow up actions from previous management reviews, changes that could affect the packaging material safety and quality management systems and recommendations for improvement.</del>	Modification	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: <ul style="list-style-type: none"> <li>– a review of objectives and policies, including elements of product safety culture</li> <li>– results of audits and site inspections</li> <li>– positive and negative customer feedback, including customer audit results</li> <li>– process compliance and changes / improvements</li> <li>– authenticity and conformity issues</li> <li>– status of corrections and corrective actions</li> <li>– notifications from authorities.</li> </ul>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
1.4.2	<p><del>This review shall include the evaluation of measures for the control of the quality and packaging material safety management system and for the continuous improvement process.</del></p>	Modification	1.4.2	<p>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.</p>
1.4.3	<p>The <del>company</del> shall identify and review regularly (e.g. by internal audits or on-site inspection) the infrastructure needed to <del>achieve conformity</del> to product requirements. This shall include, <del>as a minimum, the following:</del></p> <ul style="list-style-type: none"> <li>– buildings</li> <li>– supply systems</li> <li>– machines and equipment</li> <li>– transport.</li> </ul> <p>The results of the review shall be considered, with due consideration to risk, for investment planning.</p>	Modification	1.4.3	<p>The <b>senior management</b> shall identify and regularly review (e.g. by internal audits or on-site inspection) the infrastructure <b>and work environment</b> needed to <b>conform</b> to product requirements. This shall include, <b>at a minimum:</b></p> <ul style="list-style-type: none"> <li>– buildings</li> <li>– supply systems</li> <li>– machines and equipment</li> <li>– transport</li> <li>– <b>staff facilities</b></li> <li>– <b>environmental conditions</b></li> <li>– <b>hygienic conditions</b></li> <li>– <b>workplace design</b></li> <li>– <b>external influences (e.g. noise, vibration).</b></li> </ul> <p>The results of the review shall be considered, with due consideration to risk, for investment planning.</p>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
1.4.4	<del>The company shall identify and review regularly (e.g. by internal audits or on-site inspection) the work environment needed to achieve conformity to product requirements. This shall include, as a minimum the following: – 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.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 1.4.3
<b>2</b>	<b>Quality and Packaging Material Safety Management System</b>	Modification	<b>2</b>	<b>Product safety and quality management system</b>
<b>2.1</b>	<b>Quality management</b>	None	<b>2.1</b>	<b>Quality management</b>
<b>2.1.1</b>	<b>Documentation requirements</b>	Modification	<b>2.1.1</b>	<b>Document management</b>
2.1.1.1	<del>The system of packaging material safety and quality management shall be documented and implemented, and shall be retained in one location (packaging material safety and quality manual or electronic documented system).</del>	Modification	2.1.1.1	The <b>product safety and quality management system</b> shall be documented and implemented, and shall be <b>kept</b> in one secure location. <b>This is applicable for physical and / or digital documentation systems.</b>
2.1.1.2	A documented procedure shall exist for the control of documents and their amendments.	Modification	2.1.1.2	A documented procedure shall exist for the control of documents and their amendments. <b>All documents which are necessary for compliance with the product requirements shall be available in their latest version.</b> <b>The reason for any amendments to documents,</b>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				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.	None	2.1.1.3	All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times.
2.1.1.4	<del>All documents which are necessary for compliance with the product requirements shall be available in their latest version.</del>	Deletion		Merged in new 2.1.1.2
2.1.1.5	<del>The reason for any amendments to documents critical for the product requirements shall be recorded.</del>	Deletion		Merged in new 2.1.1.2
<b>2.1.2</b>	<b>Record keeping</b>	Modification	<b>2.1.2</b>	<b>Records and documented information</b>
2.1.2.1	<del>All relevant records necessary for the product requirements shall be complete, detailed and maintained and shall be available on request.</del>	Modification	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	<del>Records shall be legible and genuine. They shall be maintained in a way that subsequent manipulation of records is prohibited.</del>	Deletion		Merged in new 2.1.2.1



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
2.1.2.3	All records shall be kept in accordance with legal requirements and for a minimum of one year after the <del>recommended</del> converting time. For products which have no <del>recommended</del> converting time, the duration of record keeping shall be justified and this justification shall be documented.	Modification	2.1.2.2	All records <b>and documented information</b> shall be kept in accordance with legal requirements <b>and customer requirements</b> . <b>If no such requirements exist, records and documented information shall be kept</b> for a minimum of one year after the specified converting time. For products which have no <b>specified</b> converting time, the duration of record <b>and documented information</b> keeping shall be justified and this justification shall be documented.
2.1.2.4	Any amendments to records shall only be carried out by authorized persons.	Modification	2.1.2.3	Any amendments to records shall only be carried out by <del>authorised</del> persons.
2.1.2.5	<del>Records shall be securely stored and easily accessible.</del>	Deletion		<b>Merged in new 2.1.2.1</b>
<b>2.2</b>	<b>Packaging Material Safety Management</b>	Modification	<b>2.2</b>	<b>Product safety and quality management</b>
<b>2.2.1</b>	<b>Hazard analysis and risk assessment system</b>	None	<b>2.2.1</b>	<b>Hazard analysis and risk assessment system</b>
		Inclusion	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
<del>2.2.1.1</del>	The basis of the company's <del>packaging material safety control</del> system shall be a fully implemented, systematic and comprehensive hazard analysis and/or risk assessment system, based upon the Codex Alimentarius principles or on industry guidelines. It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The hazard analysis and/or risk assessment system shall be implemented at each production site.	Modification	2.2.1.2	The basis of the company's <b>product safety and quality management</b> system shall be a fully implemented, systematic, comprehensive <b>and documented</b> hazard analysis and risk assessment system, based upon the Codex Alimentarius principles or on <b>other applicable and recognised</b> industry guidelines. It shall take into account any legal <b>and regulatory</b> requirements of the production and destination countries which may go beyond such principles <b>or guidelines</b> . The hazard analysis and risk assessment system shall be <b>specific and</b> implemented at each production site.
<del>2.2.1.2</del>	The hazard analysis and/or risk assessment system shall cover all raw materials, products or product groups as well as every process from goods <del>into</del> dispatch, including product development <del>and product packaging</del> .	Modification	2.2.1.3	The hazard analysis and risk assessment system shall cover all raw materials, <b>wrapping materials</b> , products or product groups as well as every <b>production / conversion</b> process ( <b>including outsourced process</b> ) from <b>incoming goods up to the dispatch of finished products</b> , including product development.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
<del>2.2.1.3</del>	The company shall ensure that the hazard analysis and/or risk assessment system is based upon scientific literature, or technical verified <del>specifications or other legally required documentations</del> relating to the manufactured products and <del>procedures</del> . This shall be maintained in line with new technical process development.	Modification	2.2.1.4	The company shall ensure that the hazard analysis and risk assessment system is based upon scientific literature, or technical verified <b>information related</b> to the manufactured products and processes, <b>or expert advice obtained from other sources, which may include:</b> <ul style="list-style-type: none"> <li>– trade and industry associations,</li> <li>– independent experts,</li> <li>– and regulatory authorities.</li> </ul> This <b>information</b> shall be maintained in line with <b>any new technical and scientific</b> process development.
<del>2.2.1.4</del>	The hazard analysis and/or risk assessment system shall be reviewed and <del>necessary changes shall be made when any modification is made in the product, process or any step.</del>	Modification	2.2.1.5	The hazard analysis and risk assessment system shall be regularly reviewed, <b>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.</b>
<b>2.2.2</b>	<b>Hazard analysis and/or risk assessment team</b>	Modification	<b>2.2.2</b>	<b>Hazard analysis and risk assessment team</b>
2.2.2.1	Assemble hazard analysis and/or risk assessment team The hazard analysis and/or risk assessment team shall be multidisciplinary and include operational staff. Personnel appointed as hazard analysis and/or risk assessment team members shall have specific knowledge of hazard analysis and/or risk assessment, product and process knowledge and the	Modification	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 <b>associated to products and processes.</b>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
	<del>associated hazards. Where competent knowledge is not available, external expert advice shall be obtained.</del>			
2.2.2.2	Those responsible for the development and maintenance of the hazard analysis and/or risk assessment system <del>shall have an internal team leader</del> and shall have received adequate training in the application of the hazard analysis and/or risk assessment principles.	Modification	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. <b>An internal team leader shall be designated.</b>
2.2.2.3	<del>The hazard analysis and/or risk assessment team shall have strong senior management support and shall be well known and established across the whole facility.</del>	Deletion		<b>The req. 2.2.2.3 was erased due to the senior management engagement with the HA/RA team is part of the commitment with the Quality and Product Safety Management System; therefore, it shall be audited according to the requirement 1.2.3 that was reworded. Specific questions in guidance were included to check this topic.</b>
<b>2.2.3</b>	<b>Hazard analysis and risk assessment</b>	None	<b>2.2.3</b>	<b>Hazard analysis and risk assessment</b>

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
2.2.3.1	<p>Describe product</p> <p><del>The assessment shall make reference to the full description of the product including all applicable relevant information on product safety such as:</del></p> <ul style="list-style-type: none"> <li><del>– composition (raw materials, rework, reprocessing, recycled waste etc.),</del></li> <li><del>– physical, chemical and microbiological parameters,</del></li> <li><del>– methods of treatment,</del></li> <li><del>– wrapping, labeling,</del></li> <li><del>– durability (shelf life),</del></li> <li><del>– conditions for storage and method of transport.</del></li> </ul>	Modification	2.2.3.1	<p>Describe product</p> <p>A full description of the product including all applicable relevant information on product requirements shall exist, such as:</p> <ul style="list-style-type: none"> <li>– composition (raw materials, rework, reprocessing, recycled materials, plant based materials, functional additives, etc.)</li> <li>– physical, sensory, chemical, functional and microbiological characteristics</li> <li>– legal requirements in regard to product safety and quality</li> <li>– methods of treatments</li> <li>– wrapping and labelling</li> <li>– durability (converting time)</li> <li>– conditions for storage, method of transport and distribution</li> </ul>
2.2.3.2	<p>Identify intended use</p> <p>The intended use of the product shall be described in relation to the expected use of the product by the consumer, <del>taking into account vulnerable groups of consumers.</del></p>	Modification	2.2.3.2	<p>Identify intended use</p> <p>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:</p> <ul style="list-style-type: none"> <li>– Products are intended to be sold to consumers</li> <li>– There is no subsequent transformation process that changes the characteristics and / or intended use of the product after it is sold to the customers.</li> </ul> <p>When consumers shall be considered, possible</p>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				misuse and vulnerable groups shall be taken into account.
2.2.3.3	<p>Construct flow diagram</p> <p><del>A process flow diagram shall be evaluated against</del> each product, or product group, and for all variations of the processes and sub-processes.</p>	Modification	2.2.3.3	<p>Construct flow diagram</p> <p>A flow diagram shall <b>exist for</b> each product, or product group, and for all variations of the processes and sub-processes (<b>including rework and reprocessing</b>).</p> <p>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.</p>
2.2.3.4	<p>On-site confirmation of the flow diagram</p> <p>The risk assessment team shall review the processes at all operation stages against the flow diagram. Where appropriate, amendments of the diagram will be made.</p>	Modification	2.2.3.4	<p>On-site confirmation of the flow diagram</p> <p>The <b>hazard analysis and risk assessment team, or their defined representatives, shall verify the flow diagram by on-site verifications</b> at all operation stages and shifts.</p> <p>Where appropriate, amendments to the diagram shall be made.</p>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
		Inclusion	<b>2.2.3.5</b>	<b>Conduct a hazard analysis and risk assessment for each step</b>
2.2.3.5	<p><del>Conduct a hazard analysis and risk assessment for each step</del>            An assessment shall be available of all physical, chemical and biological hazards that may reasonably be expected.</p>	Modification	2.2.3.5.1	<p>A hazard analysis and risk assessment shall be conducted for all possible and reasonably expected physical, chemical (including radiological and allergens) and biological hazards.</p> <p>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.</p>
<del>2.2.3.5.1</del>	<p><del>The hazard analysis shall demonstrate the motivation if a hazard is a risk, taking into account the likelihood of harm to the consumer and the potential severity of damage (effect, potential consequences).</del></p>	Modification	2.2.3.5.2	<p>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.</p>
		Inclusion	<b>2.2.3.6</b>	<b>Determine Critical Control Points (CCP) and other control measures</b>
		Inclusion	2.2.3.6.1	<p>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.</p>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
		Inclusion	<b>2.2.3.7</b>	<b>Establish limits for each CCP and other control measures</b>
		Inclusion	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.
2.2.3.5.2	<del>All risks that need specific monitoring and/or preventive actions shall be identified as Control Points (CP). Clear limits and registration of the risk identification shall be available.</del>	Modification	2.2.3.7.2	For other control measures defined, appropriate limits shall be determined.
		Inclusion	<b>2.2.3.8</b>	<b>Establish a monitoring system for each CCP and other control measures</b>
		Inclusion	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.



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
2.2.3.5.3	<del>For all risks that are identified as Control Points (CP) to manage the identified risk, the company shall implement, maintain and document specific preventive measures and monitoring procedures. Records of monitoring shall be maintained for a relevant period.</del>	Modification	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.
		Inclusion	<b>2.2.3.9</b>	<b>Establish corrective actions</b>
2.2.3.6	<del>Establish corrective actions For each CP corrective actions shall be established. In case the monitoring indicates that a particular CP is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any non-conforming products.</del>	Modification	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.
		Inclusion	<b>2.2.3.10</b>	<b>Establish verification procedures</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
2.2.3.7	<p><del>Establish verification procedures</del>            Procedures of verification shall be established to confirm that the risk management system is effective. Verification of the risk management system shall be performed at least once a year. Examples of verification activities include:</p> <ul style="list-style-type: none"> <li>– internal audits,</li> <li>– analysis,</li> <li>– sampling,</li> <li>– evaluations,</li> <li>– complaints by authorities and customers.</li> </ul> <p>The results of this verification shall be incorporated into the risk management system, and shall be communicated to and reviewed by the senior management</p>	Modification	2.2.3.10.1	<p>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:</p> <ul style="list-style-type: none"> <li>– results of internal audits and site factory inspections</li> <li>– analyses</li> <li>– sampling</li> <li>– complaints by authorities and customers</li> <li>– deviations</li> </ul> <p>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.</p>
		Inclusion	2.2.3.11	<b>Establish documentation and record keeping</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
2.2.3.8	<del>Establish documentation</del> Documentation shall be available, covering all processes, procedures, measures and records. Documentation and record keeping shall be appropriate to the nature and size of the company.	Modification	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.
<b>3</b>	<b>Resource Management</b>	None	<b>3</b>	<b>Resource management</b>
<b>3.1</b>	<b>Human resources management</b>	Modification	<b>3.1</b>	<b>Human resources</b>
3.1.1	All personnel performing work that affects product safety, legality and quality shall have the required competence by education, work experience and/or training, commensurate with their role, based on hazard analysis and assessment of associated risks.	Modification	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
		Inclusion	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.
<b>3.2</b>	<b>Human resources</b>	Deletion		<b>Deleted for clarity on titles and content of related requirements.</b>
<b>3.2.1</b>	<b>Personnel hygiene</b>	Modification	<b>3.2</b>	<b>Personal hygiene</b>
3.2.1.1	<p><del>There shall be documented requirements relating to personnel hygiene. These include, as a minimum, the following fields:</del></p> <ul style="list-style-type: none"> <li><del>– protective clothing</del></li> <li><del>– hand washing and disinfection</del></li> <li><del>– eating and drinking</del></li> <li><del>– smoking</del></li> <li><del>– actions to be taken in case of cuts or skin abrasions</del></li> <li><del>– fingernails, jewelry and personal belongings</del></li> <li><del>– hair and beards.</del></li> </ul> <p><del>The requirements shall be based on hazard analysis and assessment of associated risks in relation to product and process.</del></p>	Modification	3.2.1	<p>Based on hazard analysis and assessment of associated risks, the requirements for personal hygiene shall consider, at a minimum, the following topics:</p> <ul style="list-style-type: none"> <li>– coverage of hair and beards</li> <li>– protective clothing (including their condition of use in productive areas and staff facilities)</li> <li>– hand washing, disinfection and hygiene</li> <li>– eating, drinking and smoking</li> <li>– actions to be taken in case of cuts or skin abrasions</li> <li>– fingernails, personal belongings (including medicines), and prohibition to use jewellery</li> <li>– notification of infectious diseases and conditions impacting product safety via a medical screening procedure, subject to legal restrictions in the country of operation.</li> </ul>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				The requirements relating to personal hygiene shall be documented and in place.
<b>3.2.1.2 KO no. 2</b>	<b>The requirements for personnel hygiene shall be in place and applied by all relevant personnel, contractors and visitors.</b>	Modification	3.2.2 KO No. 3	The requirements for personal hygiene shall be in place and applied by all relevant personnel, contractors and visitors.
3.2.1.3	Compliance with personnel hygiene requirements shall be checked regularly.	Modification	3.2.3	Compliance with personal hygiene requirements shall be checked regularly.
3.2.1.4	Visible jewelry (incl. piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated by hazard analysis and assessment of associated risks in relation to product and process. This shall be effectively managed.	Deletion		Merged in new 3.2.1
3.2.1.5	Cuts and skin abrasions shall be covered by a colored plaster/bandage (different from the product color) containing a metal strip, where appropriate — and in case of hand injuries, in addition to a plaster/bandage, a single use glove shall be worn.	Modification	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.



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
<del>3.2.2</del>	<b>Working conditions and protective clothing for personnel, contractors and visitors</b>	Deletion		Deleted for clarity on titles and content of related requirements.
3.2.2.1	Company procedures shall exist to ensure that all personnel, contractors and visitors are aware of the rules regarding the management of wearing and changing of protective clothing in specified areas in accordance with product requirements.	Deletion		Merged in IFS PACsecure version 2, in the requirements 3.2.1 & 3.2.2
3.2.2.2	In work areas where wearing headgear and/or beard snood (coverings) is required, the hair shall be covered completely, so that product contamination is prevented.	Deletion		Merged in new 3.2.1
3.2.2.3	Clearly defined usage rules shall exist for work areas/activities where it is required to wear gloves (colored differently from the product color). Compliance with these rules shall be checked on a regular basis.	Deletion		Merged in IFS PACsecure version 2, in the requirements 3.2.1, 3.2.2 and 3.2.3
3.2.2.4	Suitable protective clothing shall be available in sufficient quantity for each employee, <del>when required.</del>	Modification	3.2.5	Suitable protective clothing shall be available and in sufficient quantity for each employee.
3.2.2.5	When required, all protective clothing shall be thoroughly and regularly laundered. <del>Hazard analysis and assessment of associated risks, together with consideration given to the processes and products of the company shall determine if clothing shall be washed by a contract laundry, on site laundry or by the employee.</del>	Modification	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, <b>and the decision shall be justified by risk assessment.</b> Defined requirements shall ensure, at a minimum: – sufficient segregation between dirty and clean clothing at all times

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				– avoidance of contamination until use The effectiveness of the laundering conditions defined shall be appropriately monitored.
3.2.2.6	Guidelines shall exist for laundering of protective clothing and a procedure shall be in place for checking its cleanliness, when required.	Deletion		Merged in new 3.2.9
3.2.2.7	Senior management shall ensure hazardous working conditions that could cause injuries to personnel are identified and preventive measures are managed.	Deletion		Requirement not related to product safety.
3.2.2.8	The company shall review that preventive measures to ensure personnel safety related to hazardous working conditions are effective, in line with applicable legislation or recognized conventions.	Deletion		Requirement not related to product safety.
<b>3.2.3</b>	<b>Procedures applicable to infectious diseases</b>	Deletion		Deleted for clarity on titles and content of related requirements.
3.2.3.1	<del>There shall be written and communicated measures for personnel, contractors and visitors to declare any infectious disease which may have an impact on packaging material safety. In case of declaration of infectious disease, actions shall be taken in order to minimize risk of contamination of products.</del>	Modification	3.2.7	In case the personnel, contractors and / or visitors <b>have infectious diseases and / or conditions that may have an impact on product safety</b> , actions shall be taken to minimise contamination <b>risks</b> .
<b>3.3</b>	<b>Training and instruction</b>	None	<b>3.3</b>	<b>Training and instruction</b>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
3.3.1	<p>The company shall implement documented training and/or instruction programs with respect to the product requirements and the training needs of the employees based on their job and shall include:</p> <ul style="list-style-type: none"> <li>– training contents</li> <li>– training frequency</li> <li>– employee’s task</li> <li>– languages</li> <li>– qualified trainer/tutor</li> <li>– <del>evaluation methodology.</del></li> </ul>	Modification	3.3.1	<p>The company shall implement documented training and / or instruction programs with respect to the product <b>and process</b> requirements and the training needs of the employees based on their job and shall include:</p> <ul style="list-style-type: none"> <li>– <b>training objectives</b></li> <li>– training contents</li> <li>– training frequency</li> <li>– employee's task</li> <li>– languages</li> <li>– qualified trainer / tutor</li> </ul> <p><b>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.</b></p>
3.3.2	<p>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 in accordance with the documented training/instruction programs.</p>	Modification	3.3.2	<p>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 / <b>instructed</b> in accordance with the documented training / instruction programs.</p>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
3.3.3	Records shall be available of all training/instruction events, stating: <ul style="list-style-type: none"> <li>– list of participants (this shall include their signature)</li> <li>– date</li> <li>– duration</li> <li>– contents of training</li> <li>– name of trainer/tutor.</li> </ul> <del>There shall be a procedure or program in place to prove the effectiveness of the training and/or instruction programs.</del>	Modification	3.3.3	Records shall be available of all training / instruction events, stating: <ul style="list-style-type: none"> <li>– list of participants (this shall include their signature)</li> <li>– date</li> <li>– duration</li> <li>– contents of training</li> <li>– name of trainer / tutor.</li> </ul>
3.3.4	The contents of training and/or instruction shall be reviewed and updated <del>regularly and take into account company's specific issues,</del> packaging material safety, packaging material related legal requirements and product/process modifications.	Modification	3.3.4	The contents of training and / or instruction shall be <b>regularly</b> reviewed and updated <b>when necessary</b> . <b>Special considerations shall be given as a minimum to these specific topics:</b> <ul style="list-style-type: none"> <li>– <b>product safety culture</b></li> <li>– product safety, quality and legal requirements</li> <li>– <b>product fraud,</b></li> <li>– <b>product defence,</b></li> <li>– product / process modifications,</li> <li>– <b>complaints and non-conformities related to product compliance and its impact on customers (and consumers, if applicable)</b></li> <li>– <b>feedback from the previous documented training / instruction program.</b></li> </ul>
3.4	<del><b>Sanitary facilities, equipment for personnel hygiene and staff facilities</b></del>	Modification	3.4	<b>Staff facilities</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
3.4.1	The company shall provide staff facilities, which shall be proportional in size, equipped for the number of personnel and designed and operated so as to minimize <del>packaging material</del> safety risks. Such facilities shall be kept in clean and good condition.	Modification	3.4.1	The company shall provide <b>suitable</b> staff facilities, which shall be proportional in size, equipped for the number of personnel and designed and operated so as to minimise <b>product</b> safety risks. Such facilities shall be kept in <b>a</b> clean and good condition.
3.4.2	The risk of product contamination by foreign material from staff facilities shall be evaluated and minimized. Consideration shall <del>also</del> be given to food <del>and other material</del> brought to work by personnel <del>and personal belongings</del> .	Modification	3.4.2	The risk of product contamination by <b>food, drink and / or</b> foreign material from staff facilities shall be evaluated and minimised. Consideration shall be given to food <b>and drink from vending machines, canteen and / or</b> brought to work by personnel.
3.4.3	<del>There shall be in place rules and facilities to ensure the correct management for personnel belongings and for food and other material brought to work by personnel, food coming from dining room and from vending machines. The food and other material shall only be stored and/or used in designated areas.</del>	Deletion		<b>Merged in IFS PACsecure version 2, in the requirements 3.2.1, 3.2.2 &amp; 3.2.3.</b>
3.4.4	<del>The company shall provide suitable changing rooms for personnel, contractors and visitors. Where necessary, outdoor clothing and protective clothing shall be stored separately.</del>	Modification	3.4.3	<b>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.</b> Where necessary, outdoor clothing and protective clothing shall be stored separately.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
3.4.5	Toilets shall <del>not have direct access to an area where packaging material</del> products are handled. The toilets shall be equipped with adequate hand washing facilities. Sanitary facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.	Modification	3.4.4	Toilets shall <b>neither have direct access nor pose a contamination risk to an area where</b> 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.
3.4.6	<del>Adequate hand hygiene facilities shall be provided at access points to and within production areas, as well as at staff facilities. Based on hazard analysis and assessment of associated risks, further areas (e.g. wrapping area) shall be similarly equipped.</del>	Modification	3.4.5	<b>Hand hygiene facilities shall be provided and shall address, at a minimum:</b> <ul style="list-style-type: none"> <li>– sufficient number of wash basins,</li> <li>– suitably located at access points to and / or within production areas,</li> <li>– sole use for cleaning hands only.</li> </ul> Where similar equipment is needed in further areas (e.g. storage area), these shall be based on hazard analysis and assessment of associated risks.
3.4.7	Hand <del>washing</del> facilities shall provide <del>as a minimum:</del> <ul style="list-style-type: none"> <li>– running potable water at an appropriate temperature</li> <li>– <del>liquid soap</del></li> <li>– appropriate <del>equipment</del> for hand drying.</li> </ul>	Modification	3.4.6	Hand <b>hygiene</b> facilities shall provide: <ul style="list-style-type: none"> <li>– running potable water at an appropriate temperature,</li> <li>– <b>appropriate cleaning and disinfection equipment,</b></li> <li>– appropriate <b>means</b> for hand drying.</li> </ul>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
3.4.8	<del>If necessary, following additional requirements regarding hand hygiene shall also be provided:</del> <ul style="list-style-type: none"> <li><del>– hand contact-free fittings</del></li> <li><del>– hand disinfection</del></li> <li><del>– adequate hygiene equipments</del></li> <li><del>– signage highlighting hand hygiene requirements</del></li> <li><del>– waste container with hand contactfree opening.</del></li> </ul>	Modification	3.4.7	Where the processes require a higher standard of hygiene, the hand washing equipment shall provide in addition: <ul style="list-style-type: none"> <li>– hand contact-free fittings,</li> <li>– hand disinfection,</li> <li>– waste container with hand contact-free opening.</li> </ul>
3.4.9	Based on hazard analysis and assessment of associated risks, <del>there shall be a program to control effectiveness of hand hygiene.</del>	Modification	3.4.8	Based on hazard analysis and assessment of associated risks, <b>a program shall be in place</b> to control effectiveness of hand hygiene.
3.4.10	<del>Changing rooms shall be separated from production area and shall be situated so that they allow direct access to the areas where packaging material products are handled.</del> Based on hazard analysis and assessment of associated risks, exceptions shall be justified and managed.	Deletion		<b>Merged in 3.4.1</b>
3.4.11	<del>Where the hazard analysis and assessment of associated risks show the necessity,</del> cleaning facilities shall be available and used for boots, shoes and further protective clothing.	Modification	3.4.9	<b>Where it is justified by risk assessment,</b> cleaning and disinfection facilities shall be available and used for boots, shoes and further protective clothing.
<b>4</b>	<b>Planning and Production Process</b>	Modification	<b>4</b>	<b>Operational processes</b>
<b>4.1</b>	<b>Contract agreement</b>	None	<b>4.1</b>	<b>Contract agreement</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.1.1	The requirements <del>which are</del> defined between the <del>contract partners</del> shall be established, agreed upon and reviewed concerning their acceptability before a supply agreement is concluded. All <del>clauses</del> related to quality and <del>packaging material</del> safety shall be <del>known</del> and communicated to each relevant department.	Modification	4.1.1	The requirements defined between <del>the company and its customers</del> shall be established, agreed upon and reviewed concerning their acceptability before the supply agreement is concluded. All requirements related to <del>product</del> safety and quality <del>within defined agreement with customers, and any revision of these clauses,</del> shall be communicated to <del>and implemented by</del> each relevant department.
4.1.2	<del>Changes of existing contractual agreements shall be documented and communicated between the contract partners.</del>	Deletion		Merged in 4.4.1
<del>4.2.11</del>	<del>The company shall inform its customers, as soon as possible, of any issue related to product specifications or other legally required documentation in particular of all non-conformity(ies) identified by competent authorities related to products which could have, has or has had a defined impact on safety and/or legality of respective products. This could include, but are not limited to cautionary issues.</del>	Inclusion	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	<b>Specifications and formulas / configurations</b>	None	4.2	<b>Specifications and formulas / configurations</b>
4.2.1	<b>Specifications and other legally required documentation</b>	Modification	4.2.1	<b>Specifications</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.2.1.5	<p><del>There shall be a procedure for the creation, the modification and approval of specifications or other legally required documentation for all parts of the process, which shall include the preliminary acceptance of the customer, if specifications or other legally required documentation have been agreed with customers.</del></p>	Modification	4.2.1.1	<p>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:</p> <ul style="list-style-type: none"> <li>– 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.</li> <li>– how to communicate the information and its changes inside the company and, when applicable, to the customer.</li> <li>– the management of customers' specifications and the protection of its information, when existing.</li> </ul>
4.2.1.6	<p><del>The specification/other legally required documentation control procedure shall include the update of finished product specification in case of any modification:</del></p> <ul style="list-style-type: none"> <li><del>– of raw material</del></li> <li><del>– of formula/configuration</del></li> <li><del>– of process with influence on the final products</del></li> <li><del>– of wrapping material with influence on the final products.</del></li> </ul>	Deletion		Merged in 4.2.1

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.2.1.2 KO no. 3:	<del>Specifications or other legal required documentation shall be available and in place for all raw materials (raw materials, additives, inks, adhesives, solvents, wrapping materials, rework).</del> <b>Specifications shall be up to date, unambiguous and be in compliance with legal requirements and, if existing, with customer requirements.</b>	Modification	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.
4.2.1.1	<del>Specifications or other legally required documentation 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.</del>	Modification	4.2.1.3	Specifications shall be available and in place for all finished products. They shall be up to date, unambiguous and be in compliance with legal and customer requirements.
4.2.1.3	Where required by customers, product specifications shall be formally agreed.	Deletion		Merged in 4.2.1.1
4.2.1.4	<del>Specifications or other legally required documentation and/or their contents shall be provided in the relevant location and accessible to all relevant personnel.</del>	Modification	4.2.1.4	Specifications and / or their components shall be available on-site for all relevant personnel.
		Inclusion	4.2.1.5	A procedure shall be in place to verify and ensure, when applicable: <ul style="list-style-type: none"> <li>– 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.).</li> <li>– the clearness, accuracy and truthfulness of claims according to the intended use of products,</li> </ul>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				by means of scientific evidence and the relevant tests / analysis.
<b>4.2.2</b>	<b>Formula / configuration</b>	None	<b>4.2.2</b>	<b>Formula / configuration</b>
<b>4.2.2.1 KO no. 4</b>	<b>Where there are customer agreements <del>in relation to the product formula/configuration and technological requirements, these shall be complied with.</del></b>	Modification	<b>4.2.2.1 KO No. 5</b>	Where there are customer agreements <b>related to:</b> <ul style="list-style-type: none"> <li>– product formulation / configuration</li> <li>– <b>process and</b> technological requirements</li> <li>– <b>labelling</b></li> <li>– <b>wrapping</b></li> </ul> <b>they shall be complied with.</b>
<b>4.3</b>	<b>Product development/Product modification/Modification of production processes</b>	Modification	<b>4.3</b>	<b>Product development, product modification, and / or modification of production / conversion processes</b>
4.3.1	<del>A procedure for product development shall be in place which incorporates the hazard analysis principles, in accordance with the HACCP and/or risk assessment system.</del>	Modification	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.





## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				When applicable, necessary changes shall be made.
4.3.2	<p><del>Product formulation/configuration, manufacturing processes, process parameters and the fulfilment of product requirements shall be established and shall have been assured by factory trials and product testing.</del></p>	Modification	4.3.2	<p>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.</p> <p>The progress and results of the product development / modification and modification of production / conversion process shall be recorded.</p>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
		Inclusion	4.3.3	<p>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:</p> <ul style="list-style-type: none"> <li>– responsibilities and activities related to the management of artwork and customer-approved reference material between the company and customer.</li> <li>– approval of final artwork, of product concepts, of printing specifications and the identification of critical information, by the customer, when applicable.</li> <li>– Usage and storage conditions of approved artwork master, customer-approved reference material and printing materials, in order to avoid their degradation, misuse and loss.</li> <li>– management of renewal, changes and obsolescence of artwork masters, customer-approved reference material and printing materials, including their disposal.</li> </ul>
4.3.3	<p><del>Recommendation for use tests or adequate processes shall be carried out and consideration given to product formulation/configuration, wrapping material, manufacturing and declared conditions.</del></p>	Modification	4.3.4	<p>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.</p>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				In accordance with this evaluation, the conversion time shall be established.
4.3.4	Product development shall consider the results of organoleptic assessments.	Deletion		Merged in IFS PACsecure version 2, in the requirements 4.3.3 and 4.3.4
4.3.5	A process shall be in place to ensure that the finished product complies with current legislation of destination country and customer requirements.	Modification	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 and/or use of the packaging materials shall be established. Where appropriate, customer requirements shall be included.	Modification	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	The progress and results of product development shall be properly recorded.	Deletion		Merged in 4.3.3
4.3.8	The company shall ensure that in the event of changes to product formulation/configuration, including rework and wrapping material, process characteristics are reviewed in order to assure that product requirements are complied with.	Modification	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	<b>Purchasing</b>	None	4.4	<b>Purchasing</b>
4.4.1	<b>General purchasing</b>	Deletion		Deleted for clarity on titles and content of related requirements.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.4.1.1	The company shall control purchasing processes to ensure that all externally sourced materials and services, which have an impact on packaging material safety and quality, conform to requirements. <del>Where a company chooses to outsource any process that may have an impact on packaging material safety and quality, the company shall ensure control over such processes. Control of such outsourced processes shall be identified and documented within the packaging material safety and quality management system.</del>	Modification	4.4.1	The company shall control purchasing processes to ensure that all externally sourced raw materials, <b>semi-finished products, wrapping materials</b> and services, which have an impact on <b>product safety and quality</b> , conform to <b>defined</b> requirements.
4.4.1.2	There shall be a procedure for approval and monitoring of suppliers ( <del>internal and external</del> ), <del>outsourced production or part of it.</del>	Modification	4.4.2	A procedure for the approval and monitoring of suppliers <b>shall be in place. The approval and monitoring procedure shall contain clear assessment criteria, such as:</b> <ul style="list-style-type: none"> <li>– audits performed by an experienced and competent person</li> <li>– certificates of analyses</li> <li>– supplier reliability</li> <li>– complaints</li> <li>– required performance standards.</li> </ul>
4.4.1.3	<del>The approval and monitoring procedure shall contain clear assessment criteria such as: audits, certificates of analysis, supplier reliability and complaints, as well as required performance standards.</del>	Deletion		<b>Merged in 4.4.2</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.4.1.4	The results of suppliers' assessments shall be reviewed regularly and this review shall be based on <del>hazard analysis and assessment of associated risks</del> . There shall be records of the reviews and of the <del>actions taken as a consequence of assessment</del> .	Modification	4.4.3	The results from the supplier assessments shall be reviewed regularly and this review shall be <b>justified by risk assessment</b> . There shall be records of the reviews and <b>the consequential actions of the assessment shall be documented</b> .
4.4.1.5	The purchased products shall be checked in accordance with the existing specifications <del>or other legally required documentation</del> . The schedule of these checks shall, as a minimum, <del>take into account the following criteria: product requirements, supplier status (according to its assessment) and impact of the purchased products on the finished product</del> . If mentioned in the <del>specifications or other legally required documentation</del> additional required topics shall be checked.	Modification	4.4.4	The purchased raw materials, semi-finished products and wrapping materials shall be checked in accordance with the existing specifications <b>and justified by risk assessment for their authenticity</b> . The schedule of these checks shall take <b>at a minimum, defined product safety and quality risks</b> . The frequency and scope of sampling shall be based on: – the impact of the raw materials, semi-finished product and wrapping materials on the finished product – the supplier's status
4.4.1.6	The purchased services shall be checked in accordance with the existing specifications <del>or other legally required documentation</del> . The schedule of these checks shall at least take into account <del>the following items: service requirements, supplier status (according to its assessment) and impact of the service on the finished product</del> .	Modification	4.4.5	The purchased services shall be checked in accordance with the existing specifications. The schedule of these checks shall take into account, <b>at a minimum:</b> – the <b>defined</b> service requirements, – the supplier status <b>according to its assessment</b> – the impact of the service on the finished product.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
		Inclusion	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.
		Inclusion	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.
		Inclusion	4.4.8	The company shall approve the supplier of the outsourced processes through: <ul style="list-style-type: none"> <li>– certification to IFS PACsecure or other GFSI recognised production of food packaging certification standard, or</li> <li>– documented supplier audit, performed by an experienced and competent person, and shall cover at least the requirements related to product safety, quality, legality and authenticity.</li> </ul>
<b>4.5</b>	<b>Product wrapping</b>	None	<b>4.5</b>	<b>Product wrapping</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.5.1	Based on hazard analysis, assessment of associated risks and intended use, the company shall determine the key parameters for the wrapping material.	Modification	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 <b>in detailed specifications complying with the current relevant legislation and other relevant hazards or risks.</b> The company shall check and verify the suitability of the wrapping material used on products by means of the relevant test / analysis, such as: <ul style="list-style-type: none"> <li>– sensory tests</li> <li>– chemical analysis</li> <li>– functional test</li> <li>– storage and distribution tests</li> <li>– migration test results.</li> </ul>
4.5.2	<del>Detailed specifications shall exist for all wrapping materials which comply with the current relevant legislation.</del>	Deletion		<b>Merged in 4.5.1</b>
4.5.3	For all wrapping material which could have an <del>influence</del> on products, certificates of conformity shall exist <del>which comply with current legal requirements.</del> In the event that no specific legal requirements are applicable, evidence shall be available to demonstrate that wrapping material is suitable for use. This applies for wrapping material which could have an influence on raw materials, <del>semiprocessed</del> and finished products.	Modification	4.5.2	For all wrapping material which could have an <b>impact</b> on products, certificates of conformity shall exist <b>which attest conformance with legal requirements.</b> 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, <b>semi-finished</b> and finished products.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.5.4	<del>Based on hazard analysis and assessment of associated risks, the company shall verify the suitability of the wrapping material for each relevant product (e.g. organoleptic tests, storage tests, chemical analysis, migration tests).</del>	Deletion		Merged in 4.5.1
4.5.5	<del>The company shall ensure that the wrapping used corresponds to the product being wrapped. The use of correct wrapping shall be regularly checked.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 4.5.3
4.5.6	<del>Printing and labeling information shall be legible, indelible and shall comply with agreed customer product specifications or other legally required documentations. This shall be regularly checked and checks shall be documented.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 4.5.3
		Inclusion	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	<b>Factory location</b>	None	4.6	<b>Factory location</b>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.6.1	The company shall investigate <del>to what extent</del> the factory environment (e.g. ground, air) may have an adverse impact on product safety and product quality. If <del>product safety and quality could be</del> compromised, appropriate <del>measures</del> shall be <del>established</del> . The effectiveness of the <del>established measures</del> shall be periodically reviewed (examples: extremely dusty air, strong smells).	Modification	4.6.1	The company shall investigate <b>the extent to which</b> the factory environment (e.g. ground, air) may have an adverse impact on product safety and product quality. <b>Where it is established that product safety and / or product quality is at risk of being</b> compromised, appropriate <b>control activities</b> shall be <b>implemented</b> . The effectiveness of the <del>implemented control activities</del> shall be periodically reviewed (examples: extremely dusty air, strong smells).
<b>4.7</b>	<b>Factory Exterior</b>	None	<b>4.7</b>	<b>Factory exterior</b>
4.7.1	<del>The factory exterior shall be maintained to be clean and tidy.</del>	Modification	4.7.1	<b>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.</b>
4.7.2	<del>All external areas of the factory shall be maintained in good condition. Where natural drainage is inadequate, a suitable drainage system shall be installed.</del>	Deletion		<b>Merged in IFS PACsecure version 2, in the requirement 4.7.1</b>
4.7.3	Outdoor storage shall be kept to a minimum. Where goods are stored outside, <del>hazard analysis and assessment of associated risks shall be undertaken in order</del> to ensure that there is no risk of contamination or adverse effect on <del>quality and packaging material safety</del> .	Modification	4.7.2	Outdoor storage shall be kept to a minimum. Where goods are stored outside, <b>it shall be justified by risk assessment</b> to ensure that there is no risk of contamination or adverse effects on <b>product safety and quality</b> .
<b>4.8</b>	<b>Plant layout and process flows</b>	None	<b>4.8</b>	<b>Plant layout and process flows</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.8.1	<del>Plans clearly describing internal flows of finished products, packaging materials, raw materials, waste, personnel, water, etc. shall be in place. A site map covering all buildings of the facility shall be available.</del>	Modification	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	<del>The process flow, from receipt of goods to dispatch, shall be in place so that contamination of raw materials, packaging, semi-processed and finished products is avoided. The risk of cross-contamination shall be minimized through effective measures.</del>	Modification	4.8.2	The process flow from receipt of goods to dispatch, shall be established, reviewed and where necessary, modified to ensure that microbiological, chemical and physical contamination risks of raw materials, wrapping, semi-finished and finished products are avoided. The risk of cross-contamination, mix-ups and mixing, shall be minimised through effective control activities.
4.8.3	In case of sensitive production areas, these shall be operated and monitored to ensure product safety is not compromised.	Modification	4.8.3	In the case of areas sensitive to microbiological, chemical and physical risk(s) which is / are justified by risk assessment, they shall be designed, operated and monitored to ensure product safety is not compromised.
4.8.4	Laboratory facilities and in-process controls shall not affect the product safety.	Modification	4.8.4	Laboratory facilities and in-process controls shall not affect product safety.
<b>4.9</b>	<b>Constructional requirements for production and storage areas</b>	Modification	<b>4.9</b>	<b>Production and storage premises</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
<b>4.9.1</b>	<b>Constructional requirements</b>	None	<b>4.9.1</b>	<b>Constructional requirements</b>
4.9.1.1	Rooms where <del>packaging material</del> products are prepared, treated, processed and stored shall be designed and constructed so <del>that packaging material safety is ensured.</del>	Modification	4.9.1.1	<b>Premises</b> , where products are prepared, treated, processed <b>and / or converted, wrapped</b> and stored, shall be designed and constructed to ensure product safety.
<b>4.9.2</b>	<b>Walls</b>	None	<b>4.9.2</b>	<b>Walls</b>
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.	Modification	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. <b>Walls shall be impervious, wear-resistant, and their surfaces shall be clean and in good condition, to minimise product contamination risks.</b>
4.9.2.2	The surfaces of walls shall be in a good condition and easy to clean; they shall be impervious and wear-resistant.	Deletion		<b>Merged in IFS PACsecure version 2, in the requirement 4.9.2.1</b>
4.9.2.3	The junctions between walls, floors and ceilings shall <del>be designed to facilitate cleaning.</del>	Modification	4.9.2.2	The junctions between walls, floors, and ceilings shall <b>be clean, in good condition, and shall not pose contamination risks.</b>
<b>4.9.3</b>	<b>Floors</b>	None	<b>4.9.3</b>	<b>Floors</b>
4.9.3.1	Floor covering shall be designed to meet production requirements <del>and shall be in good condition and easy to clean.</del> Surfaces shall be impervious and wear-resistant.	Modification	4.9.3.1	Floor coverings shall be designed to meet production requirements, <b>and to facilitate cleaning.</b> <b>Floors shall be impervious, wear-resistant, and their surfaces shall be clean and in good</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				condition, to minimise product contamination risks.
4.9.3.2	The hygienic disposal of waste water shall be ensured. Drainage systems shall be easy to clean and designed to minimize the risk of product contamination (e.g. ingress of pests, etc.).	Modification	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, using appropriate measures. Puddles shall be avoided.	Modification	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 packaging material handling areas, machinery and piping shall be arranged so that waste water, if possible, goes directly into a drain.	Modification	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.
<b>4.9.4</b>	<b>Ceilings / Overheads</b>	None	<b>4.9.4</b>	<b>Ceilings / Overheads</b>
4.9.4.1	Ceilings (or, where no ceilings exist, the inside of roofs) and overhead fixtures (incl. piping, cableway, lamps etc.) shall be constructed to minimize the accumulation of dirt and shall not pose any risk of physical and/or microbiological contamination.	Modification	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, an access to the void shall be provided in order to facilitate cleaning, maintenance and inspections for pest control.	Modification	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
<b>4.9.5</b>	<b>Windows and other openings</b>	None	<b>4.9.5</b>	<b>Windows and other openings</b>
4.9.5.1	Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in good condition.	Modification	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 <b>clean and</b> good condition.
4.9.5.2	Where there is <del>risk of contamination</del> , windows and roof glazing shall remain closed and fixed during production.	Modification	4.9.5.2	Where there <b>are contamination risks</b> , 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 <del>easily removable, good condition pest screens or other measures in order to avoid any contamination.</del>	Modification	4.9.5.3	Where windows and roof glazing are designed to be opened for ventilation purposes, they shall be fitted with <b>protective barriers to minimise the product contamination risk. If pest screens are utilised, they shall be maintained in good condition and clean.</b>
4.9.5.4	In areas where <del>unpackaged product</del> is handled, windows shall be protected against breakage.	Modification	4.9.5.4	In areas where <b>exposed products are</b> handled (e.g. <b>not covered or protected by wrapping</b> ), windows shall be protected against breakage.
<b>4.9.6</b>	<b>Doors and gates</b>	None	<b>4.9.6</b>	<b>Doors and gates</b>
4.9.6.1	Doors and gates shall be in good condition ( <del>e.g. no splintering parts, flaking paints or corrosion</del> ) and <del>easy to clean.</del>	Modification	4.9.6.1	Doors and gates shall be <b>maintained in a clean and</b> good condition. <b>They shall be constructed with materials which avoid:</b> <ul style="list-style-type: none"> <li>– splintering parts</li> <li>– flaking paint</li> <li>– corrosion.</li> </ul>
4.9.6.2	<del>Based on hazard analysis and assessment of associated risks</del> external doors and gates shall be	Modification	4.9.6.2	External doors and gates shall be constructed to prevent the <b>access</b> of pests; if possible, they shall be self-closing.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
	constructed to prevent the ingress of pests; if possible, they shall be self-closing.			
		Inclusion	4.9.6.3	Plastic strip curtains separating the internal areas shall be clean and in good condition.
<b>4.9.7</b>	<b>Lighting</b>	None	<b>4.9.7</b>	<b>Lighting</b>
4.9.7.1	All working areas shall have adequate lighting.	Modification	4.9.7.1	All production / conversion, storage, receipt and dispatch areas shall have the levels of light according to the activities carried out.
4.9.7.2	All lighting equipment shall be protected by shatter proof covers and installed to minimise the risk of breakage.	Deletion		Merged in IFS PACsecure version 2, in chapter 4.12.
<b>4.9.8</b>	<b>Air conditioning / Ventilation</b>	None	<b>4.9.8</b>	<b>Air conditioning / Ventilation</b>
4.9.8.1	Adequate natural and/or artificial ventilation shall exist in all areas.	Modification	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 equipments are installed, filters and other components which require cleaning or replacement shall be easily accessible.	Modification	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 lead to any product safety or quality risks.	Modification	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.	None	4.9.8.4	Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated.
<b>4.9.9</b>	<b>Water supply</b>	Modification	<b>4.9.9</b>	<b>Water</b>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.9.9.1	Water which is used as ingredient in the production process, or for cleaning, shall <del>comply with legal requirements and shall be</del> supplied in sufficient quantity; this also applies to steam and ice used within the production area. <del>A supply of such water shall be available at all times.</del>	Modification	4.9.9.1	Water which is used as an ingredient in the production / <b>conversion</b> process or for cleaning shall <b>be of potable quality at the point of use and</b> supplied in sufficient quantity; this also applies to steam and ice used within the production / <b>conversion</b> area.
4.9.9.2	Recycled water which is used in the process shall not pose a contamination risk. <del>The water shall comply with applicable legal requirements for potable water; records of compliance testing shall be available.</del>	Modification	4.9.9.2	Recycled water, which is used in the process, shall not pose contamination risk.
4.9.9.3	The quality of water, <del>whatever the condition of aggregation,</del> shall be monitored following a risk based sampling plan.	Modification	4.9.9.3	The quality of water ( <b>including recycled water</b> ), <b>steam or ice</b> shall be monitored following a <b>sampling plan based on hazard analysis and assessment of associated risks.</b>
4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall <del>not be</del> connected to the drinking water system, <del>or</del> allow the possibility of reflux to contaminate potable water sources or the factory environment.	Modification	4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall <b>neither be</b> connected to the drinking water system <b>nor</b> allow the possibility of reflux to avoid contamination of potable water sources or the factory environment.
<b>4.9.10</b>	<b>Compressed air</b>	Modification	<b>4.9.10</b>	<b>Compressed air and gases</b>
4.9.10.1	The quality of <del>compressed</del> air that comes in direct contact with <del>packaging material or wrapping material</del> shall be monitored based on hazard analysis and assessment of associated risks.	Modification	4.9.10.1	The quality of air ( <b>including compressed air</b> ) that comes in direct contact with <b>products or surfaces in direct contact with products</b> , shall be monitored based on hazard analysis and assessment of associated risks. <b>If gases are used, their safety and quality shall be demonstrated through a</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				declaration of compliance and shall be suitable for the intended use.
4.9.10.2	Compressed air shall not pose a risk of contamination.	None	4.9.10.2	Compressed air shall not pose a risk of contamination.
<b>4.10</b>	<b>Cleaning and disinfection</b>	None	<b>4.10</b>	<b>Cleaning and disinfection</b>
4.10.1	Based on hazard analysis and assessment of associated risks, cleaning and disinfection schedules shall be available and implemented. These shall specify: <ul style="list-style-type: none"> <li>– objectives</li> <li>– responsibilities</li> <li>– the products used and their instructions for use</li> <li>– the areas to be cleaned and/or disinfected</li> <li>– cleaning frequency</li> <li>– documentation requirements</li> <li>– hazard symbols (if necessary).</li> </ul>	Modification	4.10.1	Based on hazard analysis and assessment of associated risks, cleaning and disinfection schedules shall be available and implemented. These shall specify: <ul style="list-style-type: none"> <li>– objectives</li> <li>– responsibilities</li> <li>– the products used and their instructions for use</li> <li>– dosage of cleaning and disinfection chemicals</li> <li>– the areas to be cleaned and / or disinfected</li> <li>– cleaning and disinfection frequency</li> <li>– documentation requirements</li> <li>– hazard symbols (if necessary).</li> </ul>
4.10.2	Cleaning and disinfection schedules shall be implemented and documented.	Modification	4.10.2	Defined cleaning and disinfection methods shall be implemented, documented, monitored, and shall result in effectively cleaned premises, facilities and equipment.
		Inclusion	4.10.3	Monitoring records for cleaning and disinfection shall be available.



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.10.3	Only qualified personnel shall be allowed to undertake cleaning and disinfection. The personnel shall be trained and retrained to carry out the cleaning schedules.	Modification	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 <b>and disinfection</b> schedules.
4.10.4	The effectiveness and safety of the cleaning and disinfection <del>measures, based on hazard analysis and assessment of associated risks,</del> shall be verified and <del>documented according to a sampling schedule by using appropriate procedures.</del> Resulting corrective actions shall be documented.	Modification	4.10.5	The effectiveness and safety of the cleaning and disinfection <b>activities shall be verified and justified by risk assessment.</b> The verification shall be based on an appropriate sampling schedule and shall consider: <ul style="list-style-type: none"> <li>– visual inspection</li> <li>– rapid testing</li> <li>– analytical testing methods</li> </ul> <b>Resultant</b> corrective actions shall be documented.
4.10.5	Cleaning and disinfection schedules shall be reviewed and modified, <del>if necessary, in the event of a change to product, process or cleaning equipment.</del>	Modification	4.10.6	Cleaning and disinfection schedules shall be reviewed and modified <b>in the event of a change to products, processes, cleaning and disinfection activities and / or equipment, if necessary.</b>
4.10.6	The intended use of cleaning utensils shall be clearly identified. Cleaning utensils shall be used in a way to avoid contamination.	Modification	4.10.7	The intended use of cleaning <b>and disinfection</b> utensils shall be clearly identified. Cleaning <b>and disinfection</b> utensils shall be used in a way <b>that</b> avoids contamination.
4.10.7	<del>Current</del> safety data sheets (SDS) and instructions for use shall be available for chemicals and cleaning agents. Personnel responsible for cleaning shall be able to demonstrate their knowledge of such instructions, which shall be always available on site.	Modification	4.10.8	Safety Data Sheets and instructions for use shall be available for chemicals and cleaning <b>and disinfection</b> agents. Personnel responsible for cleaning <b>and disinfection</b> shall be able to demonstrate their knowledge of such instructions, which shall be always available on-site.



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.10.8	Cleaning chemicals shall be clearly labeled, used and stored appropriately, to avoid contamination.	Modification	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.
4.10.9	Cleaning activities shall be carried out in periods of non-production. If this is not possible, these operations shall be controlled as to not affect the product.	Modification	4.10.10	Cleaning and disinfection activities shall be carried out in periods of non-production. If this is not possible, these operations shall be controlled in order not to affect the products.
4.10.10	Where a company hires a third-party service provider for cleaning and disinfection activities, all requirements specified within section 4.10 shall be clearly defined in the respective contract.	Modification	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.
<b>4.11</b>	<b>Waste disposal</b>	Modification	<b>4.11</b>	<b>Waste management</b>
4.11.1	A waste management procedure shall exist and shall be implemented to avoid cross contamination.	Modification	4.11.1	A waste management procedure shall be in place to avoid cross contamination.
4.11.2	All current legal requirements for waste disposal shall be met.	Modification	4.11.2	All local legal requirements for waste disposal shall be met.
4.11.3	<del>Packaging material</del> waste and other waste shall be removed as quickly as possible from areas where <del>packaging material</del> is handled. The accumulation of waste shall be avoided.	Modification	4.11.3	Product waste and other waste shall be removed as quickly as possible from areas where the product is handled. The accumulation of waste shall be avoided.
4.11.4	Waste collection containers shall be clearly marked, suitably designed, in good state of repair, easy to clean, and where necessary disinfected.	Modification	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.11.5	Waste collection rooms and containers ( <del>incl.</del> compactors) shall be <del>designed to be kept clean</del> to minimize pest attraction.	Modification	4.11.5	Waste collection rooms and containers ( <del>including</del> compactors) shall be <del>maintained tidy, clean and in good condition</del> 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 by authorised third parties only. Records of waste disposal shall be kept by the company.	Modification	4.11.6	Waste shall be collected in separate containers in accordance with the intended means of disposal. Such waste shall be disposed <del>of</del> by authorised third parties only. Records of waste disposal shall be kept by the company.
4.11.7	A <del>system</del> to control the disposal and / or destruction of trademark materials shall be in place. The <del>system</del> shall comply with legal requirements and customer agreements, when is applicable. <del>Trademark materials and its disposal</del> shall be included in the traceability system of the company	Modification	4.11.7	A <del>procedure</del> to <del>manage and</del> control the disposal and / or destruction of trademark materials / <del>products</del> shall be in place. The <del>procedure</del> shall comply with legal requirements and customer agreements, when applicable. <del>The disposal and / or destruction of trademark materials / products shall be recorded, and</del> shall be included in the traceability system of the company
4.12	<del>Risk of foreign material, metal, broken glass and wood</del>	Modification	4.12	<b>Foreign material risk mitigation</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
		Inclusion	4.12.1	<p>The products being processed shall be protected against physical contamination, which includes but is not limited to:</p> <ul style="list-style-type: none"> <li>– environmental contaminants</li> <li>– oils or dripping liquids from machinery</li> <li>– dust spills.</li> </ul> <p>Special consideration shall be given to product contamination caused by:</p> <ul style="list-style-type: none"> <li>– equipment and utensils,</li> <li>– pipes,</li> <li>– walkways,</li> <li>– platforms,</li> <li>– ladders.</li> </ul> <p>In the event that this is not possible due to technological characteristics and / or requirements, appropriate controls shall be defined and applied.</p>
<b>4.12.1 KO no. 5</b>	<b>Based on hazard analysis and assessment of associated risks, procedures shall be in place to avoid contamination with foreign material. Contaminated products shall be treated as non-conforming products.</b>	Modification	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.
4.12.3	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.	None	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.12.5	The appropriate accuracy of detectors shall be specified. Checks of proper function of detectors shall be carried out regularly. In case of malfunction or failure of a metal and/or foreign material detector, corrective actions shall be defined, implemented and documented.	Modification	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.
4.12.4	Potentially contaminated products shall be isolated. Access and actions for further handling or checking for these isolated products shall be carried out only by authorized personnel according to defined procedures. After this check, contaminated products shall be treated as non-conforming products.	Modification	4.12.5	Potentially contaminated products shall be isolated. Access and actions for the further handling or checking of these isolated products shall only be carried out by authorised personnel according to defined procedures. After this check, contaminated products shall be treated as non-conforming products.
4.12.7	In all areas, e.g. handling of raw materials, converting, wrapping and storage, where hazard analysis and assessment of associated risks have identified a potential product contamination, the presence of glass and brittle material shall be excluded. Where the presence of glass or brittle plastic cannot be avoided, appropriate measures shall be in place to protect against breakage.	Modification	4.12.6	In areas where raw materials, wrapping materials, semi-finished and finished products are handled, the use of glass and / or brittle materials shall be excluded; however where the presence of glass and / or brittle materials cannot be avoided, the risks shall be controlled and the glass and / or brittle materials shall be clean and pose no risks to product safety.
4.12.6	In cases where special equipment or methods are used to detect foreign material, these shall be properly validated and maintained.	Deletion		Merged in IFS PACsecure version 2, in the requirement 4.12.4

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.12.8	All stationary objects made of or incorporating glass or brittle material present in areas of handling of raw materials, converting, wrapping and storage shall be listed in a specific register, including details of their exact location. An assessment of the condition of objects on the register shall be performed on a regular basis and recorded. Frequency of this check shall be justified by documents.	Deletion		Merged in IFS PACsecure version 2, in the requirements 4.12.7 and 4.12.8
4.12.14	Based on hazard analysis and assessment of associated risks, preventive measures shall be in place for handling of all kinds of containers in the production process ( <del>turn over, blow, rinse, etc.</del> ).	Modification	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.
4.12.10	Procedures shall be in place describing the measures to be taken in case of breakage of glass and / or brittle material. Such measures shall include identifying the scope of goods to be isolated, specifying authorized personnel, cleaning the production environment and release of production line for continued production.	Modification	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.	None	4.12.9	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.12.2	<del>In all areas, e.g. handling of raw materials, converting, wrapping and storage, where hazard analysis and assessment of associated risks have identified the potential for product contamination, the use of wood shall be excluded. Where the use of wood cannot be avoided, the risk shall be controlled and the wood shall be in good order and clean.</del>	Modification	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.
4.12.12	Where visual inspection is used to detect foreign material, the employees shall be trained and operative change shall be performed at an appropriate frequency to maximize effectiveness of process.	Modification	4.12.11	Where visual inspection is used to detect foreign materials, the employees shall be trained and operative changes shall be performed at an appropriate frequency to maximise the effectiveness of the process.
4.13	<b>Pest monitoring/Pest control</b>	Modification	4.13	<b>Pest monitoring and control</b>
		Inclusion	4.13.1	Site infrastructure and operations shall be designed and built to prevent pest infestation.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.13.1	<p><del>The company shall have a pest control system in place which is in compliance with local legal requirements, taking into account, as a minimum:</del></p> <ul style="list-style-type: none"> <li><del>– the factory environment (potential pests)</del></li> <li><del>– site plan with area for application (bait map)</del></li> <li><del>– identification of the baits on site</del></li> <li><del>– responsibilities, in-house/external</del></li> <li><del>– used products/agents and their instructions for use and safety</del></li> <li><del>– the frequency of inspections.</del></li> </ul> <p><del>The pest control system shall be based on hazard analysis and assessment of associated risks.</del></p>	Modification	4.13.2	<p>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:</p> <ul style="list-style-type: none"> <li>– factory environment (potential pests)</li> <li>– type of raw material / finished products</li> <li>– site plan with area for application (bait map)</li> <li>– constructional designs susceptible for pest activity, such as ceilings, cellars, pipes, corners</li> <li>– identification of the baits on-site</li> <li>– responsibilities, in-house / external</li> <li>– agents used and their instructions for use and safety</li> <li>– frequency of inspections</li> <li>– rented storage if applicable.</li> </ul>
4.13.2	<p><del>The company shall have qualified and trained in-house staff and/or employ the services of a qualified external provider. Where an external provider is used, the activities required on site shall be specified in a written contract.</del></p>	Modification	4.13.3	<p>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.</p> <p>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.</p>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.13.3	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded.	Modification	4.13.4	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded. <b>Any infestation shall be documented and control activities taken promptly.</b>
4.13.4	Baits, traps and insect exterminators shall be functioning, shall be in sufficient numbers and shall be placed in an appropriate position. <del>They shall be constructed and positioned as not to cause any contamination risk.</del>	Modification	4.13.5	Baits, traps and insect exterminators shall be <b>fully</b> functioning, sufficient in number, <b>designed for purpose</b> , placed in appropriate positions <b>and used in a way that avoids any contamination risks.</b>
4.13.5	Incoming deliveries shall be <del>checked</del> on arrival for the presence of pests. Any <del>infestation</del> shall be <del>documented and control measures taken.</del>	Modification	4.13.6	Incoming deliveries shall be <b>inspected</b> on arrival for the presence of pests. Any <b>findings</b> shall be <b>recorded and control activities taken.</b>
4.13.6	The effectiveness of the pest control shall be monitored <del>with the help of regular trend analyses.</del>	Modification	4.13.7	The effectiveness of the pest control activities shall be monitored, <b>including trend analysis, to take actions as soon as possible. Records of this monitoring shall be available.</b>
<b>4.14</b>	<b>Receipt of goods and storage</b>	Modification	<b>4.14</b>	<b>Receipt and storage of goods</b>
4.14.1	All incoming goods, including wrapping materials, shall be checked for conformity against specifications/other legally required documentation and to a determined inspection plan. The inspection plan shall be risk based. Test results shall be documented.	Modification	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.
4.14.2	<del>The storage conditions of raw materials, semi-processed and finished products as well as wrapping shall in each case correspond to product</del>	Deletion		<b>Merged in IFS PACsecure version 2, in the requirement 4.14.2</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
	<del>requirements (e.g. protective covers) and shall not be detrimental to other products.</del>			
4.14.3	<del>Raw materials, packaging, semiprocessed and finished products shall be stored so as to minimize the risk of cross-contamination.</del>	Modification	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: <ul style="list-style-type: none"> <li>– be clearly identified,</li> <li>– allow cleaning and inspection,</li> <li>– be clean and in good conditions to minimise the contamination risks or other negative impact (e.g. cross-contamination, mixing issues).</li> </ul>
4.14.4	Appropriate storage facilities shall be available for the management and storage of working materials, process aids, and additives. The personnel responsible for the management of storage facilities shall be trained.	Modification	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.14.5	<del>All products shall be clearly identified. Use of products shall be undertaken in accordance with the principles of First In/First Out and/or First Expired/First Out.</del>	Modification	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: <ul style="list-style-type: none"> <li>– clear identification of all products</li> <li>– control activities to ensure the storage conditions correspond to product specification and shall not have any negative impact on other products</li> <li>– Usage of products in accordance with the principles of First In / First Out and / or First Expired / First Out.</li> <li>– how to proceed when converting time established or expiry date of products is exceeded</li> <li>– how to manage incoming goods, including wrapping materials, which have no converting time established or expiry date.</li> </ul>
4.14.6	Where a company hires a third-party storage service provider, the service provider shall be subject to IFS Logistics requirements. <del>If the third party service provider is not certified to IFS Logistics, all relevant requirements equivalent to the company's own warehousing practices shall be fulfilled and this shall be clearly defined in the respective contract.</del>	Modification	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. <del>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.</del>

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
<b>4.15</b>	<b>Transport</b>	None	<b>4.15</b>	<b>Transport</b>
4.15.1	<del>Before loading transport vehicles, their condition (e.g. absence of strange smells, high dust load, adverse humidity, pests, mould) shall be checked and action taken, if necessary.</del>	Modification	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: <ul style="list-style-type: none"> <li>– cleanliness,</li> <li>– pests,</li> <li>– foreign materials (e.g. wood splinters, stones, organic contaminants, etc.),</li> <li>– strange odours,</li> <li>– surfaces,</li> </ul> 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 shall be implemented (packaging material/nonpackaging material/different categories of goods).	Modification	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 <del>must</del> be transported at certain conditions, before loading, the condition inside the vehicle shall be checked and documented.	Modification	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.15.4	Where goods must be transported at certain conditions maintaining these conditions during transport shall be ensured and documented.	Deletion		Merged in IFS PACsecure version 2, in the requirement 4.15.3
4.15.5	Adequate hygienic requirements for all transport vehicles and equipment used for loading / unloading (e.g. hoses of silo installations) shall exist. There shall be records of the <del>measures taken</del> .	Modification	4.15.4	Hygienic requirements for all transport vehicles and equipment used for loading / unloading (e.g. hoses of silo installations) <b>covering product and process needs</b> shall exist. There shall be records of the <b>control activities and actions taken</b> .
4.15.6	<del>Loading and unloading areas shall have equipment in place to protect transported products from external influences.</del>	Modification	4.15.5	<b>The loading / unloading area shall be appropriate for its intended use. They shall be constructed in a way that:</b> <ul style="list-style-type: none"> <li>– the risks of pest ingress are mitigated</li> <li>– products are protected from adverse weather conditions and external influences</li> <li>– accumulation of waste is avoided</li> <li>– condensation and growth of mould are prevented</li> <li>– cleaning can be easily undertaken.</li> </ul>
4.15.7	Where a company hires a third-party transport service provider, <del>all the requirements specified within section 4.15 shall be clearly defined in the respective contract or the service provider shall be subject to IFS Logistics requirements.</del>	Modification	4.15.6	Where a company hires a third-party transport service provider, <b>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.</b>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.15.8	Security of transport vehicles shall be appropriately maintained.	Deletion		Topic covered in product defense/product fraud
<b>4.16</b>	<b>Maintenance and repair</b>	None	<b>4.16</b>	<b>Maintenance and repair</b>
4.16.1	An adequate <del>system</del> of maintenance shall be in place, maintained and documented, covering all critical equipment ( <del>incl.</del> transport) for compliance with product requirements. This applies both <del>for internal and external maintenance activities.</del>	Modification	4.16.1	An adequate maintenance <b>plan</b> shall be in place, maintained and documented, <b>that covers all</b> critical equipment ( <b>including</b> transport) for compliance with product requirements. This applies both <b>to internal maintenance activities and service providers. The plan shall include responsibilities, priorities and due dates.</b>
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.	None	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.	Modification	4.16.3	All materials used for maintenance and repair shall be fit for the intended use <b>and shall not pose contamination risks.</b>
4.16.4	Failures <del>of plant and equipment (incl. transport)</del> covered by the maintenance system shall be documented and reviewed <del>with a view to adapting the maintenance system.</del>	Modification	4.16.4	Failures <b>and malfunctions of plant and equipment (including transport) essential for product safety and quality shall be notified</b> , documented and reviewed <b>to carry out prompt actions and to improve the maintenance plan.</b>
4.16.5	Temporary repairs shall be carried out so that product requirements are not affected. Such work shall be documented and a short-term deadline set for eliminating the fault.	Modification	4.16.5	Temporary repairs shall be carried out so that product requirements are not affected. Such work shall be <b>identified</b> , documented and a short-term deadline set for eliminating the fault.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.16.6	Where a company hires a third-party maintenance and repair service provider, all the company specified requirements regarding material and equipment shall be clearly defined, documented and maintained.	Modification	4.16.6	Where a company hires a third-party maintenance and repair service provider, all the company specified requirements regarding material, equipment <b>and operational rules</b> shall be clearly defined, documented and maintained <b>in the service contract or agreement, to prevent any negative impact on products.</b>
<b>4.17</b>	<b>Equipment</b>	None	<b>4.17</b>	<b>Equipment</b>
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.	None	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 with direct packaging material contact, certificates of conformity shall exist which confirm compliance with current legal requirements. In case no specific legal requirements are applicable, evidence shall be available to demonstrate that all equipment and tools are suitable for use. This applies for all equipment and tools in direct contact with raw materials, semi-processed and finished products.	Modification	4.17.2	For all equipment and tools in direct contact with products, a certificate of conformity shall <b>be in place</b> , which confirms compliance with legal requirements. In case no specific legal requirements are <b>in place</b> , evidence shall be available, <b>such as:</b> <ul style="list-style-type: none"> <li>– certificate of conformity</li> <li>– technical specifications</li> <li>– manufacturer's self-declaration to demonstrate that they are suitable for the intended use.</li> </ul>
4.17.3	<del>Equipment shall be designed and located so that cleaning and maintenance operations can be effectively performed.</del>	Modification	4.17.3	<b>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</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				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	<del>The company shall ensure that all product equipment is in good condition without any negative influence on packaging material safety.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 4.17.3
4.17.5	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 <del>are complied with.</del>	Modification	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, <b>as agreed with customers, are complied with.</b>
<b>4.18</b>	<b>Traceability (including <del>GMOs and allergens</del>)</b>	Modification	<b>4.18</b>	<b>Traceability</b>
<b>4.18.1 KO no. 6</b>	<b>A traceability system shall be in place which enables the identification of product <del>lots</del> and their relation to batches of raw materials and wrapping materials <del>intended or expected to be in direct contact with produced products.</del> The traceability system shall incorporate all relevant <del>receiving, converting and distribution</del> records. Traceability shall be ensured and documented until delivery to the customer.</b>	Modification	4.18.1 KO No. 7	A traceability system shall be in place which enables the identification of product <b>batches</b> and their relation to batches of raw materials and wrapping materials. The traceability system shall <b>incorporate all relevant records of:</b> <ul style="list-style-type: none"> <li>– receipt</li> <li>– production / conversion processes</li> <li>– use of rework</li> <li>– distribution</li> </ul> Traceability shall be ensured and documented until delivery to the customer.



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.18.2	<del>Downstream traceability records (from production sites to the customers) shall be available. The timeframe for producing these records for review shall be compliant with customer's requirements.</del>	Modification	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.
		Inclusion	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.
4.18.3	Traceability shall be in place to identify the relationship between batches of final products and their labels.	None	4.18.4	Traceability shall be in place to identify the relationship between batches of final products and their labels.
4.18.4	The traceability system shall be tested on a periodic basis at least annually and each time traceability system changes. The test shall verify upstream and downstream traceability (from delivered products to raw materials, and vice versa), including quantity checking. Test results shall be recorded.	Deletion		Merged in IFS PACsecure version 2, in the requirement 4.18.2
4.18.5	Traceability shall be ensured at all stages, including work in progress, post treatment and rework.	None	4.18.5	Traceability shall be ensured at all stages, including work in progress, post treatment and rework.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.18.6	Labeling of semi-finished or finished product <del>lots</del> shall be made at the time when <del>the goods are directly packed/ wrapped to ensure a clear traceability of goods. Where goods are labeled at a later time, the temporarily stored goods shall have been provided with a specific lot labeling. The recommended converting time of the labeled goods shall be calculated from the original production batch.</del>	Modification	4.18.6	Labelling of semi-finished or finished product <b>batches</b> shall be made at the time when <b>they are directly wrapped to ensure their clear traceability.</b> Where they are labelled at a later time, the temporarily stored of semi-finished or finished products shall have a specific batch labelling.
4.18.7	If required by customer, identified samples representative for the manufacturing <del>lot</del> 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.	Modification	4.18.7	If required by the customer, identified samples representative for the manufacturing <b>batch number</b> 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.
<b>4.19</b>	<b>Allergens and specific conditions of production</b>	Modification	<b>4.19</b>	<b>Allergen risk mitigation</b>
4.19.1	<del>When specified by the customer, the company shall maintain a continuously up to date listing of all raw materials containing allergens used at its premises (e.g. starch as a glue), which also identifies all blends and formulas/configurations to which such raw materials containing allergens are added.</del>	Modification	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.19.2	<del>The manufacturing of products which contain allergens requiring declaration shall be carried out as to ensure cross contamination is minimized as far as possible.</del>	Modification	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: <ul style="list-style-type: none"> <li>– all allergens entry are identified</li> <li>– 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.</li> <li>– 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.</li> </ul>
-	-	Inclusion	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.19.3	<del>Where customers specifically require that products are “free from” certain substances or ingredients (e.g. starch), or that certain methods of treatment or production are excluded, verifiable procedures shall be in place.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 4.2.1.6
<b>4.20</b>	<b>Product fraud</b>	None	<b>4.20</b>	<b>Product fraud</b>
		Inclusion	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.
4.20.1	<del>A documented product fraud vulnerability assessment shall be undertaken on all raw materials (raw materials, additives, inks, adhesives, solvents, wrapping, materials, rework), product formula/configuration, processes (including outsourced) wrapping and labelling, to determine the risk of fraudulent activity in relation to substitution, mislabelling, adulteration or counterfeiting. The criteria considered within the vulnerability assessment shall be defined..</del>	Modification	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.
4.20.2	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.	None	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.



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
4.20.3	<del>In the event of increased risks, the vulnerability assessment and mitigation plan shall be reviewed and amended accordingly. Otherwise all the vulnerability assessments, shall be reviewed at least annually.</del>	Modification	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	<b>Measurements, Analysis, Improvements</b>	None	5	<b>Measurements, Analysis, Improvements</b>
5.1	<b>Internal audits</b>	None	5.1	<b>Internal audits</b>
5.1.1 KO no. 7	<del>Effective internal audits shall be conducted according to a defined agreed audit program and shall cover at least all requirements of the IFS PACsecure Standard. Scope and frequency of internal audits shall be determined by hazard analysis and assessment of associated risks. This is also applicable for off site storage locations owned or rented by the company.</del>	Modification	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	<del>Internal audits of activities which are critical to packaging material safety and product specifications or other legally required documentations shall be carried out at least once a year.</del>	Modification	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.	None	5.1.3	The auditors shall be competent and independent from the audited department.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
5.1.4	Audit results shall be communicated to the senior management and to responsible persons of concerned <del>department</del> . Necessary corrective actions and a schedule for implementation shall be determined and documented and communicated to every relevant person.	Modification	5.1.4	Internal audit results shall be communicated to the senior management and to persons <b>responsible for the concerned activities</b> . Necessary <b>corrections</b> , corrective actions and a schedule for implementation shall be determined, documented and communicated to the relevant persons. <b>All corrections and corrective actions resulting from the internal audits shall be verified.</b>
5.1.5	<del>It shall be documented how and when the corrective actions resulting from the internal audits shall be verified</del>	Deletion		<b>Merged in IFS PACsecure version 2, in the requirement 5.1.4</b>
<b>5.2</b>	<b>Site factory inspections</b>	Modification	<b>5.2</b>	<b>Site and factory inspections</b>
5.2.1	Factory inspections shall be planned and carried out ( <del>e.g. product control, hygiene, foreign material hazards, personnel hygiene and housekeeping</del> ). The frequency of inspections <del>in every area (including outdoor areas) and every single activity</del> shall be based on hazard analysis and assessment of associated risks and on the history of previous experience.	Modification	5.2.1	Site and factory inspections shall be planned and carried out <b>for topics, such as:</b> <ul style="list-style-type: none"> <li>– <b>constructional status of production and storage premises</b></li> <li>– <b>external areas</b></li> <li>– <b>product control during processing</b></li> <li>– <b>hygiene during processing and within the infrastructure</b></li> <li>– <b>foreign material hazards</b></li> <li>– <b>personal hygiene</b></li> <li>– <b>product defence</b></li> </ul> <b>The frequency of inspections shall be justified by risk assessment and be based on the history of previous experience.</b>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				Any deviation and the associated actions shall be documented.
<b>5.3</b>	<b>Process validation and control</b>	Modification	<b>5.3</b>	<b>Validation and control of the process and working environment</b>
5.3.1	<del>The criteria for process validation and control shall be clearly defined.</del>	Modification	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
5.3.2	<del>In circumstances where the control of process and working environment parameters (temperature, time, pressure, chemical properties etc.) is essential to ensure the product requirements, such parameters shall be monitored and recorded continuously and/or at appropriate intervals.</del>	Modification	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.
5.3.5	<del>Process validation shall be performed using the collected data that is relevant for product safety and the processes. If substantial modifications occur, a revalidation shall be carried out.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 5.3.1





## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
		Inclusion	5.3.3	When applicable, the control of process shall take into account the following aspects: <ul style="list-style-type: none"> <li>– Handling of products in print trials, testing activities, start-up processes and production samplings.</li> <li>– Clearance activities among the production of different products and processes.</li> <li>– 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.</li> <li>– In case the product has critical information printed, control activities shall be implemented to: <ul style="list-style-type: none"> <li>– ensure the information is legible and correctly reproduced;</li> <li>– 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.</li> </ul> </li> </ul> The company shall verify the control activities and monitor their effectiveness. Records of the verification and monitoring shall be available.
5.3.3	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.	None	5.3.4	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.
5.3.4	<del>There shall be appropriate procedures for prompt notification, recording and monitoring of equipment malfunction and process deviations.</del>	Deletion		<del>Process deviation is included in 5.3.1 and equipment malfunction is covered in chapter 4.16. Also covered in updated requirements of Ch. 5.3.</del>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
5.4	<b>Calibration, adjustment and checking of measuring and monitoring devices</b>	Modification	5.4	<b>Calibration, adjustment and checking of measuring, monitoring devices and inspection equipment</b>
5.4.1	The company shall identify the measuring and monitoring devices required to ensure compliance with product requirements. <del>These devices shall be recorded on a document and clearly identified.</del>	Modification	5.4.1	The company shall identify <b>and record</b> the measuring and monitoring devices required to ensure compliance with product requirements. <b>Their calibration status shall be recorded, and when possible, visible on the device (e.g. labelled).</b> 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, under a monitoring system, at specified intervals and in accordance with defined recognized standard/methods. The results of the checks, adjustments and calibrations shall be documented. Where necessary, corrective actions on devices and, if necessary, on process and products shall be carried out.	Modification	5.4.2	All measuring devices shall be checked, adjusted and calibrated at specified intervals under a monitoring system in accordance with defined, recognised <b>national or international</b> standard / methods <b>and within relevant limits of the process parameter values.</b> The results of the checks, adjustments and calibrations shall be documented. <b>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</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
				operation and efficiency of the inspection equipments to control the parameters under the values and limits defined shall be monitored on a regular basis.
5.4.3	All measuring devices shall be used exclusively for their defined purpose. Where the results of measurements indicate a malfunction, the device in question shall be immediately repaired or replaced.	Modification	5.4.3	All measuring, <b>monitoring devices and inspection equipment</b> shall be used exclusively for their defined purpose. Where the results of measurements <b>or the status of the device / equipment</b> indicate a malfunction <b>or failure</b> , the device in question shall be immediately repaired or replaced. <b>Where necessary, corrections and corrective actions on processes and products shall be carried out.</b>
5.4.4	<del>The calibration status of the measuring devices shall be clearly identified (labeled at the machine or on a list of test devices).</del>	Deletion		<b>Merged in IFS PACsecure version 2, in the requirement 5.4.1</b>
<b>5.5</b>	<b>Control of quantity/filling quantity</b>	Modification	<b>5.5</b>	<b>Quantity control monitoring</b>
5.5.1	<del>The frequency and methodology of control of quantity shall be determined so that the legally requirements and customer specifications or other legally required</del>	Modification	5.5.1	<b>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</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
	documentation, or if appropriate, guidelines for nominal quantity are met.			production and destination countries, and customer specifications.
5.5.2	<del>A procedure shall exist to define criteria for compliance checking. This procedure shall also, among others, take into consideration the tare, the density and other critical attributes.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 5.5.1
5.5.3	Checks shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing lot.	Modification	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.
5.5.4	<del>Results of these checks shall be compliant with defined criteria for all products ready to be delivered.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 5.5.2
5.5.5	<del>For purchased, already pre-packed products from third parties, there shall be evidence about the compliance with the legal requirements.</del>	Deletion		Deleted
5.5.6	<del>If applicable, all equipment used for final checking shall be approved.</del>	Deletion		Included in Chapter 5.4
5.6	<b>Product analysis</b>	Modification	5.6	<b>Product and process analyses</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
5.6.1	<del>There shall be procedures ensuring that all specified product requirements are met, including legal requirements and specifications. Chemical, physical and microbiological analysis required for that purpose shall be performed internally and/or subcontracted.</del>	Modification	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: <ul style="list-style-type: none"> <li>– raw materials</li> <li>– semi-finished products</li> <li>– finished products</li> <li>– wrapping materials</li> <li>– contact surfaces of processing equipment</li> <li>– relevant parameters for the control of the process and environmental monitoring.</li> </ul> All test results shall be recorded.
5.6.2	Analyses, which are relevant for packaging material safety, shall preferably be performed by laboratories having appropriate accredited programs / methods (ISO 17025). If the analyses are performed by a factory internal or a laboratory not having appropriate accredited programs / methods, the results shall be verified on a regular basis by laboratories accredited on these programs / methods (ISO 17025).	Modification	5.6.2	Analyses, which are relevant for product safety, shall preferably be performed by laboratories with appropriate accredited programs / methods (ISO/IEC 17025). If the analyses are performed internally by the factory or a laboratory without appropriate accredited programs / methods, the results shall be verified on a regular basis by laboratories accredited to these programs / methods (ISO/IEC 17025).
5.6.3	Procedures shall exist which ensure the reliability of the internal analysis results <del>on the basis of official</del> recognized analysis methods. This shall be demonstrated by ring tests or other proficiency tests.	Modification	5.6.3	Procedures shall exist which ensure the reliability of the internal analyses results, <b>based on officially</b> recognised analysis methods. This shall be demonstrated by ring tests or other proficiency tests.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
5.6.4	<del>A test plan shall be drawn up for internal and external analysis, based on hazard analysis and assessment of associated risks, which covers raw materials, semi-processed and finished products as well as processing equipments and packaging materials, and where necessary environmental tests. The test results shall be documented.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirements 5.6.1 and 5.6.3
5.6.5	Results of analysis shall be evaluated promptly. Appropriate corrective measures shall be introduced for any unsatisfactory results. The analytical results shall be reviewed regularly in order to identify trends. <del>Trends indicating potential unsatisfactory results shall be taken into consideration.</del>	Modification	5.6.4	Results of analyses shall be evaluated promptly by competent personnel. Appropriate corrective actions shall be undertaken for any unsatisfactory results. The analytical results shall be reviewed regularly to identify trends and, where necessary, corrective actions shall be taken.
5.6.6	<del>Where internal analysis is undertaken, qualified and trained personnel shall be in place, as well as appropriate equipment and premises.</del>	Modification	5.6.5	Where internal analyses or controls are undertaken, these shall be carried out in accordance with defined procedures, by trained and approved personnel, in defined areas or laboratories using appropriate equipment.
5.6.7	<del>For verification of finished product quality, internal organoleptic tests shall be carried out regularly when specified by the customer. These tests shall be in accordance with specifications or other legally required documentation and related to the impact on respective parameters of product characteristic. The results of these tests shall be documented.</del>	Modification	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
5.6.8	<del>Based on any internal or external information on product risks which may have an impact on packaging material safety, the company shall update its control plan and/or take any appropriate measure to control impact on finished products.</del>	Modification	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.
<b>5.7</b>	<b>Product quarantine (blocking/hold) and product release</b>	Modification	<b>5.7</b>	<b>Product release</b>
5.7.1	<del>A procedure shall be in place, based on hazard analysis and assessment of associated risks, for the quarantine (blocking/hold) and release of all raw materials, semi-processed and finished products and wrapping materials. The procedure shall ensure that only products and materials conforming to product requirements are converted and dispatched.</del>	Modification	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.
<b>5.8</b>	<b>Management of complaints from authorities and customers</b>	Modification	<b>5.8</b>	<b>Management of complaints</b>
5.8.1	<del>A system shall be in place for the management of product complaints.</del>	Modification	5.8.1	A procedure shall be in place for the management of complaints. The procedure shall consider, at a minimum: <ul style="list-style-type: none"> <li>– Product complaints by customers, and when applicable, by consumers</li> <li>– 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.</li> <li>– Raw materials complaints by the company to its suppliers</li> </ul>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
5.8.2	All complaints shall be assessed by competent staff. Where it is justified appropriate actions shall be taken immediately, <del>if necessary.</del>	Modification	5.8.2	All complaints shall be <b>registered, readily available and</b> assessed by competent staff. Where it is justified, appropriate actions shall be taken immediately.
5.8.3	Complaints shall be analyzed with a view to implementing <del>preventive</del> actions which avoid the recurrence of the non-conformity.	Modification	5.8.3	Complaints shall be analysed with a view to implementing <b>appropriate</b> 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.	None	5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons and to the senior management.
<b>5.9</b>	<b>Management of incidents, product withdrawal, product recall</b>	None	<b>5.9</b>	<b>Management of incidents, product withdrawal, product recall</b>
5.9.1	A documented procedure shall be defined for management of incidents and of potential emergency situations <del>that impact packaging material safety, legality and quality. This procedure shall be implemented and maintained. This includes as a minimum: the nomination and training of a crisis team, an alert contact list, sources of legal advice (if necessary), contacts availability, customer information, and a communication plan, including information to consumers.</del>	Modification	5.9.1	A procedure shall be <b>implemented and maintained for</b> the management of incidents and of potential emergency situations <b>with an impact on product safety, legality and quality. It shall include, at a minimum:</b> <ul style="list-style-type: none"> <li>– the decision-making process</li> <li>– the nomination of a person, authorised by the company and permanently available, to initiate the incident management process promptly</li> <li>– the nomination and training of an incident management team</li> <li>– an up to date alert contact list including customer information, sources of legal advice, contacts availability</li> <li>– a communication plan including authorities.</li> </ul>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
5.9.2 KO no. 8	<del>There shall be an effective procedure for the withdrawal/recall of all products, which ensures that involved customers are informed, as soon as possible. This procedure shall include a clear assignment of responsibilities.</del>	Modification	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	<del>Updated emergency contact details (such as names and phone numbers of suppliers, customers and competent authorities) shall be available. A person of the company, who has the authority to initiate the incident management process, shall be permanently available.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 5.9.1.
5.9.4	<del>The feasibility, effectiveness and timeliness of implementation of the withdrawal procedure shall be subject to regular internal testing, based on hazard analysis and assessment of associated risks but carried out at least once a year. This shall be carried out in a manner to ensure the effective implementation and operation of the procedure.</del>	Modification	5.9.3	The procedures for the management of incidents and withdrawal / recall shall be regularly tested for effectiveness, at least annually. The tests shall be carried out to ensure the effective implementation and operation of both procedures and shall include the verification of the updated contact data.
5.10	<b>Management of non-conformities and non conforming products</b>	None	5.10	<b>Management of non-conformities and non conforming products</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
5.10.1	A procedure shall <del>exist</del> for the management of all non-conforming raw materials, semi-finished and finished products, converting equipment and wrapping materials. This shall include, <del>as</del> a minimum: <ul style="list-style-type: none"> <li>– isolation/quarantine procedures</li> <li>– <del>hazard analysis and assessment of associated risks</del></li> <li>– identification (<del>e.g. labeling</del>)</li> <li>– decision about the further use (e.g. release, rework/post treatment, blocking, quarantine, rejection/disposal).</li> </ul>	Modification	5.10.1	A procedure shall be <b>in place</b> for the management of all non-conforming raw materials, semi-finished products, finished products, converting / <b>processing</b> equipment and wrapping materials. This shall include, <b>at</b> a minimum: <ul style="list-style-type: none"> <li>– <b>defined responsibilities</b></li> <li>– isolation / quarantine procedures</li> <li>– <b>risk assessment</b></li> <li>– identification <b>including labelling</b></li> <li>– decision about the further use (e.g. release, rework, blocking, quarantine, rejection / disposal).</li> </ul>
5.10.2	<del>The responsibilities for the management of non-conforming products shall be clearly identified. The procedure for the management of non-conforming products shall be understood by all relevant employees.</del>	Modification	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 <del>present</del> , immediate <del>corrections</del> shall be taken to ensure that product requirements are complied with.	Modification	5.10.3	Where non-conformities are <b>identified</b> , immediate <b>actions</b> shall be taken to ensure that product requirements are complied with.
5.10.4	<del>Out of specification finished goods or finished goods that do not meet other legal requirements are not allowed to be put on the market. The material has to be destroyed appropriately. Exceptions shall be agreed in writing with the contract partners.</del>	Modification	5.10.4	<b>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.</b>
<b>5.11</b>	<b>Corrective actions</b>	None	<b>5.11</b>	<b>Corrective actions</b>

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
5.11.1	A procedure shall be in place for the recording and analysis of the non-conformities with the objective to avoid recurrences by preventive actions and/or corrective actions.	Modification	5.11.1	A procedure shall be in place for the recording and analysis of non-conformities <b>and non-conforming products, by preventive actions, corrections</b> and / or corrective actions. <b>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.</b>
<b>5.11.2 KO no. 9</b>	<b>Corrective actions shall be clearly formulated, documented and undertaken, as soon as possible to avoid further occurrence of nonconformity. The responsibilities and the timescales for corrective action shall be clearly defined. The documentation shall be securely stored, and easily accessible.</b>	Modification	5.11.2 KO No. 10	Corrective actions shall be clearly formulated, documented and undertaken as soon as possible. <b>The actions defined shall be focused on avoiding the recurrences of non-conformities.</b> The responsibilities and the timescales for corrective actions shall be clearly defined.
5.11.3	The performance of the implemented corrective actions shall be documented and the effectiveness shall be checked.	Modification	5.11.3	The <b>effectiveness</b> of the implemented corrective actions shall be <b>assessed</b> and the <b>results of the assessment documented.</b>
<b>6</b>	<b>Product defense plan and external inspections</b>	Modification	<b>6</b>	<b>Product defence plan</b>
<b>6.1</b>	<b>Defense assessment</b>	Deletion		<b>Deleted for clarity on titles and content of related requirements.</b>
6.1.1	Responsibilities for product defense shall be clearly defined. Those responsible shall be key staff or shall have access to the top management team. Sufficient knowledge in this area shall be demonstrated.	Modification	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.

## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
6.1.2	<p>A product defense hazard analysis and assessment of associated risks shall have been performed and documented. Based on this assessment, and based on the legal requirements, areas critical to security shall be identified.</p> <p>Product defense hazard analysis and assessment of associated risks shall be conducted annually or upon changes that affect packaging material integrity. An appropriate alert system shall be defined and periodically tested for effectiveness.</p>	Modification	6.2	<p>A documented product defence assessment shall be undertaken to determine the risks of malicious and ideologically motivated threats. This shall include, at a minimum:</p> <ul style="list-style-type: none"> <li>– legal requirements</li> <li>– customer requirements</li> <li>– site security conditions</li> <li>– identification of critical or high risk areas of the site</li> <li>– practices and policy of access by employees, visitors and contractors</li> <li>– any other appropriate control activities</li> </ul> <p>The criteria considered within the vulnerability assessment shall be defined.</p>
		Inclusion	6.3	<p>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.</p>
-	-	Inclusion	6.4	<p>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</p>
6.1.3	<p><del>If legislation makes registration or on-site inspections necessary, evidence shall be provided.</del></p>	Deletion		<p><b>Merged in IFS PACsecure version 2, in the requirement 6.1.</b></p>



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
<del>6.2</del>	<del><b>Site Security</b></del>	Deletion		Deleted for clarity on titles and content of related requirements.
6.2.1	<del>Based on a hazard analysis and assessment of associated risks, identified areas critical to security shall be adequately protected to prevent unauthorized access. Access points shall be controlled.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 6.2.
6.2.2	<del>Procedures shall be in place to prevent tampering and/or allow identification of signs of tampering.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 6.2.
<del>6.3</del>	<del><b>Personnel &amp; Visitor Security</b></del>	Deletion		Deleted for clarity on titles and content of related requirements.
6.3.1	<del>Visitor policy shall contain aspects of product defense plan. Delivery and loading staff in contact with the product shall be identified and shall respect the access rules of the company. Visitors and external service providers shall be identified in areas with product storage and shall be registered at the time of access. They should be informed about the site policies and their access controlled accordingly.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 6.2.
6.3.2	<del>All employees shall be trained in product defense on an annual basis or when significant program changes occur. The training sessions shall be documented. Employee hiring and employment termination practices shall consider security aspects as permitted by law.</del>	Deletion		Merged in IFS PACsecure version 2, in the requirement 6.2. Also, in req. 3.3.4 the product defense training was added as mandatory.
<del>6.4</del>	<del><b>External Inspections</b></del>	Deletion		Deleted for clarity on titles and content of related requirements.



## IFS PACsecure V1.1 checklist compared with IFS PACsecure V2 checklist

Req. No.	IFS PACsecure Requirements Version 1.1	Type of change	Req. No.	IFS PACsecure Requirements Version 2
6.4.1	A documented procedure shall exist for managing external inspections and regulatory visits (if applicable). Relevant personnel shall be trained to execute the procedure.	Modification	6.5	A documented procedure shall exist for managing external inspections and regulatory visits. Relevant personnel shall be trained to execute the procedure.