



IFS PACsecure

Standard for auditing quality and
safety of packaging materials

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changed

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Part 1: Audit Protocol

1 The history of International Featured Standards and IFS PACsecure Standard

Supplier audits have been a permanent feature of retailer's systems and procedures for many years. Until 2003 they were performed by the quality assurance departments of the individual retailers, wholesalers and food services. The ever-rising demands of consumers, the increasing liabilities of retailers, wholesalers and food services, the increasing of legal requirements and the globalisation of product supply, all made it essential to develop a uniform quality assurance and food safety Standard. Also, a solution had to be found to reduce the time associated with a multitude of audits for involved stakeholders.

The associated members of the German retail federation – Handelsverband Deutschland (HDE) – and of its French counterpart – Fédération des Entreprises du Commerce et de la Distribution (FCD) – drew up a quality and food safety standard for retailer branded food products named the IFS Food, the first Standard of the IFS family, which is intended to allow the assessment of suppliers' food safety and quality systems in accordance with a uniform approach. This Standard is now managed by IFS Management GmbH, a company owned by FCD and HDE, and applies to all the post-farm gate stages of food processing. IFS Food Standard has been benchmarked with GFSI Guidance Document and is recognised by GFSI (Global Food Safety Initiative).

The first version implemented (version 3) of the IFS Standard was developed by the HDE and launched in 2003. In January 2004, an updated version, version 4, was designed and introduced in collaboration with the FCD. Within 2005/2006, the Italian retail associations also joined the International Food Standard and the development of version 5 was a collaboration of retail federations from France, Germany and Italy as well as retailers from Switzerland and Austria.

For IFS Food version 6, the International Technical Committee and the French, German and Italian working groups have been actively involved, in addition to retailers, stakeholders and representatives of industry, food services and certification bodies. During the development of IFS Food version 6, IFS gained input from a recently formed IFS North American working group and retailers from Spain, Asia and South America.

Based on this experience, the IFS PACsecure Standard is a new one in the IFS (International Featured Standards) family covering another part of the supply chain.

The fundamental objectives of IFS PACsecure, as well as for other IFS Standards, are:

- to establish a common standard with a uniform evaluation system,
- to work with accredited certification bodies and qualified IFS approved auditors,
- to ensure comparability and transparency throughout the entire supply chain,
- to reduce costs and time for both suppliers and retailers,
- to meet GFSI requirements.

As announced on February 15th 2012, IFS Management GmbH, owner of the GFSI benchmarked IFS Food Standard, IFS Logistics and other supply chain Standards, together with The Packaging Association of Canada (currently Packaging Consortium), have joined to bring the world's foremost packaging standard for primary and secondary packaging to the industry.

added

The current version IFS PACsecure 1.1, December 2017 is a consolidated version of IFS PACsecure version 1, October 2012 taking into consideration necessary adaptations. This updated version of the Standard is applicable with the existing normative documents referenced in this standards from 2nd July 2018.

PACsecure was created by PAC to provide packaging manufacturers and converters the ability to certify primary and secondary packaging materials for the food industry. However, the IFS PACsecure Standard is applicable to all kinds of packaging materials. Developed by a technical working group made up of some of North America's largest global packaging and food manufacturers, the Standard is now managed by a joint effort of the PAC through their technical expertise and know-how in the packaging industry and IFS and its global network of food safety and quality standards infrastructure.

2 Introduction

2.1 Purpose and contents of the audit protocol

This audit protocol describes the specific requirements made on the organisations involved in IFS PACsecure audits.

added

The purpose of the protocol is to define the criteria to be followed by a certification body performing **announced** audits against the IFS requirements, and in accordance with the accreditation norm ISO/IEC 17065.

added

For unannounced audits the protocol is described in part 5 of this document.

It also details the procedures to be observed by the companies being audited, and clarifies the rationale of auditing them. Only certification bodies accredited to ISO/IEC 17065 for the scope of IFS PACsecure, and which have signed an agreement with the scheme owner can perform audits against the IFS PACsecure Standard and can issue IFS PACsecure certificates. The IFS requirements for certification bodies are clearly described in Part 3 of this document.

2.2 Extraordinary information to the certification body by the certified company

~~In accordance with ISO/IEC Guide 65, The company shall inform its certification body about any change or information indicating that the products may no longer comply with the requirements of the certification system (e.g. recall, alert on products, etc.). This information shall be made within 3 working days.~~

| deleted

2.3 General requirements for the quality and product safety management system

In general, when auditing in accordance with IFS, the auditor assesses if the various elements of a company's quality and product safety management system are documented, implemented, maintained, and continuously improved. The auditor shall examine the following elements:

- organisational structure in relation to responsibility, authority, qualification and job description,
- documented procedures and the instructions concerning their implementation,
- inspection and testing: specified requirements and defined acceptance/tolerance criteria,
- actions to be taken in case of non-conformities,
- investigation of the causes of non-conformities and the implementation of corrective actions,
- conformity analysis of safety and quality data and review of implementation in practice,
- handling, storage and retrieval of quality and packaging material safety records, such as traceability data, document control.

All processes and procedures shall be clear, concise and unambiguous and the personnel responsible shall understand the principles of the quality and product safety management system.

The quality and product safety management system is based on the following methodology:

- to identify the processes needed for the quality and product safety management system,

added

- to determine the sequence and interaction of these processes,
 - to determine the criteria and methods required to ensure the effective operation and control of these processes,
 - to ensure the availability of information necessary to support the operation and monitoring of these processes,
 - to measure, monitor and analyse these processes, and implement the necessary action to achieve planned results and continuous improvement.
- **to verify the quality and product safety management system to confirm that the system continues to be effective.**

3 Types of audit

3.1 Initial audit

An initial audit is a company's first audit to IFS PACsecure. It is performed at a time and date agreed between the company and the selected certification body. During this audit the entire company is assessed, both in relation to its documentation and the processes themselves. During the audit, all criteria of the IFS requirements shall be assessed by the auditor. In the case of a pre-audit, the auditor who performs this audit shall be different from the auditor who performs the initial audit.

3.2 Follow-up audit

A follow-up audit is required in a specific situation when the results of the audit (an initial audit or a renewal audit) have been insufficient to allow the award of the certificate (see chart N° 6). During the follow-up audit, the auditor focuses on the implementation of the actions taken to correct the Major non-conformity determined during the previous audit. The follow-up audit shall be performed within a six months period from the date of the previous audit. In general, the auditor who performed the audit where a Major non-conformity has been identified shall perform the follow-up audit.

If the Major non-conformity is related to production failure(s), the follow-up audit shall be performed at least 6 weeks after the previous audit and no later than 6 months after the previous audit. For other kinds of failures (e.g. documentation), the certification body is responsible for the determination of the date of the follow-up audit.

If there is no follow-up audit performed after 6 months from the date of the previous audit, then a complete new audit is necessary.

In the event that the follow-up audit establishes that requirements remain inadequate, a complete new audit is necessary. The elimination of Major non-conformities shall always be established by an on-site visit by the auditor.

3.3 Renewal audit (for recertification)

Renewal audits are those which are performed after the initial audit. The period in which a renewal audit shall be performed is shown on the certificate. A renewal audit involves a full and thorough audit of a company resulting in the issue of a new certificate. During the audit, all criteria of the IFS requirements shall be assessed by the auditor. Particular attention is paid to the deviations and non-conformities identified during the previous audit, as well as to the effectiveness and implementation of corrective actions and preventive measures laid down in the company's corrective action plan.

Note: corrective action plans from the previous audit shall always be assessed by the auditor, even if the previous audit has been performed more than one year ago. Therefore, audited companies shall always inform their certification body if they have already been IFS certified in the past.

The date of the renewal audit shall be calculated from the date of the initial audit and not from the date of issue of the certificate. Furthermore, the renewal audit can be scheduled at earliest 8 weeks before and at latest 2 weeks after the renewal audit due date (see also section 6.2). Companies are responsible for maintaining their certification. The certification bodies shall contact companies in advance in order to set a date for a new audit.

In general, the expected date of each audit shall be uploaded in the IFS Audit Portal, in the diary function and at latest 2 weeks (14 calendar days) before the audit due date (it is possible to change the date short term).

3.4 Extension audit

In specific situations, such as new products and/or processes to be included in the audit scope or each time the audit scope would need to be updated on the certificate, then, for an IFS PACsecure certified company, it is not necessary to perform a complete new audit, but to organise an on-site extension audit during the validity period of the existing certificate. The certification body is responsible for determining relevant requirements to be audited and relevant audit duration. The extension audit shall be performed by the auditor who performed the "normal" audit. The report of this extension audit shall be represented as an annex adjoined with the current audit report. Conditions for passing the extension audit (relative score $\geq 75\%$) are the same as normal one, but only

focused on specific requirements which have been audited; the original audit score does not change.

If the extension audit demonstrates compliance, the certificate shall be updated with the new scope and uploaded in the Audit Portal.

The updated certificate shall keep the same due date of end of validity as the current certificate.

If, during the extension audit, a Major non-conformity or a KO (Knock Out non-conformity) has been identified, the full audit is failed and the current certificate shall be suspended as described in 5.8.1 and 5.8.2.

4 Scope of the audit

IFS PACsecure is a Standard for auditing primary and secondary packaging material manufacturers and converters.

Although initially developed for **food contact** packaging material manufacturers (e.g. plastic foils for vegetables, cans for beverages, paper wrapping for flour, etc.) IFS PACsecure is also applicable to **non-food contact** packaging materials, such as:

- packaging materials for products intended to be used on the skin (e.g. cosmetic products),
- packaging materials for products not intended to be used on the skin (e.g. household products, consumer goods, hardware, etc.).

The Standard can only be used when packaging material is “processed”, converted or printed and applies both to B to B and B to C businesses. As a result, IFS PACsecure shall not apply to the following activities:

- importation (offices, e.g. typical broker companies)
- transport, storage and distribution.

For clarification of the scope determination between IFS PACsecure and other IFS Standards (Food, Broker, Logistics, Cash & Carry/Wholesale and HPC) please see Annex 1.

deleted

~~If the company trades packaging materials as finished products and if it wants to include them in the audit scope, the suppliers of these products shall themselves be IFS PACsecure certified (if the trade products are under the same product scope) or certified under a comparable scheme (if the trade products are under a different product scope) and the specific requirements in the audit check-list (Part 2) related to trade of packaging materials (4.4.2.1 to 4.4.2.3) shall be fulfilled. If this is not the case, those products shall be excluded from the certificate and the certificate shall mention: “trade activity is not included”~~

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~~If the above mentioned requirements are fulfilled, those traded packaging materials shall clearly be specified on the certificate, detailing the product scope(s), and specified in the report, both in the audit scope and in the company profile.~~

The scope of the audit shall be defined and agreed between the company and the certification body before the audit takes place. The scope shall be clearly and unambiguously stated in the contract between the company and the certification body, in the audit report and on the certificate.

The audit shall be performed at a time to ensure the full scope of products and processes, as mentioned in the report and on the certificate, can be effectively assessed.

If, between two certification audits, new products and/or processes different from those included in the scope of the current IFS PACsecure audit are implemented, the certified company shall immediately inform its certification body, who shall perform a risk assessment to decide whether an extension audit should be performed or not (see also 3.4). The results of this risk assessment, based on hygiene and safety risks, shall be documented.

The audit shall be specific to the site where all the processing of the products is undertaken. Where decentralised structures exist and the audit of a certain location is insufficient for gaining a complete view of the company's processes, then all other relevant facilities shall also be included in the audit. Full details shall be documented within the company profile in the audit report.

The audit scope shall include the complete activity of the company (i.e. the same kind of production on several lines for products under industry brands and retailer/wholesaler brands). The scope shall be reviewed and agreed at the beginning of the audit after an initial risk assessment. Furthermore, the scope can be modified after the risk assessment (for instance, if a further activity interferes with the one concerned by the audit scope).

The audit scope shall make reference to the audited product scope(s) corresponding to the type of packaging materials being processed/converted during the audit (see Annex 3).

If, under exceptional circumstances, the company decides to exclude specific product ranges (product lines) from the scope of the audit, then this shall be clearly noted and included in the audit report and on the IFS PACsecure certificate.

Auditing of multi-location companies with central management

If defined processes are centrally organised in a company with several production sites (e.g. purchasing, personnel management, complaint management), the central managing site – headquarter – shall also be audited and relevant audited requirements outcome shall be considered in the audit reports of each production site.

Note: Each production site shall be audited separately in a period of maximum 12 months after the central managing site and shall have its own audit report and certificate. Each site shall be mentioned in the relevant contract. If the central managing site does not have any production activity, this site cannot be IFS certified as an independent company. The time for auditing the central managing site shall be described in the company profile of the report.

The audit of the managing site shall always take place before the audit of each production site in order to have a preliminary overview.

Note: If it is not possible to perform an audit at the managing site, then it shall be ensured that, during the audit of the production site, all necessary information from the managing site is available (e.g. a representative of the managing site should attend at the audit(s) of the production site(s)).

5 The certification process

5.1 Preparation of an audit

added |

Before being audited, the company shall review all requirements of the IFS PACsecure Standard in detail **and, if existing, IFS doctrine and erratum**". On the day of the audit, the current version of the Standard shall be available at the site being audited. The company is responsible for acquiring the current version of the Standard. In order to prepare for an initial audit, a company may carry out a pre-audit, which is only intended to be used in-house. The pre-audit cannot include any recommendations.

If the audit is not an initial audit, the company shall also inform the certification body so that the auditor can check the corrective action plan from the previous audit.

The expected date for the initial or renewal audit shall be communicated to the IFS offices via the IFS Audit Portal. This shall be the responsibility of the certification body.

5.2 Certification body selection – contractual arrangements

In order to undertake the IFS PACsecure audit, the company shall appoint a certification body which is approved to perform such audits. It is the responsibility of the company to verify that the certification body is accredited for IFS PACsecure certification.

Only those IFS approved certification bodies – which shall be accredited to ISO/IEC 17065 for IFS PACsecure and shall have signed a contract

with IFS (see Part 3) – can carry out IFS PACsecure audits and issue certificates. The list of all IFS international approved certification bodies, by country, is available on the website www.ifs-certification.com.

Certification bodies can have auditors qualified for one or several product scopes. Confirmation of the product scopes for which the certification body can perform audits shall be obtained from the individual certification body.

IFS PACsecure audits can be carried out by an audit team only if all members of the audit team are IFS approved auditors. Additional requirements for audit teams are described in detail in Part 3 of the Standard, chapter 3.6.

An auditor is not allowed to perform more than 3 consecutive audits of the same **production site** (whatever the time between audits); rules in case of audit team are also detailed in Part 3, chapter 3.6.

changed

A contract shall exist between the company and the certification body detailing the scope of the audit, the duration and reporting requirements. The contract shall have a reference to Integrity Program (see chapter 12), in relation to the possibility of on-site audits organized by Quality Assurance Management of the IFS offices.

The audit shall take place when products of the audit scope are being processed/converted.

The audit shall preferably be carried out in the language of the company being audited and the certification body shall make every attempt to appoint an auditor whose native language or main working language is the language of the company. If this is not possible, the audit should be carried out in English language. Furthermore, languages used by the auditor for leading an audit – others than native language – shall be approved by IFS offices prior to undertaking audits (see also Part 3). ~~Nevertheless, and in all cases, the audit report, certificate and action plan shall be written in English language.~~

deleted

5.3 Duration of an audit

The certification bodies have an appropriate system for estimating the minimum time needed for an audit.

A number of factors, which are detailed in the contract between the certification body and the company, play a role in determining the time required for a comprehensive audit. They include:

- the size of the site
- the type of production/conversion process
- the scope of the audit
- the number of production lines involved
- the number of personnel employed at the site
- the number of non-conformities found in the previous audit.

Experience shows that the minimum audit duration on site shall be 2 working days. Exceptions to this requirement, including decreasing linked to multi-site companies, shall be precisely explained by the certification body/the auditor on the first page of the report, in the “company profile” field.

The audit duration might be extended, depending on the above factors. If the auditor estimates that additional time is necessary, the audit duration shall be extended.

The above-mentioned requirements shall apply equally to renewal audits, which shall be considered as completely new audits.

A normal audit day duration is 8 hours.

Independently from audit duration, besides on-site audit, preparation of the audit shall be at least 2 hours.

1/3 of the audit duration shall be spent, as a minimum, in the production/converting area of the site.

Additionally, time for generation of the audit report is typically 0,5 days.

Note 1: For multi-location companies, audit duration could be decreased by a maximum of 0,5 days, if requirements have already been audited at the central managing site.

Note 2: For an audit team, the minimum audit duration shall be 1 day. In addition to the calculated audit time, minimum 2 hours shall be added. This additional time shall be allocated to the team and not to an individual auditor for common tasks (e.g. opening and closing meeting, discussion about audit findings, etc.).

See also Part 3, chapter 3.6 about audit team.

5.4 Drawing up an audit time schedule

The certification body shall provide the audit time schedule. The audit time schedule includes appropriate details concerning the scope covered and the complexity of the audit. The audit time schedule shall be sufficiently flexible to respond to any unexpected events which may arise during the site inspection activity within the certification audit. The audit time schedule takes into consideration a review of the audit report and action plan relating to the previous audit, whatever the date when the previous audit has been performed. It also specifies which of the company's products or product ranges are to be audited. The company can only be audited at a time when it is actually producing/converting the products specified in the scope of the audit. The audit time schedule shall be sent to the auditee before the audit, to ensure availability of responsible persons at the day of the audit.

In case of an audit team, the audit time schedule shall clearly indicate which auditor performs which part of the audit.

If the IFS PACsecure audit is performed in combination with another standard/norm, the audit time schedule shall clearly indicate when each standard or part of it has been audited.

The audit shall be scheduled based on the following steps:

- the opening meeting
- the evaluation of existing quality and product safety systems; achieved by checking documentation (HACCP/risk assessment, quality management documentation)
- the on-site inspection and interviewing of the personnel
- the final conclusions drawn from the audit
- the closing meeting.

The company will assist and co-operate with the auditor during the audit. As part of the audit, personnel from different levels of management are interviewed. It is advisable that the company's senior managers are present at the opening and closing meetings so that any deviations and non-conformities can be discussed.

The auditor(s) who conduct(s) the audit will assess all the requirements of IFS PACsecure which are relevant to the company's structure and function.

During the closing meeting, the auditor (or lead auditor in the case of an audit team) shall present all findings and discuss all deviations and non-conformities which have been identified. As specified by ISO/IEC 17065, the auditor may only issue a provisional assessment of company's status during the closing meeting. The certification body shall issue a provisional audit report and outline an action plan to the company, which shall be used as a basis for drawing up corrective actions for the determined deviations and non-conformities.

The certification body is responsible for making the certification decision and the preparation of the formal audit report after the receipt of the completed action plan. The issue of the certificate is dependent on the audit results and on agreement on an appropriate action plan.

5.5 Evaluation of requirements

The auditor assesses the nature and significance of any deviation or non-conformity. In order to determine whether compliance with a requirement of IFS PACsecure has been met, the auditor has to evaluate every requirement in the Standard. There are different levels to rank the findings.

5.5.1 Scoring a requirement as a deviation

In IFS PACsecure there are 4 scoring possibilities. Scoring with:

- A:** Full compliance with the requirement specified in the Standard
- B:** Almost full compliance with the requirement specified in the Standard, but a small deviation was found
- C:** Only a small part of the requirement has been implemented
- D:** The requirement in the Standard has not been implemented

Points are awarded for each requirement according to the following chart:

Chart N° 1: Scoring

Result	Explanation	Points
A	Full compliance	20 points
B (deviation)	Almost full compliance	15 points
C (deviation)	Small part of the requirement has been implemented	5 points
D (deviation)	Requirement has not been implemented	-20 points

The auditor shall explain all scorings with B, C and D in the audit report.

In addition to this scoring, the auditor can decide to give the company a "KO" or a "Major" non-conformity that will subtract points from the total amount. These possibilities are explained within the next chapters.

5.5.2 Scoring a requirement as a non-conformity

In IFS, there are two (2) kinds of non-conformities which are **Major** and **KO**. Both will lead to a subtraction of points from the total amount. If the company gets at least one of these non-conformities, the certificate cannot be awarded.

5.5.2.1 Major

A Major is defined as follows:

A Major non-conformity can be given to any requirement which is not defined as KO requirement.

When there is a substantial failure to meet the requirements of the Standard, which includes product safety and/or the legal requirements of the production and destination countries. A Major can also be given when the identified non-conformity can lead to a serious health hazard.

A Major will subtract 15% of the possible total amount of points.

Chart N° 2: Evaluation of a Major

Evaluation	Scoring	Result
Major	15% of possible total amount is subtracted	No certificate awarding is possible

See also section 5.8 for the general management of audit process in case of Major non-conformity(ies).

5.5.2.2 KO (Knock out)

In IFS, there are specific requirements which are designated as KO requirements (KO – Knock Out).

If during the audit the auditor establishes that these requirements are not fulfilled by the company, this results in non-certification.

In IFS PACsecure the following 9 requirements are defined as KO requirements:

- 1.2.4 Responsibility of the senior management
- 3.2.1.2 Personnel hygiene
- 4.2.1.2 Raw material specifications
- 4.2.2.1 Product formula compliance
- 4.12.1 Foreign material management
- 4.18.1 Traceability system
- 5.1.1 Internal audits
- 5.9.2 Procedure for withdrawal and recall
- 5.11.2 Corrective actions

KO requirements shall be evaluated according to the following scoring rules:

Chart N° 3: Scoring for a KO requirement

Result	Explanation	Awarded scores
A	Full compliance	20 points
B (deviation)	Almost full compliance	15 points
C (deviation)	Small part of the requirement is implemented	No "C" scoring is possible
KO (= D)	The requirement is not implemented	50% of the possible total amount of points is subtracted => No certificate awarding is possible

Important note

A "C" scoring is not possible for KO requirements. In this respect, the auditor can only use A, B or D (= KO).

When a KO requirement has been scored as “D”, 50% of the possible total amount of points will be subtracted automatically meaning that the company is “not approved” for IFS PACsecure certification.

A KO cannot be scored with N/A, except KO 4.2.2.1.

See also section 5.8 for the general management of audit report in case of one or several KO requirements.

5.5.3 Scoring a requirement with N/A (not applicable)

When the auditor decides that a requirement is not applicable for a company, the auditor has to use as scoring:

N/A: Not applicable and provide a short explanation in the audit report.

N/A scoring is possible for any requirements of the IFS PACsecure audit checklist, except for KO requirements (exception for KO 4.2.2.1).

N/A requirements shall not be included in the outline action plan, but they shall be listed in a separate table in the audit report.

If there are a significant number of requirements which are deemed as not applicable, using a total points score for the audit may be misleading; however, the scoring system for IFS PACsecure is based on a percentage of the total available score and it is this which is used to decide the status of the site i.e. foundation or higher level.

5.6 Determination of the audit frequency

For all products and for all certification levels, the audit frequency for IFS PACsecure audits is 12 months, starting from the date of the audit and not the date of issue the certificate. Further regulations are described in 6.2 (certification cycle).

5.7 Audit report

Following each audit, a full written report shall be prepared in the agreed format (see Part 4).

5.7.1 Structure of the audit report

The audit report shall provide transparency and confidence to the reader and will be completed by the auditor. The audit report is subdivided into different sections.

- General information about the company with compulsory fields (see Part 4)

- General audit result with detailed description of the scope
- General summary in a tabular format for all chapters. The result of the audit will specify the level and percentage
- General summary of all chapters and comments about follow-up of corrective actions implemented from the previous audit
- Observations on KO requirements and Major non-conformities
- Summary of all established deviations and non-conformities for each chapter (1 to 6)
- Separate list (including explanations) of all requirements evaluated with N/A (not applicable)

All deviations (B, C, D) and KO requirements scored with a B, non-conformities (Major, KO requirement scored with a D) identified during the audit, are presented in a separate action plan. Following the allocation of a grade, non-conformities and deviations, the company has to produce a corrective action plan. In this way, the reader of the report can see the non-conformities and deviations, and also the corrective actions that the company is initiating.

5.7.2 The different steps for the audit report

5.7.2.1 Drawing up the pre-report of the audit and the outline of the action plan

The auditor shall explain all non-conformities (KO requirements scored with a D and Majors), all deviations (B, C, D) and KO requirements scored with a B, and all requirements that are found N/A.

The action plan shall include all the requirements which are not evaluated with A or N/A. The outline action plan shall conform to the ~~outline action plan as specified in Part 4, Annex 3. It shall include the elements of the chart N° 4.~~ **auditXpressX™ software (IFS audit report writer assistant) outline action plan. It shall include the elements of the following chart.**

changed

The auditor shall complete all of field A in chart N° 4 explaining and justifying the deviations and non-conformities finding before sending the company the outline action plan and the pre-report of the audit.

The certification body or the auditor shall send the company both the pre-report of the audit and the outline action plan within two weeks of the audit date.

Note: If the auditor identified deviations during the audit and the audited company has already planned corrective actions, the deviations shall be noted in the audit report and a comment shall be added indicating the company has already planned corrective actions.

Chart N° 4: Outline action plan

Number of the requirement	IFS requirement	Evaluation	Explanation (by the auditor)	Corrective action (by the company)	Responsibility Date and status of implementation (by the company)	Release by the auditor
			Field A	Field B	Field C	Field D
1.2.1	An organisation chart ...	B				
1.2.2	Competences and responsibilities ...	C				
1.2.3	Job descriptions with clearly ...	D				
1.2.4 KO	The senior management shall ensure ...	KO/D				
1.2.5	Employees with influence ...	Major				

5.7.2.2 Company's completion of the corrective action plan

The company shall enter proposed corrective actions (field B of chart N° 4) for all deviations (B, C, D) and KO requirements scored with a B and non-conformities (Major, KO requirements scored with a D) listed by the auditor.

For all evaluated deviations with score C and D, as well as non-conformities, Major or KO requirements scored with a B and/or a D, the company shall clearly state the responsibilities and implementation deadlines for corrective action (chart N° 4, field C). The company shall forward the corrective action plan to the certification body within 2 weeks of having received the pre-report of the audit and the action plan layout. If this deadline is not respected, the company has to undergo a complete initial or renewal audit.

An IFS PACsecure certificate shall not be awarded unless the corrective actions for requirements scored with a C or D, and KO requirements scored with B, specify responsibilities and implementation dates in the action plan.

The final decision of awarding the IFS PACsecure certificate is dependent both on final scoring and on relevance of corrective action plan communicated by the company to the certification body.

The company shall always submit a written corrective action plan before receiving the final report and the certificate. The intention of the corrective action plan is for the company to strive for continuous improvements.

5.7.2.3 Auditor validation of the action plan

The auditor or a representative of the certification body shall validate the relevance of the corrective actions in the last column of the action plan before preparing the final audit report (Field D of the chart N° 4). If the corrective actions are not valid or are inadequate, the certification body shall return the action plan to the company for completion in due time.

5.7.3 Further rules about the audit report

5.7.3.1 Link between two consecutive audit reports (initial and renewal audits)

When the auditor scores a requirement with C or D, corrective actions shall be implemented before the renewal audit. This means the certification body shall read the audit report and the action plan of the previous audit, even if the report was issued by another certification body.

If C and/or D scorings remain the same from one audit to the next, or if scorings are getting worse, the auditor shall assess in accordance with the IFS chapter related to "Corrective actions" (chapter 5.11 of the audit check-list, Part 2). This link between two consecutive audits ensures a continuous improvement process.

5.7.3.2 Translation of the audit report

| added

As the IFS standards are used internationally, it is important that customers understand the audit report; this is particularly important in relation to deviations and non-conformities identified by the auditor, as well as corrective actions proposed from the audited company. To make use of IFS internationally and to make it widely understandable, the following explanations for deviations and non-conformities shall always be translated into English in the action plan (chart N° 5, Field A) and in the audit report:

- Requirements evaluated with a C or D
- Major non-conformities
- KO requirements scored with a B or a D
- The audit scope (on the relevant page of the audit report)
- Detailed activity (operating processes, if there are subcontracted activities, etc.) of the company, which is described in the company profile.
- In the company profile, if relevant, the reasons for reducing audit duration.

The corrective actions related to these deviations and non-conformities shall also be translated into English in the action plan.

It is an obligation and the responsibility of the certification bodies to translate these explanations and corrective actions. The translation shall be made under each sentence of the original version and included in the audit report, before uploading the final audit report to the audit portal.

5.8 Scoring and conditions for issuing audit report and certificate

Chart N° 5: Scoring and awarding of certificates

Audit result	Status	Action company	Report form	Certificate
At least 1 KO scored with D	Not approved	Actions and new initial audit to be agreed upon	Report gives status	No
> 1 Major and/or < 75% of the requirements are fulfilled	Not approved	Actions and new initial audit to be agreed upon	Report gives status	No
Max 1 Major and ≥ 75% of the requirements are fulfilled	Not approved unless further actions taken and validated after follow-up audit	Send completed action plan within 2 weeks of receiving the preliminary report. Follow-up audit max. 6 months after the audit date	Report including action plan gives status	Certificate at foundation level, if the Major non-conformity is finally solved as controlled during the follow-up audit
Total score is ≥ 75% and < 95%	Approved at foundation IFS PACsecure level after receipt of the action plan	Send completed action plan within 2 weeks of receiving the preliminary report.	Report including action plan gives status	Yes, certificate at foundation level, 12 months validity
Total score is ≥ 95%	Approved at higher IFS PACsecure level after receipt of the action plan	Send completed action plan within 2 weeks of receiving the preliminary report.	Report including action plan gives status	Yes, certificate at higher level, 12 months validity

Note: the total score is calculated as follows:

Total number of points

= (total number of IFS requirements – requirements scored with N/A) × 20

Final score (in %)

= number of points awarded/total number of points.

deleted

~~The certificate shall always be issued in English language. If requested by the customer, it can additionally be issued in a different language.~~

5.8.1 Specific management of the audit process (report, certificate, uploading) in case one or several KO's has/have been scored with D during the audit (see also Annex 4)

In case one or several KO is/are scored with D during the audit, the current IFS PACsecure certificate shall be suspended in the IFS Audit Portal by the certification body as soon as possible and a maximum 2 working days after the audit date.

In the database, explanation about reasons for suspending the current certificate shall be given in **English language**. Clear explanations about the identified non-conformity(ies) shall be provided by giving the number of involved KO requirement(s). These explanations shall be detailed and be the same as those described in the action plan.

Note: All users having access to the IFS Audit Portal and having mentioned the respective company in their favourites list will get an e-mail notice from the IFS Audit Portal that the current certificate has been suspended.

In each case, the audit shall be completed and all requirements shall be evaluated in order to give the company a complete overview about its situation.

Furthermore, it is recommended to complete the action plan for improvement purposes.

The audit report where one or several KO requirement(s) have been scored with D shall always be uploaded into the IFS Audit Portal (only for administrative purpose, but will not be visible).

In these situations, a complete new audit shall be performed. The new audit shall be scheduled no earlier than 6 weeks after the audit where a KO requirement was scored with D.

5.8.2 Specific management of the audit process (report, certificate, uploading) in case one or several Major non-conformity(ies) has/have been issued (see also Annex 4)

In case one or several Major non-conformity(ies) is/are issued during the audit, the current IFS PACsecure certificate shall be suspended in the IFS Audit Portal by the certification body as soon as possible and a maximum 2 working days after the audit date.

In the database, explanation about reasons for suspending the current certificate shall be given in **English language**. Clear explanations about the identified non-conformity(ies) shall be provided by giving the number of involved requirement(s). These explanations shall be detailed and be the same as those described in the action plan.

In cases where more than one Major non-conformity have been identified, a complete new audit shall be performed. The new audit shall be scheduled no earlier than 6 weeks after the audit where Major non-conformities were issued.

If the Major non-conformity is related to production failure(s), the follow-up audit shall be performed at least 6 weeks after the previous audit and no later than 6 months after the previous audit. For other kinds of failures (e.g. documentation), the certification body is responsible for the determination of the date of the follow-up audit.

The audit report where one or several Major non-conformity(ies) has/have been identified shall always be uploaded into the IFS Audit Portal after receiving the action plan (only for administrative purpose, but will not be visible).

Specific situation in case of follow-up audit:

If a Major non-conformity has been identified with a total score of 75% or above and then resolved, **and** if the audit result is deemed positive:

The certification body shall mention on the updated audit report:

- in the “date” section: specify the date of the follow-up audit in addition to the date of audit when the Major non-conformity was identified,
- in the “final result of audit” section: specify that a follow-up audit has taken place and that the Major non-conformity has been solved,
- in the “observations regarding KO non-conformities and Majors” section explain on which requirement the Major non-conformity has been solved.
 - The company cannot be certified with higher level even if the final total score is equal or more than 95%.
 - The same valid date of the certificate remains in the certification cycle as described in 6.2.
 - It shall be defined on the certificate the date of initial audit and date of follow-up audit.
 - If it was during an initial audit, the longest certificate valid due date is calculated using initial audit date, plus one year and 8 weeks.

Example:

Initial audit date 1:	01. October, 2018
Date of issue of certificate:	26. November, 2018
Certificate valid until:	25. November, 2019
Renewal date	
(audit where Major has been issued) 2:	25. September, 2019
Follow-up audit:	03. December, 2019
Latest date of validity of the certificate:	25. November, 2020.

The report (first of the audit with the estimated Major, then updated with results of follow-up audit) shall be uploaded into the IFS Audit Portal after performing the follow-up audit with the proviso that the Major non-conformity is finally solved.

5.8.3 Specific management of the audit process in case the final score is <75%

In these situations, the certification is failed and a complete new audit shall be performed. The new audit shall be scheduled no earlier than 6 weeks after the audit where the final score was <75%.

5.8.4 Specific management of the audit process in case of multi-site companies

All KO requirements shall be audited at all sites even if some of them are partly managed at the central managing site.

In the audit report of each site, only the audit date of the respective site shall be mentioned; the audit date of managing site is not additionally necessary.

In case that a Major non-conformity or a KO scored with D has been issued during the audit of the central managing site, all audited production sites are also affected and the certificates of these sites shall be suspended (according the procedure described above).

After a successful audit of the central managing site (or after positive follow-up after a Major was issued in the central managing site), the certificates of the production sites can be reinstated. Depending upon which non-conformity has been issued in the central managing site, a new audit of the production sites may also be necessary.

6 Awarding the certificate

A certificate shall be issued to one specific site.

Detailed minimum mandatory information to be published on the IFS PACsecure certificate is determined in Part 4. **The audit scope on the IFS PACsecure certificate shall always be translated into English.**

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Note: the final audit score, in percentage, can also be published on the certificate, if required by customer and/or audited company.

6.1 Deadlines for awarding certificate

The certification body is responsible for the decision to award or not award the IFS PACsecure certificate. The decision is made by person(s) other than those who have carried out the audit. The certification shall be valid effectively from the date of issue stated on the certificate itself and shall end after 12 months. The date for the renewal audit shall be calculated from the date of the initial audit, not from the date of issue the certificate. If the audit is not performed in due time, the retailers or other users will be informed via the Audit Portal.

The time between the date of the audit and the awarding of certificate is determined as follows:

- 2 weeks to draw up the pre-report of the audit
- 2 weeks for the company to respond to the deviations and non-conformities (i.e. draw up the action plan)
- 2 weeks for the auditor to check the proposed corrective actions, for the certification procedure and upload of the audit report, the action plan and the certificate to the Audit Portal.

In total: 6 weeks between the date of audit and uploading the audit report to the Audit Portal and awarding the certificate:

- Target time: 6 weeks,
- Maximum time: 8 weeks.

6.2 Certification cycle

Even if the renewal audit due date changes every year and does not completely correspond to the anniversary date, the certificate validity date shall remain the same each year. Due date of the certificate is determined as follows: initial audit date + 8 weeks.

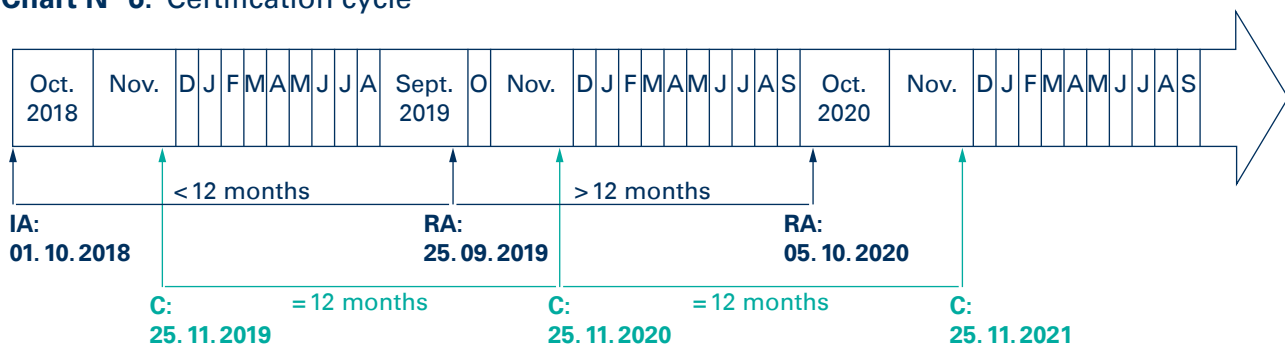
This allows to avoid gaps between two (2) consecutive certificates and to avoid that a company scheduling the audit earlier loses some months of certificate validity.

Example:

Initial audit date:	01. October, 2018
Date of issue of certificate:	26. November, 2018
Certificate valid until:	25. November, 2019

Renewal audit date:	25. September, 2019
Certificate valid until:	25. November, 2020 (independently from the renewal audit date).

Chart N° 6: Certification cycle



IA: Initial audit
 RA: Renewal audit
 C: Issue a certificate valid until

Note: the certificate shall always be edited on the basis of a certification decision and after the several steps of certification decision according to ISO/IEC 17065.

Ideally, the renewal audit shall be performed within eight (8) weeks of the date of expiry of certificate to have enough time for the several steps of the certification process.

The renewal audit shall be scheduled at earliest eight (8) weeks before and at latest two (2) weeks after the audit due date (due date is anniversary date of the initial audit). If this is not the case, or if the several steps of the certification process were not completed in time, the certificate cannot be renewed with the "due date" but with the actual new date; this will lead to a break in the certification.

In the example above, this means that the audit shall never be scheduled before 06. August and after 15. October.

The previous audit report remains a further eight (8) weeks (after audit due date) on the Audit Portal, but if the renewal audit takes place later than described above, the report will be automatically inactivated from the IFS Audit Portal.

6.3 Information about conditions of withdrawal of certificate

Withdrawal of certificate by the certification body is only permitted in case of any information indicating that the product may no longer comply with the requirements of the certification system (ISO/IEC 17065).

The only exception of this rule may be related to the non-payment of the current audit by the certified company.

The contract between certification body and audited company shall be harmonized with the certification cycle (see above chart N° 6).

7 Distribution and storage of the audit report

Audit reports shall remain the property of the company and shall not be released, in whole or part, to a third party without the company's prior consent (except where required by law). This consent for distribution of the audit report must be in writing and can be granted by the company vis-à-vis the certification body and/or vis-à-vis the relevant user. The certification body shall keep a copy of the audit report. The audit report shall be stored safely and securely for a period of five years.

Access conditions to information about audit reports are fully detailed in Part 4.

8 Supplementary action

The decision on the level of supplementary actions required on the basis of the certificate shall be made at the discretion of the individual buying organisation.

9 Appeal and complaints procedure

The certification body shall have documented procedures for the consideration and resolution of appeals against the results of an audit. These procedures shall be independent of the individual auditor and will be considered by senior management of the certification body. Appeals will be finalised within 20 working days of receiving information from the auditee.

The certification body shall have documented general procedures for handling complaints received from the companies and/or other relevant parties. An initial response will be given within ten (10) working days of receiving the complaint. A letter confirming receipt of the complaint will be issued within a maximum of five (5) working days. A full written response will be given after the completion of a full and thorough investigation into a complaint.

For the handling of complaints received by the IFS offices, the basis for the complaint management is described in the IFS framework agreement with certification bodies:

- If the complaint relates to the quality of the content of IFS PACsecure audits or IFS PACsecure audit reports, IFS offices require the certification body to provide a statement on the cause and the measures introduced to rectify the problem within 2 weeks.

- If the complaint relates to administrative errors, e.g. in IFS PACsecure audit reports, IFS PACsecure certificates or in the IFS database, IFS offices ask the certification body to provide a statement and rectify the problem within one (1) week. The statement shall be issued in writing by e-mail or post.

10 Ownership and usage of the IFS PACsecure logo

The copyright of IFS PACsecure and the registered trademark is fully owned by the IFS Management GmbH. The IFS PACsecure logo can be downloaded via the secured section of the IFS Audit Portal.

Furthermore, the below terms and conditions shall be checked by the auditor during the audit and results of this check shall be described in the company profile of the audit report as a compulsory field (see Part 4, section 1.1). If the auditor identifies during an audit that the company does not fulfil the conditions of logo usage, the auditor shall note it in the company profile of the audit report and shall inform the IFS offices accordingly.

Terms and conditions for using the IFS PACsecure logo and communication about the IFS PACsecure certification

Application

These terms and conditions apply for both IFS PACsecure and all IFS logos in general.

Form, design and colour of the IFS PACsecure logo

When used, the IFS PACsecure logo must comply with the form and colour of the scale drawing. If it is used in documents, black and white print is also permitted.

The IFS PACsecure logo can be used in print, physical and electronic form, and in films, providing the forms and formats are respected. The same conditions apply to the use of the logo as a stamp.

Restriction of comment and interpretations

When an IFS PACsecure certified company, an IFS PACsecure supporting company or an IFS PACsecure certification body publishes documents bearing the IFS logo, comment and interpretations referring to the IFS shall be clearly identifiable as such.

Use of the IFS PACsecure logo in promotional material

An IFS PACsecure certified company, an IFS PACsecure supporting company (broker, food manufacturer, retailer, logistics provider or wholesaler) which accepts IFS PACsecure certificates from their suppliers or service providers, or an IFS certification body may use the IFS logo for

promotional reasons and publish information about IFS certification provided that it is not visible on final product packaging which are available to the end-consumer (B to C business).

Companies which provide products and/or services to IFS certified or supporting companies, but which are not themselves IFS certified (e.g. manufacturers of devices, clothing, cleaning materials or service providers which would like to promote that their products and/or services help to fulfil the IFS requirements) must ask for express written permission to IFS Management GmbH to use the IFS PACsecure logo and/or any other IFS logo(s).

The IFS PACsecure logo and information about the certification may be used in correspondence with relevant IFS users. Presentations mentioning IFS on the internet are only permitted if they are in a direct link with product safety (e.g. within information about the safety/quality management system).

The IFS PACsecure logo may be displayed on any kind of general communication (e.g. exhibitions for business contacts, brochures, generic articles about packaging, product safety and quality management in general, vehicles). The IFS PACsecure Standard was developed in order to assure the product safety and quality.

It must be ensured that all information concerning certifications refers clearly to IFS. The IFS logo may not be used in presentations having no clear connection to IFS.

Further restriction on the use of the IFS PACsecure logo

The IFS PACsecure logo shall not be used in a way that could show intent that the IFS owner is responsible for the certification decision. Furthermore, the same applies for opinions and interpretations which could be derived from it. In the event of suspension or withdrawal of the IFS PACsecure certification, the certified company has to immediately stop the inclusion of the IFS logo on its documents or other associated material and cease all communications regarding IFS. The audited company must demonstrate that they have complied with these requirements.

Communication of the IFS PACsecure certification

All the above mentioned rules apply to any communication regarding IFS PACsecure. This also means that using the wordmarks "IFS", "International Featured Standards", or "IFS PACsecure" or similar is not allowed when communicating on finished products, which are available to the end-consumer.

11 Review of the Standard

The Review Committee needs to demonstrate control of the quality and content of the Standard and will review annually the Standard and the Protocol to ensure that they are still in compliance with their requirements. The Review Committee shall be formed with all participants involved in the audit process: the representatives of retailers, representatives of the industry, of (non) food services and of certification bodies. The objective of the Review Committee is to share experiences, discuss and decide about the changes to the Standard, the requirements of the audit report and training.

12 IFS Integrity Program

| changed

Note: Due to changes in IFS Integrity Program procedures, this chapter has been completely changed.

The IFS Integrity Program, launched in early 2010, includes different measures to assure the quality of the IFS certification schemes by reviewing audit reports of certified companies and by several measures to analyze and improve the work of certification bodies and auditors. The IFS Integrity Program strengthens the reliability of the IFS schemes by checking the implementation of the IFS standards in practice.

The main procedures of IFS Integrity Program are described in the Annex 4 of the framework agreement; these procedures have been developed in regular meetings of the IFS Quality Assurance Working Group composed of international members. The Annex 4 of the framework agreement has to be signed by all certification bodies having a contract with IFS Management GmbH. Auditors performing IFS audits have to accept the IFS Integrity Program procedures to assure a qualitative performance of IFS audits. Certification bodies are obliged to inform their customers applying for an IFS audit certificate about the content of the Annex 4 of the framework agreement in current version. The IFS Integrity Program mainly works on the following activities:

12.1 Complaint management

A detailed complaint management process analyzes all necessary information. Retailers or any other interested parties have the right to forward any possible complaint issue to IFS for investigation as part of the Integrity Program. The respective information can be forwarded by e-mail via complaintmanagement@ifs-certification.com or via a complaint form on the IFS website www.ifs-certification.com.

The IFS offices will gather all necessary information in order to investigate the cause of the complaint and to establish if there are deficiencies by certified companies, accredited certification bodies or IFS approved

auditors in meeting IFS requirements. Appropriate steps are taken to fully investigate a complaint, which may include a request to a certification body to carry out internal investigations and to provide a statement on the outcome of their investigations to IFS.

Finally IFS Quality Assurance Management will decide which approach could be the best to assess and solve the complaint. This might also be to plan an Integrity on-site Check at the IFS certified company to investigate the case on-site or to organize an Integrity Witness Audit for an IFS approved auditor involved in the complaint case (In this case, an Integrity auditor assesses an IFS auditor during one of his/her next regular IFS audits).

Based on the complaint reason the Integrity on-site Checks will mainly be performed unannounced (announcement 30 minutes before start of the Integrity on-site Check). In some special cases Integrity on-site Checks might also be performed announced (announcement in general about 48 hours before).

12.2 Risk based approach and monitoring of IFS Quality Assurance

Quality Assurance activities of IFS Integrity Program monitor the entire IFS system by different tools:

In order to care for correct implementation of all procedures described in IFS standards and respective regulative documents IFS Integrity Program carries out regularly office audits at certification bodies (Integrity CB Office Audits). During these Integrity CB Office Audits work performance of IFS approved auditors and of certification bodies is checked by means of several report examples and database analyses. If during these Integrity CB Office Audits special topics have to be clarified, this could also lead to Integrity Witness Audits of IFS approved auditors or to Integrity on-site Checks at companies certified by the respective certification body.

Additionally—taking into account a risk based approach—reports of certified companies are analyzed and read by IFS Quality Assurance Management staff. For the risk based approach different criteria have been defined by IFS Quality Assurance Working Group. These analyses are an ongoing monitoring procedure of IFS Quality Assurance Management taking into account both economic criteria (e.g. number of issued certificates in certain countries) or quality criteria (e.g. audit results, audit times etc.). As described before, Integrity on-site Checks will mainly be performed unannounced and in some special cases might also be performed announced. Integrity Witness Audits of IFS approved auditors may also be based on this risk based approach analysis of IFS Quality Assurance Management.

General comment for section 12.1 and 12.2:

Companies having a valid IFS certificate have to accept an unannounced/announced Integrity on-site Check and to give access and support to the commissioned Integrity auditor. The acceptance of the IFS Integrity Program is part of the regulations of all IFS standards.

Also witnessing IFS approved auditors from certification bodies by commissioned Integrity auditors during regular IFS audits has to be accepted.

Integrity on-site Checks or Integrity Witness Audits and also Integrity CB Office Audits carried out as part of the Integrity Program are conducted by Integrity auditors employed at or commissioned by IFS Management GmbH. Integrity auditors are completely independent of the auditees and the IFS certification bodies.

12.3 Sanctions

If, following a complaint or following the risk based approach/monitoring quality assurance actions, the cause of a deficiency has been found to be the fault of a certification body and or an auditor, IFS will forward all necessary information anonymously to an independent sanction committee. The sanction committee, which is made up of a lawyer and participants from industry, retailers and certification bodies, shall make a decision on whether a breach exists and on its severity.

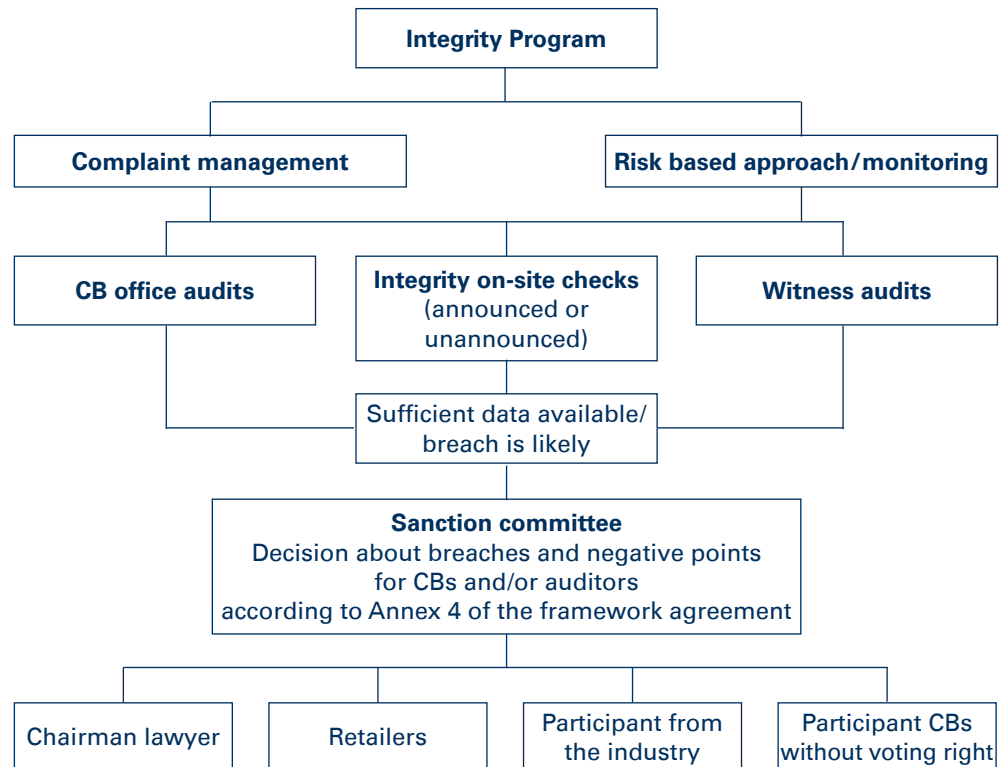
Topics concerning administrative faults of certification bodies based on database investigations can be directly assessed by the IFS Quality Assurance Management, but have to be confirmed by the chairman (lawyer) of the sanction committee.

Sanctions and/or penalties will be issued to the certification body and/or its auditors if the sanction committee concludes that a breach has been committed. The type of sanction and/or penalty depends on the severity of breach. In connection with each finally decided breach a certification body and/or an auditor may get a certain amount of "negative points". These "negative points" are summarized, but the period of limitation is 2 years (rolling system). Only in very severe cases certification bodies or auditors might be suspended for a certain time frame or contracts might be cancelled. In general the target of IFS Integrity Program activities is to improve the performance of certification bodies and/or auditors by requesting corrective actions like attending at further trainings in case of decided breaches.

IFS Management informs the appropriate accreditation body if a breach for a certification body and/or for an auditor has been decided.

All these procedures concerning breaches, penalties and “negative points” are laid down in the Annex 4 of the framework agreement between IFS and each certification body.

Chart N° 7: Summary of IFS Integrity Program activities



ANNEX 1: Clarification for the scope application of the different IFS Standards

IFS PACsecure is a Standard for auditing food and non-food packaging material manufacturers and converters and only concerns packaging processing and/or converting companies.

IFS Food is a Standard for auditing food product suppliers/manufacturers and only concerns food processing companies or companies that pack loose food products. IFS Food shall be used when a product is “processed” or when there is a hazard for product contamination during the primary packing.

IFS Logistics is a Standard for auditing companies whose activities are logistics oriented for food and non-food products, as well as packaging materials, such as transport, storage, distribution, loading/unloading, etc. It applies to all types of activities: delivery by road, rail or ship; frozen/refrigerated products or ambient stable products.

Clarifications/examples of scope application between IFS PACsecure and IFS Logistics:

- IFS Logistics only concerns logistics activities where companies have a physical contact with already processed/converted packaging materials (transport, storage and/or distribution, transport and storage of pallets). When the processing company has its own logistics and/or transport department/activities (storage and distribution), it is included in the IFS PACsecure under the specific sub-chapter about transport or storage.

Note: If the logistics operation owned by the processing company is situated in the same location as the company, and if the company or the customer wishes to get this operation IFS Logistics certified, an IFS Logistics audit can be performed.

In this case, the following requirements shall be fulfilled:

- the logistics operation is only used for already packed packaging materials,
 - in case of two (2) certificates (IFS PACsecure and Logistics), the respective scopes of each audit and certificate shall be clearly defined,
 - the requirements of IFS PACsecure concerning transport and storage shall be anyway evaluated during the IFS PACsecure audit,
 - an IFS PACsecure audit of the processing company shall be performed; IFS Logistics is an additional audit,
 - all relevant documents shall be located at the platform.
- If logistics and/or transport activities are outsourced by the processing company, the requirements specified in the appropri-

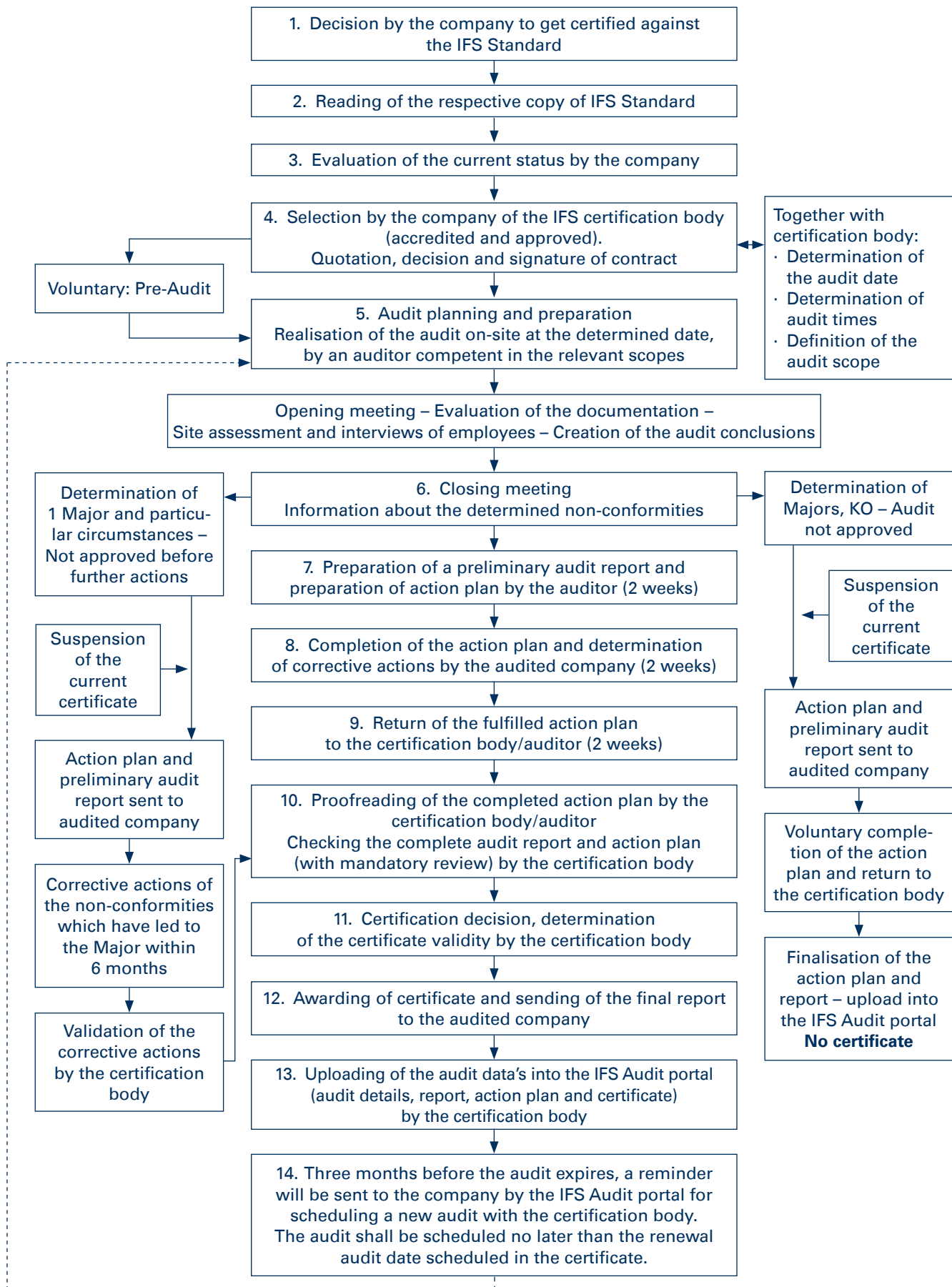
ate chapter of IFS PACsecure about storage and transport shall be clearly defined in the respective contract, or IFS Logistics applies.

IFS Broker is a Standard for auditing companies such as trade agencies, brokers or any other companies that do not take physical possession of the products or material (e.g. which do not have warehouses, packing stations or truck fleet, but are legal entities with mailboxes, offices etc.). The Standard applies to food, packaging and household and personal care products.

Matrix for the determination of the right IFS Standard

N°	Main activity of the company	International Featured Standards					
		IFS Food	IFS HPC	IFS Log. 2	IFS Broker	IFS C&C/W.	IFS PAC secure
1	Food processing (when products are processed or as soon as there is a hazard for product contamination)	X					
2	HPC processing (when products are processed or as soon as there is a hazard for product contamination)		X				
3	Food, Non-Food, HPC, packaging materials logistics activities Logistics activities only as service, no trading activities (when companies have a physical contact with already primary packed products or only for specific unpacked goods, such as meat carcasses or bulk/tanker transport (glucose syrup, milk, grain, etc.))			X			
4	Food, HPC, packaging trading without product contact (when no physical possession of products, only purchase – sale from an office, no logistics activities)				X		
5	Cash & Carry/Wholesale (when distribution of products, small amount of processing activities can be included, under specific requirements)					X	
6	Packaging materials processing/converting (when packaging products are processed/converted)						X
Combined certification							
7	Food/HPC/packaging material trading and Food/HPC/packaging material logistics Combined audit for trading AND logistics activities, with a specific combined check-list			X	X		

ANNEX 2: Certification process



ANNEX 3: Product scopes

In IFS PACsecure version 1.1, all activities of the company are related to product scopes as follows:

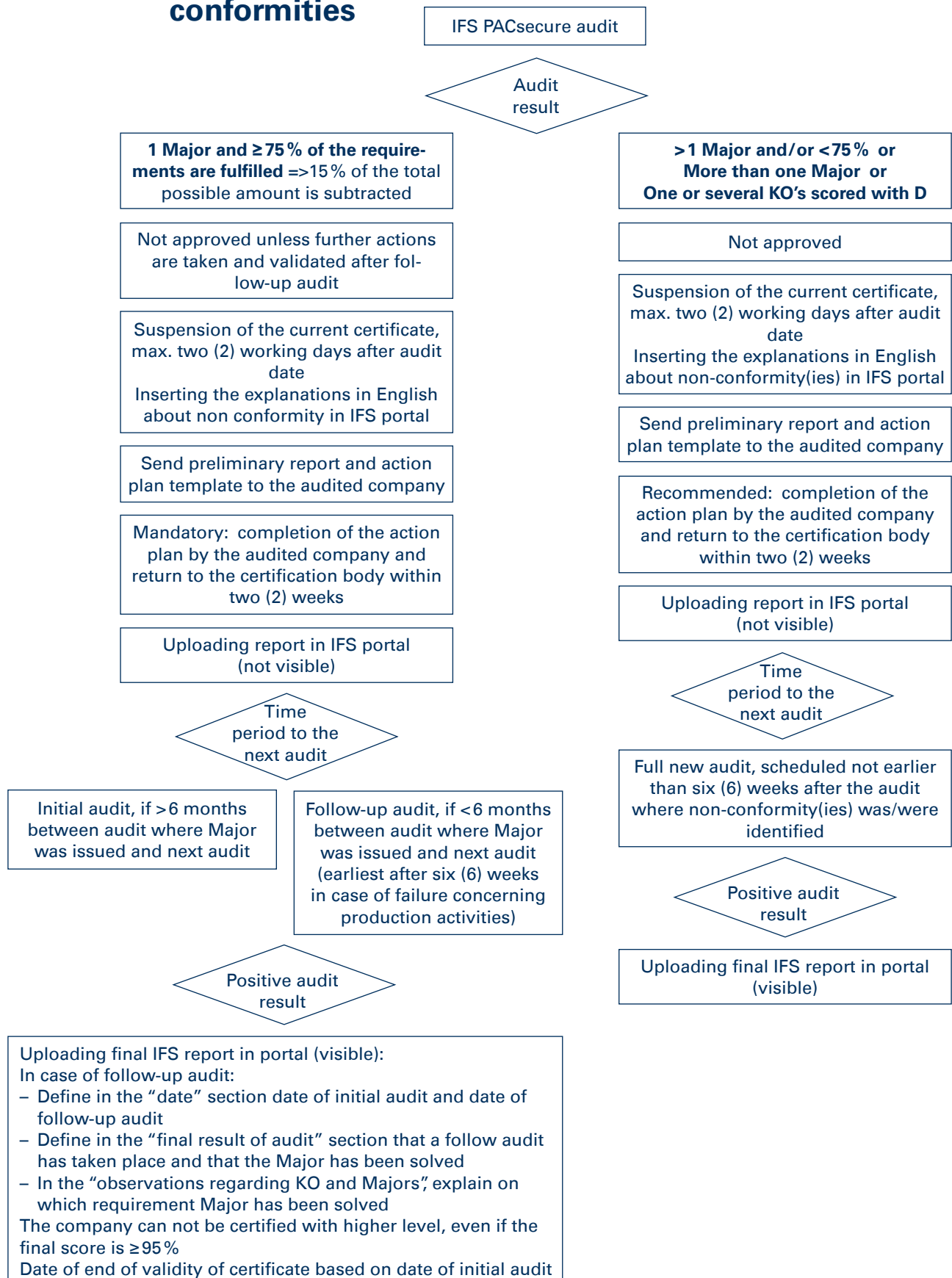
Table 1: Product scopes

1. Flexible packaging
2. Rigid plastic
3. Paper
4. Metal
5. Glass
6. Other natural materials

Multi component packaging materials (e.g. Tetra Pak) have to be assigned based on the material which is the main component of the material. The main component of multi component packaging materials shall be mentioned in the scope of the audit on the report.

Materials to be considered as “other natural materials” are, for example wood, clay, cork, jute, textiles, banana leaves, etc.

ANNEX 4: Flow chart for management of KO scored with D and Major non-conformities



Part 2: List of audit requirements

The following list contains the IFS PACsecure auditing requirements.

The below chart demonstrates the connection between IFS PACsecure and PACsecure Prerequisite Program requirements. Additionally, there are examples given on questions auditors should ask (5th column) and examples for KO or Major scoring (6th column).

The PACsecure Packaging Material Manufacturer & Converter Generic Food Safety Prerequisite Program (PP) contains foundation requirements on documentation, management and food safety program maintenance, and considers current packaging industry practices. The IFS PACsecure was developed taking into account this Program.

PACsecure documents, workbooks and plans (Packaging Material Manufacturer & Converter Generic Food Safety Prerequisite Program, HACCP Workbooks and HACCP Plans) can be obtained from Packaging Consortium of Canada. These documents can assist, for example, in implementing HACCP for a specific packaging material manufacturer, like e.g. manufacturers of flexible packaging and may be used as industry guidelines as mentioned in requirement 2.2.1.1

IFS PAC secure number	IFS PACsecure requirement	Conne- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
1	Senior Management Responsibility	5.0			
1.1	Corporate policy/Corporate principles				
1.1.1	The senior management shall draw up and implement a clear corporate policy. This shall consider as a minimum: – customer focus – environmental responsibility – sustainability – ethics and personnel responsibility – product requirements (includes: product safety, quality, legality, process and specification). The corporate policy shall be communicated to all employees.	5.0	Management commit- ment to the food safety system is required. This may be demonstrated by the development and approval of a food safety policy or other statements of commit- ment to the food safety system.	– How and where is corporate policy documented? – What are the contents of the corporate policy? – How was corporate policy communicated to all employees? – <corporate policy>, <posters> <docu- mented evidence of corporate policy communication> Environmental responsibility and sustain- ability are included in the IFS PACsecure Standard, even if it is a packaging material safety and quality standard, in order to initiate/develop in companies processes of awareness for both topics.	
1.1.2	The corporate policy shall have objectives specifying responsibilities and timelines appropriate for the size and complexity of the organization.			– What short, medium and long term quality objectives are addressed? – How are the objectives attained? – What is the time frame to attain the objec- tives? – Who is responsible for objectives attain- ment? – What actions are taken by specific departments, e.g. purchase, to attain the objectives? – <written review meeting minutes>, <list of attendees at review meeting>, <quality objectives>	

added

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
1.1.3	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.			<ul style="list-style-type: none"> - What quality objectives are defined? - Are these objectives known by concerned employees? - What tools are used to measure that the objectives have been attained? - <list of attendees at review meeting>, <mailing list of review meeting minutes>, <posters showing the different department objectives> 	
1.1.4	The senior management shall ensure that the achievement of all objectives is regularly reviewed, as a minimum at least once a year.			<ul style="list-style-type: none"> - When is objective achievement reviewed? - How often is this review performed? - <review>, <review minutes>, <internal audit report> 	There is basically no review/other rating of objectives available.
1.1.5	All relevant information related to packaging material safety and quality shall be communicated effectively and in a timely manner to the relevant personnel.			<ul style="list-style-type: none"> - How is relevant information transmitted to concerned persons? - <posters>, <distribution of meeting minutes> 	A packaging material safety and/or legality issue occurs due to missing communication within the company.
1.2	Corporate structure				
1.2.1	An organisation chart shall be available showing the structure of the company.			<ul style="list-style-type: none"> - Is an organisation chart available? - How is the organisation structured? - <organisation chart> 	
1.2.2	Competences and responsibilities, including deputation of responsibility shall be clearly laid down.			<ul style="list-style-type: none"> - For which positions do written job descriptions exist? - What is regulated in the job descriptions? - Who, for example substitutes QA manager during his absence? - <responsibility description for important key staff "dedicated to a specific person", e.g. QA Manager, Production Manager, Shift Leader ...> 	When a packaging material Safety and Legality issue occurs due to failure to define responsibilities for existing company regulations.

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
1.2.3	Job descriptions with clearly defined responsibilities shall exist and shall be applicable for employees whose work has an effect on product requirements.	5.0	For each prerequisite program and HACCP Plan the responsibility for complying with the requirements of this standard is assigned to a competent employee.	<ul style="list-style-type: none"> – What is the content of the job descriptions? – For which positions do job descriptions exist? 	
1.2.4 KO	KO N° 1: 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.	5.0	The authority to develop, implement and maintain the prerequisite programs will be established by management.	<ul style="list-style-type: none"> – How is it ensured that employees know their responsibilities? – How does senior management ensure that employees know their responsibilities? – Who is responsible for packaging material safety? 	When senior management does nothing to ensure that employees know their responsibilities. When during the audit the Auditor has evidence that key employees are not aware of their responsibilities and this leads to a packaging material safety and/or legality issue.
1.2.5	Employees with influence on product requirements shall be aware of their responsibilities, and shall be able to demonstrate their understanding of their responsibilities.	5.0	Key personnel and responsibilities will be identified in the written program.	– <interview of at least: QSMO Quality Manager , person responsible for labeling/printing, person responsible for product development, person responsible for production, person responsible for monitoring CP's >	Key employees are not aware of their responsibilities.

changed

changed

IFS PAC secure number	IFS PACsecure requirement	Connec-tion with PACsecure PP require-ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
1.2.6	The company shall have an IFS PACsecure representative nominated by senior management.			<ul style="list-style-type: none"> - Who is the IFS PACsecure representative? - What are the responsibilities of the IFS PACsecure representative? - Is the function of the IFS PACsecure representative clearly laid down? - <job description>, <organization chart> 	No IFS PACsecure representative exists.
1.2.7	The senior management shall provide sufficient and relevant resources to meet the product requirements.			<ul style="list-style-type: none"> - How were the necessary resources defined? - <budget plan> 	When senior man-agement doesn't provide enough resources and this leads to a packaging material safety and/or legality issue.
1.2.8	The department responsible for quality and packaging material safety management shall have a direct reporting relationship to the senior management.			<ul style="list-style-type: none"> - Who is the QS Quality manager? - To whom does the QS Quality manager report? - <job description>, <organization chart> 	
1.2.9	The company shall ensure that all processes (documented and undocu-mented) are known by the relevant personnel and are applied consis-tently.			<ul style="list-style-type: none"> - What criteria are used to ensure process control? - What is done to ensure that processes are known to relevant personnel (incl. permanent staff and temporary/seasonal workers)? Processes can be understood as ISO processes (see also chapter 2.3, Part 1 of the standard) 	When key personnel have no process knowledge and this leads to a packaging material safety and/or legality issue.

IFS PAC secure number	IFS PACsecure requirement	Conne- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
1.2.10	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.			<ul style="list-style-type: none"> – How does management ensure that all relevant packaging safety laws are in place and known? – How does management ensure that purchased products comply with all relevant legislation? – How does management ensure that manufactured products comply with all relevant legislation? <packaging material laws subscription>, <training> 	When absence of legal knowledge and information on relevant laws lead to a packaging material safety and/or legality issue.
1.2.11	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.			For example, if regulatory bodies come to the company and identify that something is wrong (related to legality/quality/safety) on a private label product, the company shall inform the relevant customer accordingly. If this product is also manufactured for other customers and if the identified deviation/ non-conformity also has an impact on the other private labels, the company shall also inform these other relevant customers.	
1.3	Customer focus				
1.3.1	A documented procedure shall be in place to identify fundamental needs and expectations of customers.			<ul style="list-style-type: none"> – How are customer needs and expectations identified? – How often are these identified? <questionnaire/survey regarding customer needs and expectations> 	

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
1.3.2	The results of this procedure shall be evaluated and considered to determine quality and packaging material safety objectives.			<ul style="list-style-type: none"> - What were the results of the last customer survey? <analysis of customer surveys> - How these results were evaluated regarding quality objectives? <quality objectives> - Have identified needs influence on the production process? <survey analyses> 	
1.4	Management review				
1.4.1	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.	6.1 6.6	<p>Management will determine the internal activities required to ensure the requirements of this standard are met.</p> <p>The food safety program shall be reviewed at least once per year to assess if it is:</p> <ul style="list-style-type: none"> - Current. That is, it reflects factors including, but not limited to: <ul style="list-style-type: none"> · Applicable standards. · Operational/Process/Material changes. · Organization changes. · Scientific developments. - Implemented. 	<ul style="list-style-type: none"> - When is the quality and safety management system reviewed and evaluated? - How often was the system reviewed last year? - What was the result of the review? <review report> - Does the management review take into consideration, as a minimum, the assessment of the following: <ul style="list-style-type: none"> · documents from the previous management review, · results from internal and external audits, as well as inspections, · performance indicators for customers, complaints and withdrawals/recalls, · incidents, corrective actions, results out of specifications and non-conforming materials, · process performance and product compliance, · review of hazard analysis/risk assessment system and changes which may affect quality and packaging material safety system, 	When the quality management system is not reviewed regularly and there is no assurance that it works properly.

added

IFS PAC secure number	IFS PACsecure requirement	Conne- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
			– Maintained. Results of the re-as- sessment are used to update, maintain or improve the food safety system.	<ul style="list-style-type: none"> · evolutions of scientific information related to products, · improvement of quality system efficiency and production process, · improvement of product, related to customer requirements, · needs in resources (including invest- ments)? 	
1.4.2	This review shall include the evalua- tion of measures for the control of the quality and packaging material safety management system and for the continuous improvement process.	6.1	The frequencies of completing activities will be established and will ensure the effective implementation and maintenance of the packaging material safety system.	Based on the review result, have any actions for improvement been taken? <improvement actions>	
1.4.3	The company shall identify and review regularly (e.g. by internal audits or on-site inspection) the infrastructure needed to achieve conformity to product requirements. This shall include, as a minimum, the following: – buildings – supply systems – machines and equipment – transport. The results of the review shall be considered, with due consideration to risk, for investment planning.			<ul style="list-style-type: none"> – When is infrastructure (building, machin- ery, transport) evaluated? – What was the result of infrastructure evaluation? <audit report> – Who evaluated infrastructure? – What were the results of the infra- structure assessment? <corrective actions> <investment plan> – Were the results used for further infra- structure planning? <investment plan> – What risks were identified according to the results of infrastructure assessment? <hazard analysis> – What are infrastructure related investments for the near future? <investment plan> 	When infrastructure is not evaluated and therefore a risk for legality, safety and quality of products occurs.

deleted

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
1.4.4	<p>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:</p> <ul style="list-style-type: none"> – staff facilities – environmental conditions – hygienic conditions – workplace design – external influences (e.g. noise, vibration). <p>The results of the review shall be considered, with due consideration to risk for investment planning.</p>			<ul style="list-style-type: none"> – When is the work environment (staff facilities, environmental conditions, safety and security at work, hygienic conditions, workplace design etc.) evaluated? – What was the result of work environment evaluation? <audit report> – Who evaluated work environment? – What were the results of the work environment assessment? <corrective actions> <investment plan> – Were the results used for further work environment planning? <investment plan> – What risks were identified according to the results of the work environment assessment? <hazard analysis> – What are work environment related investments for the near future? <investment plan> 	When work environment is not evaluated and therefore a risk for legality, safety and quality of products occurs.
2	Quality and Packaging Material Safety Management System				
2.1	Quality management				
2.1.1	Documentation requirements	4.1	Control of Documents Documents are created and maintained to ensure the effective development, implementation, maintenance and improvement of the food safety system. A document control procedure is established that will define how documents are:		

IFS PAC secure number	IFS PACsecure requirement	Conne- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
			<ul style="list-style-type: none"> - Approved. - Reviewed, revised and updated. - Remain legible and easily identifiable. - Identified, including current status (e.g. revision level). - Maintained so current versions are available for use and unintended use is prevented. Each prerequisite program requires proper documentation of the program elements and supporting information including, but not limited to: <ul style="list-style-type: none"> - Standard operating procedures. - Forms. - Checklists. - Corrective Action Reports. - Food Safety Program Reassessment. 		
2.1.1.1	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).	4.1		<ul style="list-style-type: none"> - Where is documentation concerning the quality system for quality assurance and packaging material safety retained? <procedure for document control> 	When there is no quality system for quality assurance and packaging material safety in place.

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
2.1.1.2	A documented procedure shall exist for the control of documents and their amendments.	4.1		<ul style="list-style-type: none"> – What rules exist regarding document control? – Do the documents have an identification code? – How is the identification code structured? – How can a revision be identified? – Who is responsible for changes <procedure for documents> 	When documents do not state clearly which exist, are in use and valid.
2.1.1.3	All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times.	4.1		<ul style="list-style-type: none"> – Are all documents legible? – Are the documents unambiguous? – Are the documents available at the right places? Also after office hours? – How do relevant employees have access to documents? – How are document changes communicated to relevant employees? – Are there any distribution lists for documents? <examples>, <procedure>, <distribution lists> 	When documents are unavailable and this endangers legality, safety or quality of the product.
2.1.1.4	All documents which are necessary for compliance with the product requirements shall be available in their latest version.	4.1		<ul style="list-style-type: none"> – How is document validity identified? – How is it ensured that only valid documents are in circulation? 	When void/obsolete or out-of date documents are not identified as such and thus endanger legality, safety or quality.
2.1.1.5	The reason for any amendments to documents critical for the product requirements shall be recorded.	4.1		<ul style="list-style-type: none"> – Are the reasons for any amendments to documents, critical for the product requirements recorded? <examples> 	

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
2.1.2	Record keeping				
2.1.2.1	All relevant records necessary for the product requirements shall be complete, detailed and maintained and shall be available on request.	4.2	Records are established to provide objective evidence of conformity to the requirements of the food safety program.	<ul style="list-style-type: none"> – What records exist? – Are the records complete? – Are the records available? 	When insufficient or no records are made and thus endanger legality, safety or quality.
2.1.2.2	Records shall be legible and genuine. They shall be maintained in a way that subsequent manipulation of records is prohibited.	4.2	<p>A procedure is established that will define how food safety related records are maintained so that they are:</p> <ul style="list-style-type: none"> – Legible. – Readily identifiable and retrievable. – Auditable. – Protected and stored to prevent damage or deterioration. – Stored for an appropriate retention period. – Properly disposed. <p>Records include, but are not limited to, completed:</p> <ul style="list-style-type: none"> – Forms. – Checklists. – Service Agreements and Contracts. – Corrective Action Reports. – Food Safety Program Reassessment. 	<ul style="list-style-type: none"> – Are records plausible? – Are records legible? – What kind of assurance is given that records cannot be subsequently manipulated? – Are the records reviewed by a supervisor? 	When records are illegible and therefore no evidence exists for legally required checks/inspections.

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2.1.2.3	All records shall be kept in accordance with legal requirements and for a minimum of one year after the recommended converting time. For products which have no recommended converting time, the duration of record keeping shall be justified and this justification shall be documented.	4.2		<ul style="list-style-type: none"> - Where are records stored? - Who stores records? - How long are records kept? On what basis were record storage times defined? - For products with a short recommended converting time, was record storage time definition based on hazard analysis? If a recommended converting time is defined, corresponding records shall be available at least until that date. <procedure documents>, <hazard analysis> 	When records are not stored in accordance to legal requirements.
2.1.2.4	Any amendments to records shall only be carried out by authorized persons.	4.1		<ul style="list-style-type: none"> - How are amendments to records carried out? - Who is authorized to make amendments? - How are amendments authorized? 	When a general problem exists regarding record changes/amendments in the company.
2.1.2.5	Records shall be securely stored and easily accessible.			<ul style="list-style-type: none"> - What is the process in place to make documents and data available and readable? <backup system>, <storage condition> 	
2.2	Packaging Material Safety Management				
2.2.1	Hazard analysis and risk assessment system	See generic HACCP models PACsecure			

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
2.2.1.1	The basis of the company's packaging material safety control 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.			<ul style="list-style-type: none"> - The company's hazard analysis/risk assessment plan system is based on what principles? - Has every site/plant a separate hazard analysis/risk assessment plan system? - Which What What specific regulations are taken care of in hazard analysis/risk assessment plan system? <hazard analysis plan> - are the legal requirements of the destination country are known, especially the labeling regulation? 	<p>If there is no hazard analysis/risk assessment plan system. If legal requirements are not included in hazard analysis/risk assessment plan system. If there is no hazard analysis/risk assessment plan system for each individual site/plant.</p>
2.2.1.2	The hazard analysis and/or risk assessment system shall cover all raw materials, products or product groups as well as every process from goods into dispatch, including product development and product packaging.			<ul style="list-style-type: none"> - Does hazard analysis/risk assessment plan system cover all product groups and processes incl. product development and product wrapping material? - Which processes are performed? <product group overview>, <flow chart> 	<p>When the hazard analysis/risk assessment plan system does not cover all product groups and processes.</p>

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2.2.1.3	The company shall ensure that the hazard analysis and/or risk assessment system is based upon scientific literature, or technical verified specifications or other legally required documentations relating to the manufactured products and procedures. This shall be maintained in line with new technical process development.			<ul style="list-style-type: none"> - Is the hazard analysis/risk assessment plan system based upon scientific literature or technically verified specifications or other legally required documentations relating to the manufactured products and procedures processes? - How are new technical developments taken care of? <references of used literature, etc.> - Does the hazard analysis/risk assessment system meet all applicable regulatory requirements of the country in which it is established, including the required and applicable risk assessments and supporting documentation? (Where applicable, such regulatory requirements will supercede requirements of the standard. Related to Canadian and US law, certain forms and formats are required.) 	When hazard analysis/risk assessment plan system is not based on scientific literature or technically verified data about products and processes and therefore causes a packaging material safety or legality risk.
2.2.1.4	The hazard analysis and/or risk assessment system shall be reviewed and necessary changes shall be made when any modification is made in the product, process or any step.			How are product development/product modification and hazard analysis interconnected?	

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2.2.2	Hazard analysis and/or risk assess- ment team				
2.2.2.1	Assemble hazard analysis and/or risk assessment team The hazard analysis and/or risk assess- ment team shall be multidisciplinary and include operational staff. Person- nel appointed as hazard analysis and/ or risk assessment team members shall have specific knowledge of hazard analysis and/or risk assessment, prod- uct and process knowledge and the associated hazards. Where competent knowledge is not available, external expert advice shall be obtained.			<ul style="list-style-type: none"> - Who is member of the hazard analysis/ risk assessment team? - Which departments/functions are included in the hazard analysis/risk assessment team? - How was qualification for hazard analy- sis/risk assessment team membership verified? <evidences for education, advanced training> - What hazards are connected to the product? - Does a contract exist with an external expert? <service contract> 	Although there is a lack of product knowledge no external expert has been consulted and this results in packag- ing material safety and legality risk.
2.2.2.2	Those responsible for the develop- ment and maintenance of the hazard analysis and/or risk assessment system shall have an internal team leader and shall have received adequate training in the application of the hazard analysis and/or risk assessment principles.			<ul style="list-style-type: none"> - What is the content of a hazard analy- sis/risk assessment training course? <hazard analysis training proofs> - When was the last hazard analysis/risk assessment training course held? <training evidences> - Who participated in the hazard analy- sis/risk assessment training course? <training evidences> 	

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2.2.2.3	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.			<ul style="list-style-type: none"> – Who is member of the hazard analysis/risk assessment team? – Is the team well known across the company? How was it announced? <job descriptions>, <team matrix>, <blackboard notice>, <presence of management in any hazard analysis brief>, <result of hazard analysis review include in Management review>, <attribution of resources> 	When no hazard analysis/risk assessment team exists or no person has been appointed hazard analysis team leader.
2.2.3	Hazard analysis and risk assessment	See generic HACCP models PACsecure			
2.2.3.1	Describe product The assessment shall make reference to the full description of the product including all applicable relevant information on product safety such as: <ul style="list-style-type: none"> – composition (raw materials, rework, reprocessing, recycled waste etc.), – physical, chemical and microbiological parameters, – methods of treatment, – wrapping, labeling, – durability (shelf life), – conditions for storage and method of transport. 	Form 1		<ul style="list-style-type: none"> – Does a complete product description exist for each product? – What is included in the product description? <product description> <product specification> 	When there are no product descriptions for each product. When product descriptions do not provide essential product data. When essential information does not match legislation (e.g. migration test values).

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2.2.3.2	<p>Identify intended use The intended use of the product shall be described in relation to the expected use of the product by the consumer, taking into account vulnerable groups of consumers.</p>	Form 1		<ul style="list-style-type: none"> - What is the intended use of the product by customer? - What is the intended use of the product by final consumer? - Are there any restrictions for usage? <product description> 	When there is a packaging material safety risk for consumers due to lack of definition for usage.
2.2.3.3	<p>Construct flow diagram A process flow diagram shall be evaluated against each product, or product group, and for all variations of the processes and sub-processes.</p>	Form 3		<ul style="list-style-type: none"> - Are flow charts available for all products? - Are the flow charts dated? <flow charts for all products> 	Flow charts are unavailable for any of the products, charts or are not conform to the specifications or other legally required documentation.
2.2.3.4	<p>On-site confirmation of the flow diagram 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>	Form 3		<ul style="list-style-type: none"> - Was the flow chart confirmed during a hazard analysis/risk assessment meeting? <meeting minutes> 	When flow charts are not validated.
2.2.3.5	<p>Conduct a hazard analysis and risk assessment for each step An assessment shall be available of all physical, chemical and biological hazards that may reasonably be expected.</p>	Form 3, 5, 6, 7		<ul style="list-style-type: none"> - Does a hazard analysis/risk assessment exist for each step? <hazard analysis> - Does it include every hazard? - Which biological, physical and chemical hazards can be expected? <hazard analysis> 	When a hazard analysis/risk assessment was not performed for each step. When hazards were not properly assessed or not all significant hazards were taken into account and a safety issue exists.

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2.2.3.5.1	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).			<ul style="list-style-type: none"> – Does a hazard analysis for all product groups including harm and likelihood exist? <hazard analysis> 	When, due to lack of a hazard analysis, a safety risk exists.
2.2.3.5.2	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.	4.1 6.5 Form 3, 5, 6, 7, 8	<p>Each prerequisite program requires proper documentation of the program elements and supporting information including, but not limited to:</p> <ul style="list-style-type: none"> – Standard operating procedures. – Forms. – Checklists. – Corrective Action Reports. – Food Safety Program Reassessment. <p>Changes to the prerequisite programs will be reviewed and approved by authorized personnel.</p>	<ul style="list-style-type: none"> – Which CPs were defined? – How many CPs exist – Is a clear limit defined for each CP? – What clear limits are defined? – How were the critical limits determined? <hazard analysis> <flow chart> <decision tree> 	When there are no clear limits for each CP or they are insufficient and this causes a safety risk.

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2.2.3.5.3	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.	Form 3, 5, 6, 7, 8		<ul style="list-style-type: none"> - How are CPs monitored? - Are the CPs under control? - How is the monitoring of each CP documented? - Who documents? - Are date, time, responsible employee and result/reading documented? - How long will records be stored? - Where are records stored? - Which prerequisite measures are documented? - How are the measures documented? <hazard analysis> <flow chart>, <decision tree>, <prerequisite measures> 	When CPs were not identified as such and/or they are not under permanent control so that a safety risk exists.
2.2.3.6	<p>Establish corrective actions</p> <p>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.</p>	Form 10		<ul style="list-style-type: none"> - What corrective actions exist for each CP? - When was a corrective action carried out? - Where are corrective actions documented? - Who documents the taken corrective actions? <CP records> <corrective actions> 	When there are no corrective actions defined or no corrective actions are taken. When corrective actions are not documented.

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2.2.3.7	<p>Establish verification procedures 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"> – internal audits, – analysis, – sampling, – evaluations, – complaints by authorities and customers. <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>	6.2 Form 10	<p>Verification activities are completed for each prerequisite program to confirm that the programs are:</p> <ul style="list-style-type: none"> – Properly implemented. – Adequately maintained. – Suitable to the operations of that establishment in controlling identified food safety hazards. <p>Verification activities may include, but are not limited to:</p> <ul style="list-style-type: none"> – Internal Inspections. – Document review. – Internal Audits. – External Audits, Assessments, Inspections. – End product testing. 	<ul style="list-style-type: none"> – How often is the hazard analysis/risk assessment plan system verified? – What was the date of the last verification? – What was the result of the last verification? – Does the hazard analysis/risk assessment plan system reflect the results of the verification? – What was the last date when the hazard analysis/risk assessment plan was changed? <audit reports or other reports for validation> 	When no verification was carried out and this leads to a safety risk.
2.2.3.8	<p>Establish documentation 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.</p>	4.1	<p>Documents are created and maintained to ensure the effective development, implementation, maintenance and improvement of the food safety system.</p>	<ul style="list-style-type: none"> – What hazard analysis/risk assessment plan system related documents exist? – Do these documents include processes, procedures and results? <inspection plans>, <records>, <product descriptions>, <hazard analysis>, <risk assessment> 	When hazard analysis/risk assessment plan system is not sufficiently documented and this leads to a legality issue.

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3	Resource Management				
3.1	Human resources management				
3.1.1	All personnel performing work that affects product safety, legality and quality shall have the required competence by education, work experience and/or training, commensurate with their role, based on hazard analysis and assessment of associated risks.	D 1.1.1	1	– How is it assured that new employees have the right capabilities for the job?	When, due to lack of education, experience or training the legality or safety of the product is jeopardized.
3.2	Human resources				
3.2.1	Personnel hygiene				
3.2.1.1	There shall be documented requirements relating to personnel hygiene. These include, as a minimum, the following fields: – protective clothing – hand washing and disinfection – eating and drinking – smoking – actions to be taken in case of cuts or skin abrasions – fingernails, jewelry and personal belongings – hair and beards. The requirements shall be based on hazard analysis and assessment of associated risks in relation to product and process.	D 1.1.1 D 2.1.1/2	2, 3, 4	– What is the policy regarding personal personnel hygiene? <hygiene rules for employees> – Do the rules regarding personnel hygiene include hand cleaning, food, beverages and other material, smoking, handling of injuries, finger nails and jewelry, hair and beards? – Are the rules based on a hazard analysis? <hazard analysis> – Where is it allowed to smoke? – How should lesions be treated/covered? – What kinds of hair restraints are needed in which areas? Example of result from the hazard analysis and assessment of associated risks: if gloves are used, then hand disinfection is not required for low risk production.	When insufficient rules for personal personnel hygiene cause a safety risk. When no corresponding hazard analysis exists.

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3.2.1.2 KO	KO N° 2: The requirements for personnel hygiene shall be in place and applied by all relevant personnel, contractors and visitors.			<ul style="list-style-type: none"> – How is the hygiene policy communicated? <hygiene rules for employees> – Are personnel hygiene rules also followed by external service providers/workmen and visitors? <hygiene rules for visitors> – How is it assured that external persons know the relevant hygiene rules? <hygiene rules for visitors> 	When, during the audit major violations of the rules are identified that lead to a safety risk.
3.2.1.3	Compliance with personnel hygiene requirements shall be checked regularly.			<ul style="list-style-type: none"> – How are employees monitored during work? <hand swab tests, etc.> – Is employee compliance to hygiene rules checked on a regular basis? <minutes site inspection>, <list of identified failures>, etc. 	
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.	D 1.1.1 D 2.1.1 D 1.2.1	2,3 1 3	<ul style="list-style-type: none"> – Is it allowed to use jewelry and watches in production areas? <personnel hygiene rules> – Is allowance based on risk hazard analysis? <hazard analysis> 	When wearing jewelry or a watch causes a packaging material or employee safety risk.
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.	D 2.2.1–3	1,2,3	<ul style="list-style-type: none"> – What color is plaster and where is it used? – Does the plaster contain a metal strip? – What is an employee required to observe in case of hand injury? <personnel hygiene rules> 	When hand injuries ensue a product safety risk (e.g. an uncovered purulent wound that comes into contact with the product).

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3.2.2	Working conditions and protective clothing for personnel, contractors and visitors				
3.2.2.1	Company procedures shall exist to ensure that all personnel, contractors and visitors are aware of the rules regarding the management of wearing and changing of protective clothing in specified areas in accordance with product requirements.	D 2.1.1–2	1,2	<ul style="list-style-type: none"> – What are the rules regarding protective clothing? <personnel hygiene rules> – Are the protective clothing rules based on hazard analysis? <hazard analysis> – When must protective clothing be changed? <personnel hygiene rules> – examples of areas: catering, changing rooms, smoking area, toilets, etc. 	When the lack of protective clothing ensues a product safety risk.
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.	D 2.1.2	1	<ul style="list-style-type: none"> – In which production areas is wearing of protective headgear and/or beard snood mandatory? – What kind of headgear is used? – How shall headgear be used? <personnel hygiene rules> 	When incorrect wearing or absence of headgear and/or beard snood ensues a product safety risk.
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.	D 2.1.2		<ul style="list-style-type: none"> – In which production areas is wearing of gloves mandatory? <personnel hygiene rules> – What kinds of gloves are used? When must gloves be changed? – How is the compliance with these rules checked? <on site inspections> 	When missing or unclean gloves ensue a product safety risk.
3.2.2.4	Suitable protective clothing shall be available in sufficient quantity for each employee, when required.			<ul style="list-style-type: none"> – How many protective suits/uniforms are at the disposal of each employee? – How often is an employee supposed to change his/her protective suit/uniform? 	When employees do not have protective clothing and therefore a product contamination risk exists.

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3.2.2.5	When required, all protective clothing shall be thoroughly and regularly laundered. 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.			<ul style="list-style-type: none"> - How is protective clothing laundered? <personnel hygiene rules> - Are there any employees who launder their protective clothing at home? - Is protective clothes laundering based on a hazard analysis? <hazard analysis> 	When insufficient laundering ensues a product contamination risk.
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.			<ul style="list-style-type: none"> - How is the laundering procedure checked for effectiveness? <protective clothes swab test results> - What guidelines exist regarding protective clothes laundering? <personnel hygiene rules> 	
3.2.2.7	Senior management shall ensure hazardous working conditions that could cause injuries to personnel are identified and preventive measures are managed.			<p>How the good working condition of personnel is followed? How are personnel informed?</p>	
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.			<p>Does an inspection plan exist? <report of inspection></p>	

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3.2.3	Procedures applicable to infectious diseases				
3.2.3.1	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.	D 2.1.1–2 D 2.2.1–3	1, 2 1, 2, 3, 4, 5	<ul style="list-style-type: none"> – How shall personnel and visitors behave in case or suspicion of an infectious disease? – How is it ensured that personnel and visitors know the guidelines? <personnel hygiene rules> <visitors hygiene rules> 	When due to an employee's infectious disease a product safety risk is given and no preventive steps are taken by the company.
3.3	Training and instruction				
3.3.1	The company shall implement documented training and/or instruction programs with respect to the product requirements and the training needs of the employees based on their job and shall include: <ul style="list-style-type: none"> – training contents – training frequency – employee's task – languages – qualified trainer/tutor – evaluation methodology. 	D 1.2.1–4 7.0 D 1/D 2 D 1.1.1	1, 2, 3 1, 2, 3, 4, 5	<ul style="list-style-type: none"> – Who is responsible for training? <training evidences> – What are the evidences for the trainer's qualification? – What was the content of the last training session? <training program> – How are foreign employees trained/instructed? – Who participates in the training sessions? – How are the instruction necessities for each employee determined? – How often are training sessions held? <training schedule> 	When due to lack or insufficient training a product safety or legality risk exists. When legally required packaging material safety instructions are not undertaken.

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3.3.2	The documented training and/or instruction shall apply to all personnel, including seasonal and temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained in accordance with the documented training/instruction programs.	D 1.2.1-4	1, 2, 3, 7	<ul style="list-style-type: none"> - Are prospective employees (incl. seasonal and temporary workers) trained/instructed upon employment? - Which employees are trained/instructed upon employment? What is the content of these instructions? <training evidences>	
3.3.3	Records shall be available of all training/instruction events, stating: <ul style="list-style-type: none"> - list of participants (this shall include their signature) - date - duration - contents of training - name of trainer/tutor. There shall be a procedure or program in place to prove the effectiveness of the training and/or instruction programs.	D 1.2.1-4	5, 7	<ul style="list-style-type: none"> - Which training courses are undertaken? - Are there any special training courses? - Are training courses documented? - What has been documented? - Have participants signed the training proofs? - How often are hygiene training sessions held? - What was the content of the last hygiene training session? <training evidences>	No training proofs exist to confirm that employees were trained/instructed.
3.3.4	The contents of training and/or instruction shall be reviewed and updated regularly and take into account company's specific issues, packaging material safety, packaging material related legal requirements and product/process modifications.	D 1.2.1-4	4, 5	<ul style="list-style-type: none"> - How are training contents reviewed? - When are training contents reviewed? - When was the latest training content update done? - What was the content of the latest update? <review test> <audit results> <ul style="list-style-type: none"> - specific issues: non-conformities, failure, complaints, etc 	During the on-site audit evidence was given that employees did not act according to knowledge transmitted in the training sessions and this lead to a product safety risk.

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3.4	Sanitary facilities, equipment for personnel hygiene and staff facilities				
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 packaging material safety risks. Such facilities shall be kept in clean and good condition.	A 3.1.2 7.0 A 3 A 3.1.1 A 3.1.2	4 1, 2, 3 1, 2, 3, 4, 5, 6, 7, 8, 9	<ul style="list-style-type: none"> - How many employees are there? - Do they have access to a cafeteria? - Are there locker-rooms? - Where are the restrooms? - Are there bathing facilities? <plant lay-out> - Staff facilities = e.g. changing room, smoking area, dining room, etc. 	When social staff facilities are underequipped or are out of proportion to the number of employees so that a safety issue arises.
3.4.2	The risk of product contamination by foreign material from staff facilities shall be evaluated and minimized. Consideration shall also be given to food and other material brought to work by personnel and personal belongings.			<ul style="list-style-type: none"> - May employees bring food and other material from home? <personnel hygiene rules> - May employees take medicine along to their work place? <personnel hygiene rules> - Does a hazard analysis exist regarding foreign material from social staff facilities? <hazard analysis> 	
3.4.3	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.				

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IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
3.4.4	The company shall provide suitable changing rooms for personnel, contractors and visitors. Where necessary, outdoor clothing and protective clothing shall be stored separately.	A 3.1.2	7,8	– Are there locker-rooms for employees and visitors with separation for outdoor and protective clothing?	
3.4.5	Toilets shall not have direct access to an area where packaging material 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.	A 3.1.2 A 3.1.1	6 3	– Do toilets open directly into production areas?	When toilet exhaustion poses a contamination risk.
3.4.6	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.	A 3.1.1	1,2	– Are there enough hand washing facilities available at the entrance to processing areas and in social staff areas?	When a contamination problem occurs due to lack of hand washing facilities.
3.4.7	Hand washing facilities shall provide as a minimum: <ul style="list-style-type: none"> – running potable water at an appropriate temperature – liquid soap – appropriate equipment for hand drying. 	A 3.1.1	1	<ul style="list-style-type: none"> – Are all hand washing facilities provided with appropriate equipment for hand drying and liquid soap? – Are all hand washing facilities provided with running potable water at an appropriate temperature? 	

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IFS PAC secure number	IFS PACsecure requirement	Connec- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
3.4.8	If necessary, following additional requirements regarding hand hygiene shall also be provided: – hand contact-free fittings – hand disinfection – adequate hygiene equipments – signage highlighting hand hygiene requirements – waste container with hand contact-free opening.	A 2.1.1	1, 2, 3, 4, 5	– Are all areas where due to risk assessment extended hygiene requirements are necessary equipped with hand washing facilities with hand contact-free fittings, hand disinfection devices and signs or pictograms? <signs/pictograms>	When a contamination problem occurs due to lack of appropriate hand washing facilities.
3.4.9	Based on hazard analysis and assessment of associated risks, there shall be a program to control effectiveness of hand hygiene.	A 3.1.1	2		
3.4.10	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. Based on hazard analysis and assessment of associated risks, exceptions shall be justified and managed.	A 3.1.2	6	– Do locker-rooms give direct access to processing areas? – How is protective clothing handled during breaks/intervals? <personnel hygiene rules> – Does a hazard analysis exist for locker-rooms with no direct access to processing areas? <hazard analysis>	When a contamination occurs due to locker-room location which leads to packaging material product safety problem.
3.4.11	Where the hazard analysis and assessment of associated risks show the necessity, cleaning facilities shall be available and used for boots, shoes and further protective clothing.			– Are there cleaning facilities for boots and protective aprons?	

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4	Planning and Production Process				
4.1	Contract agreement				
4.1.1	The requirements which are defined between the contract partners shall be established, agreed upon and reviewed concerning their acceptability before a supply agreement is concluded. All clauses related to quality and packaging material safety shall be known and communicated to each relevant department.			<ul style="list-style-type: none"> – What assurances are given that customer requirements and own specifications or other legally required documentations are in accordance with each other? – Do written supply agreements with customers exist? – Do specific customer requirements for purchased products exist? – Who checks and approves specifications or other legally required documentations? – Who ensures that the proper raw materials are available whenever needed? 	When there are no approved specifications or other legally required documentations and no clarity exists if required product can be delivered.
4.1.2	Changes of existing contractual agreements shall be documented and communicated between the contract partners.			<ul style="list-style-type: none"> – How is it ensured that customers are informed about product changes? – Who checks and approves specifications or other legally required documentations? 	
4.2	Specifications and formulas/ configurations				
4.2.1	Specifications and other legally required documentation				
4.2.1.1	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.			<ul style="list-style-type: none"> – How are specifications or other legally required documentations compiled, checked and approved? – Are there specifications or other legal required documentations for all final products? – How are up to date specifications or other legally required documentations recognizable? <specifications or other legal required documentation> 	When not all specifications for final products are up to date and in conformance with legal requirements.

IFS PAC secure number	IFS PACsecure requirement	Conne- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.2.1.2 KO	KO N° 3: 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). Specifications shall be up to date, unambiguous and be in compliance with legal requirements and, if existing, with customer requirements.	Form 2		<ul style="list-style-type: none"> – Are specifications or other legal required documentation available for all raw materials, additives, inks, adhesives, solvents, wrapping material and rework? – What assurance is given that specifications and other legally required documentation are followed? <evidence of specification compliance, e.g. lab results> – What assurance is given that specifications are in conformance with legal requirements? – Who writes, checks and approves specifications? 	When not all raw materials, additives, inks, adhesives, solvents, wrapping materials and rework have specifications or other legal required documentation. When specifications do not comply with legal requirements.
4.2.1.3	Where required by customers, product specifications shall be formally agreed.				
4.2.1.4	Specifications or other legally required documentation and/or their contents shall be provided in the relevant location and accessible to all relevant personnel.			<ul style="list-style-type: none"> – Who has access to specifications or other legally required documentation? 	When key employees do not have access to specifications or other legally required documentation and a product safety and/or legal requirement issue ensues.

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.2.1.5	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.			– Who writes, amends, checks and approves specifications or other legally required documentation?	When specifications or other legally required documentation are used but have not been properly approved and it is not clear if they can be complied with.
4.2.1.6	The specification/other legally required documentation control procedure shall include the update of finished product specification in case of any modification: <ul style="list-style-type: none"> – of raw material – of formula/configuration – of process with influence on the final products – of wrapping material with influence on the final products. 				
4.2.2	Formula/configuration				
4.2.2.1	KO N° 4: Where there are customer agreements in relation to the product formula/configuration and technological requirements, these shall be complied with.			<ul style="list-style-type: none"> – What assurance is given that specified configuration is followed? – How is configuration compliance checked? – If no specific technological requirements and/or formulas are agreed between the contract partners, the formula of the supplier is the basis. In this case the requirement shall be rated with N/A. 	When there is evidence that configuration and finished product specifications do not fit together. When during a traceability test there is evidence that agreed upon configuration is not complied with.

IFS PAC secure number	IFS PACsecure requirement	Connec- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.3	Product development/Product modification/Modification of production processes			The requirements for product development have to be checked even if there are only product modifications (new ingredient used, changes in packaging) or modifica- tions of production processes.	
4.3.1	A procedure for product develop- ment shall be in place which incor- porates the hazard analysis princi- ples, in accordance with the HACCP and/or risk assessment system.			<ul style="list-style-type: none"> - How are the processing procedures for product development built up? - Do processing procedures for product development also contain a hazard analysis? <hazard analysis> 	When no processing procedures were established for product development and a packaging material safety and/or legal issue ensues.
4.3.2	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.			<ul style="list-style-type: none"> - What do product development proce- dures look like? <product development procedures> - What tests are made while a product is developed? <test results> - Is developed product submitted to trial runs? <trial run documentation> 	When new process- ing procedures, configurations and product requirements are not ensured by tests and trial runs and enter directly into production and this entails a packaging material safety and/or legality issue which cannot be corrected.
4.3.3	Recommendation for use-tests or adequate processes shall be carried out and consideration given to product formulation/configuration, wrapping material, manufacturing and declared conditions.			<ul style="list-style-type: none"> - How is recommended converting time determined? <converting tests> - Are products submitted to converting time tests? <converting time test results> 	When no proof for defined converting time exists and a safety issue can occur.

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IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.3.4	Product development shall consider the results of organoleptic assessments.			<ul style="list-style-type: none"> – How often are organoleptic tests made? – Who participates in organoleptic tests? – Are organoleptic tests documented? – How are the results from organoleptic tests taken into consideration during product development? <organoleptic test results evaluation>	
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.			What kind of process is implemented for legislation approval? Process of information gathering approval process e.g. with customer. <ul style="list-style-type: none"> – Export goes to which countries? Which countries have special requirements? 	
4.3.6	Recommendations for handling and/or use of the packaging materials shall be established. Where appropriate, customer requirements shall be included.			<ul style="list-style-type: none"> – Who issues the cliches/printing block approval? – Who issues the labels? – Who approves labels? – How is conformity of the product and label reviewed? 	Product and labeling are not in conformity with each other, thus creating a legality problem.
4.3.7	The progress and results of product development shall be properly recorded.			<ul style="list-style-type: none"> – How are converting recommendations and/or product use information established? – How are converting requirements taken into consideration during product development? <example> 	When a safety issue occurs due to not taking customer requirements into account.

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4.3.8	The company shall ensure that in the event of changes to product formula- tion/configuration, including rework and wrapping material, process characteristics are reviewed in order to assure that product requirements are complied with.				
4.4	Purchasing				
4.4.1	General purchasing				
4.4.1.1	The company shall control purchas- ing processes to ensure that all externally sourced materials and services, which have an impact on packaging material safety and quality, conform to requirements. 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 pro- cesses shall be identified and documented within the packaging material safety and quality manage- ment system.			– How is it ensured that purchased prod- ucts and services conform to specifica- tions or other legally required documen- tation or other legal required documentation?	When purchased products do not conform to specifica- tions or other legally required documenta- tion and thus entail a safety or legality problem.

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IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
<p>changed </p> <p>4.4.1.2</p>	<p>There shall be a procedure for approval and monitoring of suppliers (internal and external), outsourced production or part of it.</p>			<ul style="list-style-type: none"> - Does an approval procedure exist for new suppliers and co-producer co-packer? <supplier procedures> - How are supplies monitored? - Are suppliers graded? <supplier grading systems> - Have suppliers been barred? - How is a barred supplier identified? - How is the qualification of suppliers ensured? <product entry monitoring> <supplier audits> <lab tests> - Are there any co-producers co-packers? <co-packers list> - How are co-producers co-packers monitored? - Are co-producers co-packers IFS PACsecure certified? <certificate> 	<p>When there are no approval procedures for suppliers and this causes a safety risk.</p>
<p>changed </p> <p>4.4.1.3</p>	<p>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.</p>			<ul style="list-style-type: none"> - How often are external audits made? <external audit plan> - Which criteria are consulted for supplier assessment? - Which supplier has analysis certificates? <analysis certificates> - How was the hazard analysis for supplier approval performed? <hazard analysis> 	<p>No hazard analysis was made.</p>

IFS PAC secure number	IFS PACsecure requirement	Conne- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.4.1.4	The results of suppliers' assess-ments shall be reviewed regularly and this review shall be based on hazard analysis and assessment of associated risks. There shall be records of the reviews and of the actions taken as a consequence of assessment.			<ul style="list-style-type: none"> - Who reviews the results of supplier assessments? - How often are the results of supplier assessments reviewed? - What actions are taken after review of the results for supplier assessments? <audit results> 	When the results for supplier assessment are not taken into account and this causes a safety or legality issue.
4.4.1.5	The purchased products shall be checked in accordance with the existing specifications or other legally required documentation. The schedule of these checks shall, as a minimum, take into account the following criteria; product require-ments, supplier status (according to its assessment) and impact of the purchased products on the finished product. If mentioned in the specifi-cations or other legally required documentation additional required topics shall be checked.			<ul style="list-style-type: none"> - How are purchased products and their specifications reviewed? <incoming product check-list> <lab tests> - Does a test schedule exist? <test schedule> 	When purchased products are never checked on compli-ance with specifica-tions or other legally required documenta-tions.
4.4.1.6	The purchased services shall be checked in accordance with the existing specifications or other legally required documentation. The schedule of these checks shall at least take into account the following items: service requirements, supplier status (according to its assessment) and impact of the service on the finished product.				

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IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.4.2	Trade of packaging materials			Mean purchased products, which have been already processed and which are bought and stored on-site of the audited company.	
4.4.2.1	In case a company trades packaging materials, it shall be ensured that a process for approving and monitoring suppliers exists and is implemented.			If the company trades packaging materials as finished products and if it wants to include them in the audit scope, the suppliers of these products shall themselves be IFS PACsecure certified (if the trade products are under the same product scope) or certified under a comparable scheme (if the trade products are under a different product scope). Compulsory field in the company profile: specify if the company has trade products.	
4.4.2.2	In case of traded packaging materials, the process for approving and monitoring suppliers shall contain clear assessment criteria such as: audits, certificates of analysis, supplier reliability, complaints as well as required performance standards.				
4.4.2.3	In case of packaging materials for private labels, a supplier approval system in accordance with customer requirements shall exist for pre-suppliers of finished or semi-finished products.				

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.5	Product wrapping				
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.			<ul style="list-style-type: none"> - Does a risk assessment also exist for wrapping material not in direct packaging material contact, to prove the evidence of direct negative influence on the product? 	
4.5.2	Detailed specifications shall exist for all wrapping materials which comply with the current relevant legislation.			<ul style="list-style-type: none"> - How is it ensured that wrapping material complies with current relevant legislation? - Who develops, reviews new wrapping material? - Are specifications or other legally required documentation available for all wrapping materials used? <p><wrapping material specifications></p>	Wrapping material that does not comply with legislation. Not all wrapping materials have specifications.
4.5.3	For all wrapping material which could have an influence on products, certificates of conformity shall exist which comply with current legal requirements. 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, semi-processed and finished products.				

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.5.4	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).			<ul style="list-style-type: none"> – How is it ensured that wrapping materials have no negative effects on the product? – Has a hazard analysis been performed in relation to suitability of wrapping material? <hazard analysis> 	No hazard analysis was made.
4.5.5	The company shall ensure that the wrapping used corresponds to the product being wrapped. The use of correct wrapping shall be regularly checked.			Which system has the company implemented to ensure that wrapping material is suitable and traceable?	
4.5.6	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.				

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4.6	Factory location				
4.6.1.	The company shall investigate to what extent the factory environment (e.g. ground, air) may have an adverse impact on product safety and product quality. If product safety and quality could be compromised, appropriate measures shall be established. The effectiveness of the established measures shall be periodically reviewed (examples: extremely dusty air, strong smells).	A 1.1.1	1, 4	<ul style="list-style-type: none"> - Does a location investigation exist? Can location have a negative influence on product quality? <location analysis> - What protective measures have been established if potentially damaging materials/substances are nearby? <protective measures> - <corrective actions> - Is efficiency of protective measures regularly reviewed? - Who reviews the efficiency of the established protective measures? - How is efficiency of established protective measures reviewed? 	When company surroundings have a negative influence on product (e.g. water treatment) and no protective measures have been established and therefore a safety problem exists. When established protective measures are unclear or with questionable efficiency and therefore a safety problem exists.
4.7	Factory Exterior	7.0 A 1			
4.7.1	The factory exterior shall be maintained to be clean and tidy.	A 1.1.1	2	<ul style="list-style-type: none"> - Are factory exteriors tidy? - Are factory exteriors reviewed through internal audits? <audit results> 	
4.7.2	All external areas of the factory shall be maintained in good condition. Where natural drainage is inadequate, a suitable drainage system shall be installed.	A 1.1.1-2	3,6,7,8	<ul style="list-style-type: none"> - Are grounds within the factory premises in good condition? - Is natural drainage sufficient? - If natural drainage is insufficient, has a suitable drainage system been installed? 	

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.7.3	Outdoor storage shall be kept to a minimum. Where goods are stored outside, hazard analysis and assessment of associated risks shall be undertaken in order to ensure that there is no risk of contamination or adverse effect on quality and packaging material safety.	A 1.1.1	5	<ul style="list-style-type: none"> – Are goods stored outdoors? – What is stored outdoors? – What rules exist for outdoor storage? – Is outdoor storage based on hazard analysis? <hazard analysis> 	No hazard analysis exists for outdoor storage. Goods under outdoor storage are influenced in a way that a safety risk is given (e.g. unprotected primary packaging material is kept outdoors, becomes moldy and is not barred from use).
4.8	Plant layout and process flows				
4.8.1	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.	A 2.1.8 Form 4	1, 2, 3	<ul style="list-style-type: none"> – How is it ensured that cross-contamination is avoided? <ul style="list-style-type: none"> <waste elimination plan> <personnel flow plan> <materials flow plan> <process flow plan> <hydraulic plan> 	When there are no flow plans and internal flows do not respect the segregation of product processes (e.g. separation of “dirty” from “clean” processing areas but personnel cross boundaries without according protective clothing).

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.8.2	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.	7.0 A 2 A 2.1.8	4, 6	– How is cross-contamination avoided within factory premises? <process flow diagram>	The process flow allows for a cross-contamination between raw materials, packaging material, half semi- finished products and finished products.
4.8.3	In case of sensitive production areas, these shall be operated and monitored to ensure product safety is not compromised.			– Are there sensitive areas? – Are sensitive areas ventilated? – What additional measures are taken?	When ventilation is missing in sensitive areas and a safety problem is given.
4.8.4	Laboratory facilities and in-process controls shall not affect the product safety.			– Is there a laboratory on site? – Has the lab a direct contact access with production premises? – Can lab waste (e.g. lab waste water) dirty contaminate the production premises? <plant lay-out> <waste water drainage system>	When product safety is endangered through the laboratory (e.g. waste water, air circulation, waste disposal).
4.9	Constructional requirements for production and storage areas				
4.9.1	Constructional requirements				
4.9.1.1	Rooms where packaging material products are prepared, treated, processed and stored shall be designed and constructed so that packaging material safety is ensured.	A 2.1.5–7 A 1.1.1–2	1, 2 10	– Are there “dirty” and “clean” areas? – Are there appropriate storage rooms?	No separation of “dirty” and “clean” areas even though legally prescribed. When there is no compliance with legal requirements.

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4.9.2	Walls				
4.9.2.1	Walls shall be designed and constructed to prevent the accumulation of dirt, to reduce condensation and mould growth, and to facilitate cleaning.	A 2.1.5–7 A 2.1.2	3 1	– Are walls mouldy?	Extreme mold build-up which ensues a contamination risk.
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.	A 2.1.5–7		– How often are walls cleaned? <cleaning schedule> <cleaning evidence>	
4.9.2.3	The junctions between walls, floors and ceilings shall be designed to facilitate cleaning.	A 2.1.5–7 A 2.1.2	2	– Are wall-floor junctions and corners rounded?	
4.9.3	Floors				
4.9.3.1	Floor covering shall be designed to meet production requirements and shall be in good condition and easy to clean. Surfaces shall be impervious and wear-resistant.	A 2.1.5–7		– Are floors cleanable? – How often are floors cleaned? <cleaning schedule> <cleaning evidence>	
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.).	A 2.1.5–7		– How is waste water disposal ensured? – How often are gullies cleaned? <cleaning evidence> <drainage schedule>	
4.9.3.3	Water or other liquids shall reach drainage without difficulties, using appropriate measures. Puddles shall be avoided.	A 2.1.5–7 A 2.1.4	1	– Are there water or other liquid puddles on the floors of production areas?	

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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.	A 2.1.5–7		– Where is machinery which produces a large amount of waste water located? <machinery lay-out>	
4.9.4	Ceilings/Overheads				
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.	A 2.1.5–7 A 1.1.1	3 11	– How often are ceilings cleaned? <cleaning evidence schedule >	Ceilings are very dirty and dirt can fall on product.
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.	A 2.1.5–7		– How often are false ceilings cleaned? <cleaning evidence schedule >	
4.9.5	Windows and other openings				
4.9.5.1	Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in good condition.	A 2.1.5–7	4	– Can dirt accumulate on window sills?	
4.9.5.2	Where there is risk of contamination, windows and roof glazing shall remain closed and fixed during production.	A 2.1.5–7	6	– Are windows kept open?	Windows are open and no insect gratings are in place so that pests can enter production areas and a contamination risk exists. Pests are visible.

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4.9.5.3	Where windows and roof glazing are designed to be opened for ventilation purposes, they shall be fitted with easily removable, good condition pest screens or other measures in order to avoid any contamination.	A 2.1.5–7 A 1.1.1	5 12	<ul style="list-style-type: none"> – Are windows sealed with insect gratings? <pest control schedule> – Is integrity of gratings regularly reviewed? <monitoring schedule> 	Windows are open and no insect gratings are in place so that pests can enter production areas and a contamination risk exists.
4.9.5.4	In areas where unpackaged product is handled, windows shall be protected against breakage.	A 2.1.5–7	7, 8	<ul style="list-style-type: none"> – How are windows protected against breakage? 	Windows with no breakage protection are in production areas where uncovered and broken and unpackaged products are handled which ensues a contamination risk.
4.9.6	Doors and gates				
4.9.6.1	Doors and gates shall be in good condition (e.g. no splintering parts, flaking paints or corrosion) and easy to clean.	A 2.1.5.7	3	<ul style="list-style-type: none"> – Are doors damaged? 	Doors are open or damaged so that pests can enter production areas and a contamination risk exists. Pests are visible.
4.9.6.2	Based on hazard analysis and assessment of associated risks external doors and gates shall be constructed to prevent the ingress of pests; if possible, they shall be self-closing.	A 2.1.5.7	4	<ul style="list-style-type: none"> – Do external doors prevent pest entrance into production areas? 	
4.9.7	Lighting				
4.9.7.1	All working areas shall have adequate lighting.	A 2.2.1	1	<ul style="list-style-type: none"> – What is the assurance that all working areas are adequately illuminated? 	

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.9.7.2	All lighting equipment shall be protected by shatter proof covers and installed to minimise the risk of breakage.	A 2.2.2	1, 2	<ul style="list-style-type: none"> – Where are fly killing units mandatory? <fly trap plan> – Are all fly killing units and lamps protected by splinter shields? <lighting protectors> 	When fly traps and lighting devices constitute a contamination risk.
4.9.8	Air conditioning/Ventilation				
4.9.8.1	Adequate natural and/or artificial ventilation shall exist in all areas.	A 2.3.1 A 2.3.3	1, 2, 3, 4 1, 2, 3, 4, 5, 6, 7, 8	<ul style="list-style-type: none"> – How is ventilation reviewed? 	
4.9.8.2	If ventilation equipments are installed, filters and other components which require cleaning or replacement shall be easily accessible.	A 2.3.1 A 1.1.1 A 2.3.3	2, 3 14 7	<ul style="list-style-type: none"> – How are air filters maintained and cleaned? <maintenance schedule> <maintenance documentation> <cleaning protocols> 	Filters which are not cleaned as programmed constitute a product contamination risk.
4.9.8.3	Air conditioning equipment and artificially generated airflow shall not lead to any product safety or quality risks.	A 2.3.1	1	<ul style="list-style-type: none"> – Is the use of air during production based on hazard analysis? <hazard analysis> – Are there production areas with under- or over-pressurization? 	When air supply causes a contamination which ensue a packaging material safety risk.
4.9.8.4	Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated.	A 2.3.3	1	<ul style="list-style-type: none"> – Are there areas where large amounts of dust are formed? – Do dust extraction devices exist in these areas? 	
4.9.9	Water supply				
4.9.9.1	Water which is used as ingredient in the production process, or for cleaning, shall comply with legal requirements and shall be supplied in sufficient quantity; this also applies to steam and ice used within the production area. A supply of such water shall be available at all times.	7.0 A 4 A 4.1.1 A 4.1.1 A 4.1.2	1, 2 5 1, 2, 3, 4, 5, 6, 7	<ul style="list-style-type: none"> – Where does water supply come from? (City supply, well water, tanker)? – Is water demand always covered? 	

changed

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4.9.9.2	Recycled water which is used in the process shall not pose a contamination risk. The water shall comply with applicable legal requirements for potable water; records of compliance testing shall be available.	A 4.1.3–6	1, 2, 3, 4, 5	<ul style="list-style-type: none"> – For what purpose is water used in the company (social staff facilities, cleaning procedures, product ingredient, for washing fruits and vegetables)? – Is water treated on site (water hardness correction, chlorination, sterilization, filtration ...)? – Are local legal requirements on hand? – Is water analysed according to legal requirements (own water supply, outside supply). Do results comply with standards? <several analysis results> 	There is evidence that water does not comply with legal standards and is used for cleaning procedures of surfaces in direct contact with packaging material or as ingredient, or company cannot show that water complies with required standards. The checking interval for relevant water safety issues has been clearly overdrawn. The company has no water analysis plan even though it is mandatory and water is used for cleaning procedures or as an ingredient.
4.9.9.3	The quality of water, whatever the condition of aggregation, shall be monitored following a risk based sampling plan.	7.0 A 4 A 3.1.2 A 4.1.1	4, 5, 6 3, 4	<ul style="list-style-type: none"> – Is water, steam or ice used – is a station monitoring in place? <maintenance> <analysis results> – What kind of piping system exists? Ring-pipes, water-tanks) – What is piping made from? – Is analysis and sampling plan based on hazard analysis? 	When contaminated water reaches the product due to bad conditions of piping or improper piping material.

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall not be connected to the drinking water system, or allow the possibility of reflux to contaminate potable water sources or the factory environment.	A 4.1.3–6 A 2.4.1	3, 4 1, 2	<ul style="list-style-type: none"> – Is drinking water system completely separated from non-potable water piping? <hydraulic system lay-out> – What other systems are there? (e.g. used water, cooling water, water used for firefighting). – Are water systems properly marked and where they are? – Are reflux avoidance equipments installed wherever necessary? 	All existing water systems are interconnected, no reflux avoidance equipments exist, therefore a contamination hazard is given.
4.9.10	Compressed air				
4.9.10.1	The quality of compressed air that comes in direct contact with packaging material or wrapping material shall be monitored based on hazard analysis and assessment of associated risks.	A 2.3.3	4		
4.9.10.2	Compressed air shall not pose a risk of contamination.	A 2.3.3	4		

IFS PAC secure number	IFS PACsecure requirement	Conne- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.10	Cleaning and disinfection				
4.10.1	Based on hazard analysis and assessment of associated risks, cleaning and disinfection schedules shall be available and implemented. These shall specify: – objectives – responsibilities – the products used and their instructions for use – the areas to be cleaned and/or disinfected – cleaning frequency – documentation requirements – hazard symbols (if necessary).	7.0 E 1 E 1.1.1–3	1, 2, 3, 4, 5, 11	– Who is in charge of cleaning and disinfection? <cleaning schedule> – What kind cleaning products and disinfectants are used? <up to date cleaning products and disinfectant list> – What must be observed when using different cleaning products and disinfectants? <product instructions> – What areas are cleaned and disinfected? <cleaning schedule> – How often are areas cleaned and disinfected? – Where are cleaning and disinfection procedures documented? <cleaning procedures documentation> – Do hazard symbols exist? – Does a contract exist for external service provider? <external services contract> – Cleaning schedules can include SSOP's.	When a contamination of packaging material products or tools exists due to the use of inefficient or wrong kind of chemicals or inefficient cleaning procedures.
4.10.2	Cleaning and disinfection schedules shall be implemented and documented.	7.0 E 1 E 1.1.1–3	4, 5, 12, 16		
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.	E 1.1.1–3	6	– Are cleaning personnel qualified? <training proof> – How often are they trained? – Who trains them? – Are these trainings documented?	When a product or tools contamination occurs due to untrained cleaning personnel or wrong use of cleaning products or when cleaning process is inefficient.

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4.10.4	The effectiveness and safety of the cleaning and disinfection measures, based on hazard analysis and assessment of associated risks, shall be verified and documented according to a sampling schedule by using appropriate procedures. Resulting corrective actions shall be documented.	7.0 E 1 E 1.1.1–3	7, 13	<ul style="list-style-type: none"> – How are cleaning and disinfection controls performed? <cleaning controls> – Who performs these controls? <cleaning controls> – How often are cleaning and disinfection controls performed? <cleaning controls> – Where are cleaning and disinfection controls documented? – When are corrective actions executed? <corrective actions> – Who executes corrective actions? – Who reviews effectiveness of corrective actions? – Where are corrective actions documented? 	When cleaning is unsuccessful and this error is not corrected.
4.10.5	Cleaning and disinfection schedules shall be reviewed and modified, if necessary, in the event of a change to product, process or cleaning equipment.	E 1.1.1–3	8, 14	<ul style="list-style-type: none"> – When are cleaning and disinfection procedures validated? – Who adapts cleaning and disinfection procedures? – How often are cleaning and disinfection schedules changed? 	When circumstances have been changed but no adaptations were made for cleaning and disinfection procedures and a contamination risk ensues.
4.10.6	The intended use of cleaning utensils shall be clearly identified. Cleaning utensils shall be used in a way to avoid contamination.				

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deleted	4.10.7	Current material safety data sheets (MSDS) 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.	B 2.2.1-4	13	<ul style="list-style-type: none"> - Are material safety data sheets available for all cleaning chemicals? - Are these no older than two years? - Are cleaning chemicals instructions up to date? - How are instructions transmitted to personnel in charge of cleaning procedures? - Where and when can the instructions be inspected? 	When a safety risk occurs due to deficient material safety data sheets.
changed	4.10.8	Cleaning chemicals shall be clearly labeled, used and stored appropriately, to avoid contamination.	A 3.2.2 B 2.2.1-4 E 1.1.1-3	1, 2, 3 8, 9, 10, 12, 14 1, 9	<ul style="list-style-type: none"> - How are cleaning utensils and chemicals recognizable? <chemicals list> - Where are cleaning utensils and chemicals stored? <chemicals storage list> 	When cleaning utensils can be mixed up with other utensils and packaging material contamination ensues risk issues . When improper storage can lead to packaging material and other utensils contamination.
	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.	A 3.2.1 E 1.1.1-3	1, 2, 3, 4, 5, 6 9, 15	<ul style="list-style-type: none"> - Where are containers cleaned? - When and where are tools cleaned? <cleaning evidence> 	The tool cleaning process is a product contamination problem; e.g. wet cleaning of containers and pallets during production and near unprotected packaging material.

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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.				
4.11	Waste disposal				
4.11.1	A waste management procedure shall exist and shall be implemented to avoid cross contamination.	A 2.4.1 A 2.4.2	1, 2, 3, 4, 5, 6 1, 2, 3, 4, 5, 6, 7, 8		
4.11.2	All current legal requirements for waste disposal shall be met.			<ul style="list-style-type: none"> – How is it ensured that current legal waste disposal requirements are met? – How is waste material disposed of? 	When legal requirements regarding waste disposal are not met.
4.11.3	Packaging material waste and other waste shall be removed as quickly as possible from areas where packaging material is handled. The accumulation of waste shall be avoided.			<ul style="list-style-type: none"> – How often are packaging material waste and other wastes removed from packaging material handling areas? – Who is responsible for waste removal? 	When wastes accumulate in packaging material handling areas which ensues a packaging material contamination risk.
4.11.4	Waste collection containers shall be clearly marked, suitably designed, in good state of repair, easy to clean, and where necessary disinfected.	A 2.4.2	1, 4, 5, 6	<ul style="list-style-type: none"> – What kind of waste exists? What wastes are collected in separate containers? How are waste containers marked? Can waste containers easily be cleaned? – How often are waste containers cleaned? <cleaning protocol> 	When waste containers can be mixed up with packaging material containers which ensues a packaging material contamination risk.
4.11.5	Waste collection rooms and containers (incl. compactors) shall be designed to be kept clean to minimize pest attraction.	A 2.4.2 A 1.1.1	7 9	<ul style="list-style-type: none"> – Are waste collection rooms kept clean? – Are waste collection rooms protected from pests? <integrated pest control> 	When waste collection rooms are not protected from pest invasions and there is a contamination risk.

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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.	A 2.4.2	5	<ul style="list-style-type: none"> – What kinds of waste disposal records exist? – Who is responsible for waste disposal? <waste disposal register> 	When wastes are removed by unauthorized persons.
4.11.7	A system to control the disposal and/or destruction of trademark materials shall be in place. The system shall comply with legal requirements and customer agreements, when is applicable. Trademark materials and its disposal shall be included in the traceability system of the company			<ul style="list-style-type: none"> – What kind of system is in place to control the disposal and/or destruction of trademark material? – What kinds of waste disposal and/or destruction records exist for trademark materials? <records related> – Who is responsible for waste disposal and/or destruction of trademark materials? – How is traceability ensured? <traceability information> 	
4.12	Risk of foreign material, metal, broken glass and wood				
4.12.1 KO	KO N° 5: 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.			<ul style="list-style-type: none"> – What kinds of foreign material may be found? – Where foreign material sources identified through hazard analysis? <hazard analysis> – Are staples used? – How are contaminated products handled? <segregation records> – What is done in case of glass breakage? <glass breakage prevention procedures> – What shall be considered when glass fixtures are replaced? <glass handling procedures> 	When a foreign material contamination occurs due to lack of hazard analysis or when foreign material sources are insufficiently considered.

added

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4.12.2	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.			<ul style="list-style-type: none"> - Under what circumstances is the use of wood allowed? <hazard analysis> Is the wooden tool in use in good and clean conditions? - Who inspects and how often is the wooden tool condition inspected? <plant inspections> 	When wood gets in contact with open product. When wood poses a contamination risk for packaging material product. When wooden tool condition is not inspected and a contamination risk ensues.
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.			<ul style="list-style-type: none"> - Where are the foreign material detectors installed? <equipment lay-out> 	When foreign material detectors are installed but later on a foreign material risk still persists which has not been taken into account.
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.			<ul style="list-style-type: none"> - Are contaminated products automatically isolated? - Who may handle/has access to isolated products? - How are isolated products handled? <non-conforming products list> <isolation protocol> 	When segregation does not work. When isolated products re-enter production line without previous inspection.

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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.			<ul style="list-style-type: none"> – How often are detector accuracies checked? – Who checks detector accuracy? <metal detector check-list> – What corrective actions exist when a detector is defective? – Are corrective actions verified? – Are operational defects documented? <defect/failure protocols> 	When proper operation or measuring accuracy is not checked and a foreign material risk occurs.
4.12.6	In cases where special equipment or methods are used to detect foreign material, these shall be properly validated and maintained.			<ul style="list-style-type: none"> – Are filters and sieves or other technical or mechanical systems like strainers, magnets, vacuum cleaner etc. being used? – How often are working conditions of filters or other technical or mechanical systems and sieves inspected? – Who inspects/maintains filters and sieves or other technical or mechanical systems? – What is the concern of inspection? <maintenance schedule> <monitoring system> 	When damage to sieves or filters passes without noticed and this leads to a foreign material contamination risk.
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.			<ul style="list-style-type: none"> – Does a hazard analysis exist concerning contamination through glass? <hazard analysis> – Where is glass used in the plant? – How is glass protected from breakage? <glass register> 	When no hazard analysis has been conducted. When there exists a contamination risk due to glass usage. When glass is unprotected and there is a contamination risk.

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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.			<ul style="list-style-type: none"> - Is there a glass fixtures register including location? <glass register> - How often and who inspects glass fixture conditions? - How often is glass fixtures register up dated? <inspection results> <glass register> 	When glass breakage happens unnoticed and a contamination risk ensues.
4.12.9	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.			<ul style="list-style-type: none"> - Is every glass breakage documented? <glass breakage registry> - Where is glass breakage documented? <glass register> - Are there exceptions to documentation? Are exceptions based on hazard analysis? <hazard analysis> 	When no hazard analysis has been made.
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.			<ul style="list-style-type: none"> - What is done in case of glass breakage? - What should be taken into account? - Who cleans the production environment? - Who permits production continual? <glass breakage prevention procedures> <glass breakage documentation> 	When a contamination risk exists due to glass breakage and because involved product has not been inspected.

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4.12.11	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 (turn over, blow, rinse, etc.).			<ul style="list-style-type: none"> – Has a hazard analysis been performed? <hazard analysis> – What preventive measures are in place? <preventive measures> 	When no hazard analysis has been made. When there exists a contamination risk due to missing preventive measures.
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.				
4.13	Pest monitoring/Pest control				
4.13.1	The company shall have a pest control system in place which is in compliance with local legal requirements, taking into account, as a minimum: <ul style="list-style-type: none"> – the factory environment (potential pests) – site plan with area for application (bait map) – identification of the baits on site – responsibilities, in-house/external – used products/agents and their instructions for use and safety – the frequency of inspections. The pest control system shall be based on hazard analysis and assessment of associated risks.	7.0 E 2 E 2.1.1	1, 2, 3, 4, 6	<ul style="list-style-type: none"> – How is pest control organized? <pest control procedures> – Which pests are controlled? – Which kinds of baits are used? <pest control chemicals list> – Is product contamination through baits being prevented? <bait map> – Who is responsible for pest control? – What is inspection schedule? 	When no pest control is made. When a product contamination can occur due to unmapped baits. When a product safety occurs due to incorrect use of pest control chemicals or wrongly laid out baits.

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4.13.2	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.	E 2.1.1 A 1.1.1-2	4, 5 15	<ul style="list-style-type: none"> - Is pest control executed by own staff members? - Who is responsible for pest control? - What kind of training has the responsible person? <training evidence> - Is pest control executed by external services provider? - Does a written contract exist between services provider and company? <written contract> - What is the content of the contract? - What kind of training has the external services provider? <training evidence> 	When a product contamination occurs due to incorrect handling of bait material.
4.13.3	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded.	E2.1.1	7,11,12	<ul style="list-style-type: none"> - Where are inspections and resulting corrective actions documented? <inspection results> - Are documents signed and dated by both parties? - Which corrective actions were executed lately? 	When inspections are not documented.
4.13.4	Baits, traps and insect exterminators shall be functioning, shall be in sufficient numbers and shall be placed in an appropriate position. They shall be constructed and positioned as not to cause any contamination risk.	E 2.1.1	8, 9, 10	<ul style="list-style-type: none"> - Where are electrical fly killers installed? <fly killer map> - Are all fly killers correctly working and connected? 	When fly killers are positioned in such a way that flies can fall directly on packaging material products.

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4.13.5	Incoming deliveries shall be checked on arrival for the presence of pests. Any infestation shall be documented and control measures taken.			<ul style="list-style-type: none"> – Are incoming goods inspected for pest contamination? – Where is this documented? <incoming goods inspection> – Is pest presence documented? <incoming goods inspection> – What control measures are taken when pests are found? <corrective actions> – Where are these control measures documented? <corrective actions> 	When incoming goods are not inspected for pest presence and an uncontrolled invasion ensues.
4.13.6	The effectiveness of the pest control shall be monitored with the help of regular trend analyses.	E 2.1.1	12		
4.14	Receipt of goods and storage	7.0 B 2			
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.	7.0 B 2 B 2.1.1–2	1, 2	<ul style="list-style-type: none"> – What goods (incl. semi-processed products) are inspected when received? <receipt checks> – What is checked when received? – Is receipt documented? – Who checks? 	<p>When no receipt checks are made. When checks do not guarantee legally legal requirements compliance.</p> <p>When receipt checks do not take into account specifications or other legally required documentation requirements which prevent that products fulfil their given specifications or other legally required documentation.</p>

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4.14.2	The storage conditions of raw materials, semi-processed and finished products as well as wrapping shall in each case correspond to product requirements (e.g. protective covers) and shall not be detrimental to other products.	7.0 B 2 B 2.1.1–2 B 1.1.1–3 B 1.2.2 B 2.3.1–2	3, 19 1–19 1 1–12	<ul style="list-style-type: none"> – Where are raw materials, half semi finished products and packaging wrapping materials stored? <storage plan> – How is cross-contamination avoided? <product flow plan> 	When goods are improperly stored and a contamination risk ensues.
4.14.3	Raw materials, packaging, semi-processed and finished products shall be stored so as to minimize the risk of cross contamination.	B 2.1.1–2		<ul style="list-style-type: none"> – Where and how are packaging materials and equipments stored? <materials flow-diagram> – How is cross-contamination through packaging materials avoided? <materials flow-diagram> – How is return of packaging materials to the storeroom regulated? – What kind of storage regulations exist? – Are pests taken into account during storage? Are pallets located approximately 1 m from walls? <plant inspection protocol> – Are there baits laid out in storage rooms? <pest control schedule> – Are there sensitive products stored? – What kinds of preventive measures are in place for these goods? <preventive measures> 	A product contamination risk is given due to storage of packaging materials and equipments (e.g. unprotected external storage of packaging material). When storage facilities are not inspected for pest presence.

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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.	B 2.2.1–4	1–15	<ul style="list-style-type: none"> – How are chemicals stored? – Who uses chemicals and takes them out of storage? <responsibility list> – Are the chemicals users trained? – Is training documented? <training documentation> 	When a packaging material or utensils contamination occurs due to inappropriate storage conditions. When a packaging material or utensils contamination occurs due to insufficient knowledge.
4.14.5	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.	7.0 B 2 B 2.1.1–2 B 2.3.1–2	18 7	<ul style="list-style-type: none"> – How is “FIFO” or “FEFO” ensured? 	When goods are taken out of storage without control and a product safety risk ensues.
4.14.6	Where a company hires a third-party storage service provider, the service provider shall be subject to IFS Logistics requirements. If the third party service provider is not certified to IFS Logistics, all relevant requirements equivalent to the company’s own warehousing practices shall be fulfilled and this shall be clearly defined in the respective contract.	B 2.1.1–2	1	<ul style="list-style-type: none"> – Is storage leased to storage service provider? – Does a contract exist? <service provider contract> – What is specified in the contract? – Has storage service provider an IFS Logistics certification? <certificate copy> 	

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4.15	Transport				
4.15.1	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.	B 1.1.1–3 B 1.2.2	1, 2, 3 1	<ul style="list-style-type: none"> – What is checked before loading? <expedition inspection> – Where is inspection documented? – What corrective actions are taken? 	
4.15.2	Procedures to prevent contamination during transport shall be implemented (packaging material/non-packaging material/different categories of goods).	7.0 B 1 B 1.1.1–3		<ul style="list-style-type: none"> – May goods be transported alongside with non packaging material products? – How is cross-contamination prevented? 	When a contamina- tion can occur during transport.
4.15.3	Where goods must be transported at certain conditions, before loading, the condition inside the vehicle shall be checked and documented.			<ul style="list-style-type: none"> – Are products which require a certain conditions (e.g. humidity during paper transportation) being loaded? – Are vehicle conditions checked and documented before loading? <expedition inspection> – What are the procedures when vehicle condition is not according to specifications or other legally required documentation? <expedition inspection> – How the company ensure the compliance of conditions during transport? 	When there are certain conditions specifications for outgoing product but they are not checked before loading and a health safety issue occurs.

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IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.15.4	Where goods must be transported at certain conditions maintaining these conditions during transport shall be ensured and documented.			<ul style="list-style-type: none"> – Are vehicles equipped with registering devices? <registering devices> – How is it ensured that products reach destination under good conditions? 	When there are condition specifications or other legally required documentations for the product and condition control is not ensured during transport so that a health safety issue may occur.
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 measures taken.	B 1.1.1–3	1, 2, 3	<ul style="list-style-type: none"> – Are transport vehicles cleaned? – Where are cleaning procedures documented? <cleaning protocol> 	When absence of cleaning procedures ensue a product contamination problem.
4.15.6	Loading and unloading areas shall have equipment in place to protect transported products from external influences.	B 1.1.1–3	17	<ul style="list-style-type: none"> – How is goods reception organized? – How is loading organized? External influences: e.g. pollen, climate, etc.	
4.15.7	Where a company hires a third-party transport service provider, 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.			<ul style="list-style-type: none"> – Are there internal or external transportation regulations? – Does a contract exist with a transportation services provider? <service provider contract> – Has storage transport service provider an IFS Logistics certification? <certificate copy> 	
4.15.8	Security of transport vehicles shall be appropriately maintained.	B 1.1.1–3	19	<ul style="list-style-type: none"> Are loading areas shuttered? Are the transports sealed? 	

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4.16	Maintenance and repair				
4.16.1	An adequate system of maintenance shall be in place, maintained and documented, covering all critical equipment (incl. transport) for compliance with product requirements. This applies both for internal and external maintenance activities.	C 1.1.1–3	1–13	<ul style="list-style-type: none"> – How is maintenance organized? <maintenance plan> – Where are maintenance procedures documented? – Which equipments are subject to external maintenance? 	No maintenance system exists.
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.	7.0 C C 1.1.1–3 C 1.2.1–2	1–13	<ul style="list-style-type: none"> – How is it ensured that maintenance and repair works do not affect product safety? – How are lighting fixtures repaired? – Where are repair works documented? – Are corrective actions necessary after repair works? – What rules are in place for re-activating equipment when maintenance is completed? <examples for repair works and maintenance> 	When a contamination risk for the product occurs due to maintenance and product is not segregated.
4.16.3	All materials used for maintenance and repair shall be fit for the intended use.	B 2.2.1–4 C 1.2.1	4, 6 1, 2, 4, 5	<ul style="list-style-type: none"> – How is it ensured that materials used in maintenance or repair work are fit for intended use? – What kinds of greases are used? <grease list> 	When materials used in maintenance or repair works are not food grade and a safety risk for the consumer ensues.
4.16.4	Failures of plant and equipment (incl. transport) covered by the maintenance system shall be documented and reviewed with a view to adapting the maintenance system.	C 1.2.1–2	1, 2, 4, 5	<ul style="list-style-type: none"> – Are processing interruptions documented? <processing interruptions> – Are processing interruptions considered in maintenance planning? 	

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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.	C 1.2.1–2	1, 2, 4, 5	<ul style="list-style-type: none"> – Are temporary repairs allowed? – Where are these documented? – How fast must temporary repairs be definitely mended? – Who verifies this? 	
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.	C 1.2.1–2	1, 2, 4, 5		
4.17	Equipment				
4.17.1	Equipment shall be suitably designed and specified for the intended use. Before commissioning, it shall be verified that the product requirements are complied with.	7.0 C C 1.1.1–3 A 2.1.3	1.2.3 1	<ul style="list-style-type: none"> – Are equipments suitably designed and were they checked before start up? <start up protocol> 	When equipment construction can lead to a packaging material contamination.
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.	C 1.1.1–3	5	<ul style="list-style-type: none"> – Are conformity certificates or other certificates available for all wrapping materials which come into direct contact with packaging material products? <conformity certificates> – Are conformity certificates available for wrapping materials which come into direct contact with raw materials, half-finished or finished products? <conformity certificates> – Are conformity certificates available for containers and conveyor belts? <conformity certificates> 	Wrappings and wrapping materials which come into direct contact with packaging material are not suitable for intended use and therefore a safety risk exists.

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
4.17.3	Equipment shall be designed and located so that cleaning and maintenance operations can be effectively performed.	C 1.1.1–3 A 2.1.8	3 5	<ul style="list-style-type: none"> – Are equipments suitably designed and were they checked before start up? <start up protocol> – What rules exist for start up of new equipments? – Were new equipments immediately considered in maintenance plan? – Does an equipment installation plan exist? <machinery installation plan> 	When equipment is installed in a way that cleaning procedures are hindered and thus constitute a contamination source.
4.17.4	The company shall ensure that all product equipment is in good condition without any negative influence on packaging material safety.	7.0 C			
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 are complied with.	C 1.1.1–3	4	<ul style="list-style-type: none"> – What happens in case of equipment failures? <equipment stops> 	When equipment stops lead to a product safety issue and these are not segregated.
4.18	Traceability (including GMOs and allergens)	7.0 F 1			
4.18.1 KO	KO N° 6: A traceability system shall be in place which enables the identification of product lots and their relation to batches of raw materials and wrapping materials intended or expected to be in direct contact with produced products. The traceability system shall incorporate all relevant receiving, converting and distribution records. Traceability shall be ensured and documented until delivery to the customer.	7.0 F1 F 1.2.1–2	1, 2, 3, 4, 5, 6, 7, 8	<ul style="list-style-type: none"> – How is traceability ensured? <traceability procedures> What products come from which supplier? – Is there a list available with all current suppliers? <supplier list> 	When no traceability system exists and the system does not include raw and wrapping materials. When traceability is not complete up to the supplier.

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4.18.2	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.	F 1.2.1-2	2, 3		
4.18.3	Traceability shall be in place to identify the relationship between batches of final products and their labels.	F 1.2.1-2	2, 3		
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.	F 1.1.1-2	10	<ul style="list-style-type: none"> – When was the last traceability test in both directions done? <traceability test results> – What percentage of total amount was traced? – How big is a lot? 	When traceability system is not tested in both directions so that no assurance is given as to its effectiveness. When test results are negative and no corrective actions are taken.
4.18.5	Traceability shall be ensured at all stages, including work in progress, post treatment and rework.	F 1.2.1-2	4,5	<ul style="list-style-type: none"> – Can rework be completely traced? <results from rework traceability test> – How is rework documented/ 	When rework traceability is not ensured.
4.18.6	Labeling of semi-finished or finished product lots shall be made at the time when 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.	F 1.2.1-2	4,5	<ul style="list-style-type: none"> – When is lot labeling done? – What is the lot labeling code? <lot labeling example> – When are labels applied to product units? – How is recommended converting time calculated? <converting time example> 	When lot labeling is done at a step where mix ups occur which unable correct traceability.

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4.18.7	If required by customer, identified samples representative for the manufacturing lot 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.	F 1.2.1–2	7	– Is a sample bank implemented?	
4.19	Allergens and specific conditions of production				
4.19.1	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.	B 2.2.1–4	15	– Are allergens identified in specifications? – Does a list exist that covers allergens in use? <allergen list>	Allergens are not identified and a customer safety issue ensues.
4.19.2	The manufacturing of products which contain allergens requiring declaration shall be carried out as to ensure cross contamination is minimized as far as possible.			– Is a procedure in place to avoid contamination of allergen free products? – How often is effectiveness of these procedures reviewed? – Where are these proofs documented? <examples>	
4.19.3	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.			– Has allergen status been documented in specifications? <finished product specifications>	Allergens are not declared and a safety risk for the consumer occurs.

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4.20	Product Fraud				
4.20.1	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) packaging 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.			<ul style="list-style-type: none"> – Has the company a documented product fraud vulnerability assessment? – Has the company identified fraud-susceptible raw material groups/product groups in the vulnerability assessment? – If yes, which main fraud-susceptible raw material groups/product groups have been identified and for what reason? 	
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.				
4.20.3	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.				

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5	Measurements, Analysis, Improvements				
5.1	Internal audits				
5.1.1 KO	KO N°7: 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.			<ul style="list-style-type: none"> - Does an up to date internal audit plan exist? <audit plan> - Is audit plan based on hazard analysis? <hazard analysis> 	No internal audits are performed.
5.1.2	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.			<ul style="list-style-type: none"> - How often are internal audits performed? <audit plan> - The following issues can be taken into consideration for internal audits: <ul style="list-style-type: none"> · all production steps (packaging area, labeling, GMP's, GHP's, CP's) · traceability, · control plan (analysis, calibration) · documentation management (updates) · management of non-conformities (complaints, internal non-conformities, withdrawal, recall) 	
5.1.3	The auditors shall be competent and independent from the audited department.			<ul style="list-style-type: none"> - Who are the auditors? <auditors list> - How are auditors qualified for this job? <continued education evidence> - Have auditors any connection with audit area? 	

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5.1.4	Audit results shall be communicated to the senior management and to responsible persons of concerned department. Necessary corrective actions and a schedule for implementation shall be determined and documented and communicated to every relevant person.			<ul style="list-style-type: none"> - How are audit results communicated to the persons in charge? <audit report distribution> - Is the communication immediate and in time to take measures? - Are corrective actions documented? <audit report> - Is a time schedule in place for corrective actions? <audit report> - From which audits were corrective actions derived? <audit report containing corrective actions> - How are audit results forwarded to senior management? <audit report distribution> - How are audit results evaluated? 	No documented audit results.
5.1.5	It shall be documented how and when the corrective actions resulting from the internal audits shall be verified.			<ul style="list-style-type: none"> - How corrective action verification regulated? <verification evidence> - Who verifies and when? 	No corrective actions taken although necessary.
5.2	Site factory inspections				
5.2.1	Factory inspections shall be planned and carried out (e.g. product control, hygiene, foreign material hazards, personnel hygiene and housekeeping). The frequency of inspections in every area (including outdoor areas) and every single activity shall be based on hazard analysis and assessment of associated risks and on the history of previous experience.	7.0 A 1 A 3.1.2	9	<ul style="list-style-type: none"> - How often and who performs site inspections? <site inspections protocol> - What is reviewed during site inspections? - For which areas do site inspections exist? 	No site inspections are performed.

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5.3	Process validation and control				
5.3.1	The criteria for process validation and control shall be clearly defined.	6.5	A mechanism of change control will be established to ensure changes to the packaging material safety system are communicated and implemented.		
5.3.2	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.			<ul style="list-style-type: none"> – How are temperatures monitored? – Where are temperatures recorded? <printed measurement data> 	In case a legality issue occurs due to missing records. 4.12.4.
5.3.3	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.			<ul style="list-style-type: none"> – How is it assured that reworks comply to specifications or other legally required documentations? – Where is rework documented? <model documentation for rework> – Who reviews rework results? – Who decides rework liberation? – How is it ensured that rework fulfils legally requirements? 	
5.3.4	There shall be appropriate procedures for prompt notification, recording and monitoring of equipment malfunction and process deviations.			<ul style="list-style-type: none"> – What happens when a failure occurs? – What happens when cold chain is interrupted? <machinery stand still protocol> 	In case failures are not noticed and result in a safety or legal problem.

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5.3.5	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.	6.4	Prerequisite program validation will be planned and implemented.		
5.4	Calibration, adjustment and checking of measuring and monitoring devices				
5.4.1	The company shall identify the measuring and monitoring devices required to ensure compliance with product requirements. These devices shall be recorded on a document and clearly identified.	C 1.2.1–2	1–13	<ul style="list-style-type: none"> – What kinds of monitoring devices exist? <monitoring devices list> – What is demanded of monitoring devices? – What monitoring device is adequate for which kind of measurement? – How are monitoring devices identified? <identification stickers on monitoring devices> – Do calibrated devices exist? <monitoring devices list> 	The company has no measuring and monitoring devices.
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.	C 1.2.1–2	1–13	<ul style="list-style-type: none"> – How is measuring devices check organized? <calibration procedures> – Are measuring devices regularly calibrated? <calibration protocol> – Who is responsible for calibration? – How is calibration done? Where is it documented? <calibration records> – What corrective actions are taken when a tolerance deviation is found? <corrective actions> <calibration protocol> – Is calibration up to date? <calibration certificate> 	No calibration is performed.

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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.	C 1.2.1–2	1–13	<ul style="list-style-type: none"> – What actions are taken when measurement results are uncertain? – How are embargoed measuring devices identified? <identification stickers> 	When defective measuring devices are not exchanged and a safety issue ensues. (e.g. defective migration measurement device e.g. gas chromatograph for migration tests).
5.4.4	The calibration status of the measuring devices shall be clearly identified (labeled at the machine or on a list of test devices).	C 1.2.1–2	1–13	<ul style="list-style-type: none"> – How is calibration status of measuring device identified? <measuring devices list> 	
5.5	Control of quantity/filling quantity				
5.5.1	The frequency and methodology of control of quantity shall be determined so that the legally requirements and customer specifications or other legally required documentation, or if appropriate, guidelines for nominal quantity are met.			<ul style="list-style-type: none"> – How is it ensured that legal requirements for amount control are met? 	Legal requirements are not met due to lack of or insufficient amount measurements being made.
5.5.2	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.				
5.5.3	Checks shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing lot.				

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5.5.4	Results of these checks shall be compliant with defined criteria for all products ready to be delivered.				
5.5.5	For purchased, already pre-packed products from third parties, there shall be evidence about the compliance with the legal requirements.			<ul style="list-style-type: none"> – How is it ensured that purchased, pre-packed products from third parties contain the correct product amount (applicable for retail branded products and other labels)? <inspection plan> <dealer trader evidence> 	No evidence exists that purchased products comply with legal requirements.
5.5.6	If applicable, all equipment used for final checking shall be approved.			<ul style="list-style-type: none"> – Are measuring devices in use regularly calibrated? – Where is calibration recorded? <calibration protocol> – Are there calibrated measuring devices ? <calibration certificate> 	
5.6	Product analysis				
5.6.1	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.			<ul style="list-style-type: none"> – Which chemical, physical or microbiological analyses are made or subcontracted? <analysis results> 	No results of analyses are available.

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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).			<ul style="list-style-type: none"> - Is there an analytical laboratory on site? Is it accredited under ISO 17025? <accreditation evidence> - Are internal lab results verified by an accredited lab? - Which external laboratories are used? Are these accredited under ISO 17025? <accreditation evidence> 	
5.6.3	Procedures shall exist which ensure the reliability of the internal analysis results on the basis of official recognized analysis methods. This shall be demonstrated by ring tests or other proficiency tests.			<ul style="list-style-type: none"> - How is it ensured that internal analytical methods are appropriate? - Are ring tests performed? <ring test performance evidence> 	
5.6.4	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.			<ul style="list-style-type: none"> - Does an inspection plan exist? <inspection plan> - Who organizes inspection plan? Which products are encompassed by inspection plan? (raw materials, half-finished and finished products, wrapping materials, environmental tests?) <inspection plan> - Is inspection plan based on hazard analysis? <hazard analysis> - Where are test results documented? <test results> 	No inspection plan exists.

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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. Trends indicating potential unsatisfactory results shall be taken into consideration.			<ul style="list-style-type: none"> - Who reviews analytical results? - How are analytical results verified? - Are trends investigated? - Are corrective actions introduced when results are unsatisfactory? <corrective actions> 	When test results exist that do not comply with legal requirements and no corrective actions were taken.
5.6.6	Where internal analysis is undertaken, qualified and trained personnel shall be in place, as well as appropriate equipment and premises.			<ul style="list-style-type: none"> - Which tests are performed internally? - What qualifications do lab technicians have? <qualification evidence> - Is an internal lab available? - How is product contamination by internal lab prevented? 	
5.6.7	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.			<ul style="list-style-type: none"> - When and how are organoleptic tests performed? <inspection plan> <documentation of organoleptic test results> 	

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5.6.8	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.			For example, if an alert system informs that a raw material sourced from a specific country regularly has specific rate of dangerous substance, and if the company is used to buying this specific raw material, the company shall increase the frequency of analysis of this raw material, to improve monitoring. On the other hand, if results of analysis always show good results, and if the raw material is considered as a low risk one, the company can decide to decrease the frequency of analysis.	
5.7	Product quarantine (blocking/hold) and product release				
5.7.1	A procedure shall be in place, based on hazard analysis and assessment of associated risks, for the quaran- tine (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.	7.0 B 2 6.3	In response to devia- tions from the prerequi- site programs correc- tive actions will be determined. Corrective actions may include, but are not limited to: – Product hold, assess- ment and disposition. – Ensuring the correc- tive action is com- pleted. – Root cause identifica- tion. – Preventive actions.	– Who quarantines or releases products? <job description> – How are quarantined products identified?	When no procedures exist for product quarantine or release. When quarantined products go unchecked into further use and a safety issue occurs.

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5.8	Management of complaints from authorities and customers				
5.8.1	A system shall be in place for the management of product complaints.			– How are complaints handled? <complaint handling procedure>	If there is no procedure for complaint handling.
5.8.2	All complaints shall be assessed by competent staff. Where it is justified appropriate actions shall be taken immediately, if necessary.			– Who ponders about complaint significance? – Who defines the actions to be taken? – Within what time frame must actions be taken?	
5.8.3	Complaints shall be analyzed with a view to implementing preventive actions which avoid the recurrence of the non-conformity.			– Who manages complaint statistics? <complaint statistics> – How often are complaint statistics compiled? – What actions are taken to avoid recurrence?	No corrective actions were taken although a failure comes up more frequently or is considered as serious.
5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons and to the senior management.			– To whom are complaint statistics data presented? <retailer complaint statistics data>	

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5.9	Management of incidents, product withdrawal, product recall				
5.9.1	A documented procedure shall be defined for management of incidents and of potential emergency situations 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.	7.0 F1 F 1.1.1–2	1–10	<ul style="list-style-type: none"> – Who belongs to incident management staff? <phone list> – Who is informed when an incident occurs? – How are incidents managed? <crisis management procedures> – What is an incident? <incident management procedures> – communication plan: definition of the internal and external communication (in the case of incidents, product withdrawal, product recall), Who is allowed to report what to whom? 	If there is no incident management system implemented.
5.9.2	KO N° 8: 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.	7.0 F1 F 1.1.1–2	1–10	<ul style="list-style-type: none"> – How much is distribution involved with incident management? – When and who informs customer? <alarm plan> <phone list> <p>A withdrawal/recall management procedure is not enough to define an incident management procedure.</p>	If there is no procedure for recall/withdrawal in place.
5.9.3	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.	F 1.1.1–2	5	<ul style="list-style-type: none"> – What kind of incident management is implemented? – Who is responsible for communication with customers, press/media and authorities? – Is a list of important telephone numbers available? <phone list>, <emergency plan> – Who is informed when a crisis occurs? <alarm plan> <phone list> – When are media involved? <incident management procedures> 	No incident management is available in the company.

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
5.9.4	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.	F 1.1.1–2	10	<ul style="list-style-type: none"> – How is effectiveness of withdrawal tested? – How often is effectiveness of withdrawal tested? <withdrawal test results>	When withdrawal procedures are not tested or when test results have shown that the procedures are ineffective but no corrective actions were implemented.
5.10	Management of non-conformities and non conforming products				
5.10.1	A procedure shall exist for the management of all non-conforming raw materials, semi-finished and finished products, converting equipment and wrapping materials. This shall include, as a minimum: <ul style="list-style-type: none"> – isolation/quarantine procedures – hazard analysis and assessment of associated risks – identification (e.g. labeling) – decision about the further use (e.g. release, rework/post treatment, blocking, quarantine, rejection/disposal). 	B 2.3.1–2	8	<ul style="list-style-type: none"> – What procedures exist for non-conforming products management? – How are non-conforming products identified? – What rules exist for product quarantine procedures? <quarantine tickets>	When no procedures exist for non-conforming products management.

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
5.10.2	The responsibilities for the management of non-conforming products shall be clearly identified. The procedure for the management of non-conforming products shall be understood by all relevant employees.			<ul style="list-style-type: none"> - Who is responsible for putting non-conforming products into quarantine? <quarantine tickets> - Who may release quarantined products? <quarantine tickets> - How is it ensured that only authorized persons release quarantined products? <quarantine tickets> 	When employees do not know who is authorized to release quarantined products or when the products are in conditions to be released or when products are quarantined and a safety issue occurs.
5.10.3	Where non-conformities are present, immediate corrections shall be taken to ensure that product requirements are complied with.	B 2.3.1–2	8, 9, 10	<ul style="list-style-type: none"> - What procedures are implemented with non-conforming products? <quarantine tickets> - Who decides about non-conforming products? <quarantine tickets> 	
5.10.4	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.	B 2.3.1–2	11, 12	For example, evidences can be provided to show that products have not been placed on the market (e.g. contracts with external waste destroying service providers). Exceptions can be checked with examples (situations which already occurred), by checking the content of the contract.	
5.11	Corrective actions			<ul style="list-style-type: none"> - In case of a renewal audit: were the corrective actions of the previous IFS audit applied? 	
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.			<ul style="list-style-type: none"> - What are corrective actions procedures? <corrective actions procedures> 	No corrective actions procedures exist.

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
5.11.2 KO	KO N° 9: Corrective actions shall be clearly formulated, documented and undertaken, as soon as possible to avoid further occurrence of non-conformity. The responsibilities and the timescales for corrective action shall be clearly defined. The documentation shall be securely stored, and easily accessible.	6, 3	In response to deviations from the prerequisite programs corrective actions will be determined. Corrective actions may include, but are not limited to: – Product hold, assessment and disposition. – Ensuring the corrective action is completed. – Root cause identification. – Preventive actions.	– Which corrective actions were implemented? <model corrective action procedures> – Where are corrective actions documented? <model corrective action procedures > – Who is responsible for corrective actions? <model corrective action procedures > – How long may it take to implement corrective actions? <model corrective action procedures >	No corrective actions are taken. Corrective actions are not implemented within a short time span. Corrective actions are not documented No responsibilities are assigned to implement corrective actions.
5.11.3	The performance of the implemented corrective actions shall be documented and the effectiveness shall be checked.			– Where are corrective actions documented? <model corrective action procedures> – How are corrective actions verified? <model with verified corrective action procedures>	Corrective actions are not documented and/or verified.

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IFS PAC secure number	IFS PACsecure requirement	Conne- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
6	Packaging material defense/Food defense plan and external inspections Product defense plan and external inspection				
6.1	Defense assessment				
6.1.1	Responsibilities for packaging material 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.			<ul style="list-style-type: none"> - Who has the accountability for the packaging material product defense program? - What are the competence and qualifications demonstrated for the person(s) responsible for the packaging material product defense program? - What is the position of the person(s) responsible for the packaging material product defense program with respect to the management team? - How do management teams support the person(s) responsible for the packaging material product defense program? - Where are the responsibilities clearly defined? - Was this communicated to the members of the company? How? 	

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IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
6.1.2	<p>A packaging material 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. Packaging material 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>			<ul style="list-style-type: none"> - What are the legal/customer packaging material product defense requirements applicable to the company? - How can the company demonstrate compliance with such requirements? - What is the process/procedure used to perform the hazard analysis and assessment of associated risks? - Is the hazard analysis in line with legal and/or customer needs and/or expectations? - How do the systems assist the company to identify critical or high risk areas? - How often is a review of the packaging material product defense program performed? - What criteria does the company consider in order to determine the frequency to perform the hazard analysis, if is not done annually? - How is the company alerted of any packaging material product defense breach? - How does the company evaluate the effectiveness of the packaging material product defense program? 	

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
6.1.3	If legislation makes registration or on-site inspections necessary, evidence shall be provided.			<ul style="list-style-type: none"> - What are the legal/customer packaging-material product defense requirements applicable to the company? - Based on legal requirements in the country where the plant is located or by the country where the product is consumed, is it required to apply for formal registration? - If registration is required, who has this information? Could the company demonstrate compliance? - Is there any requirement for periodic inspection? If yes, then: <ul style="list-style-type: none"> - Who performs it? - Against what standard? - When was the last inspection? - What was the result of the inspection? - Is it required to provide evidence that deviations have been solved? (corrective actions) - What are the implications if a major breach is identified? 	

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IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
6.2	Site Security				
6.2.1	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.			<ul style="list-style-type: none"> – Based on the hazard analysis and assessment of associated risks, what areas have been identified as critical? – What control measures are in place in order to control the entrance to those areas? – How does the company maintain control over who enters to the premises and critical areas? – What are the access controls applicable to the following people? – Temporary employees – Contractors – Visitors – Employees – Carrier drivers 	Unauthorized persons freely enter production or storage areas so that a safety risk occurs.
6.2.2	Procedures shall be in place to prevent tampering and/or allow identification of signs of tampering.			<ul style="list-style-type: none"> – Does the company define procedures to identify tampering of raw materials, Works in Process (WIP) and final goods? – Are there means to verify if products have been tampered? – Are employees trained in the identification of tampered products? – Does the design of packaging material include the identification of tamper evident measures? Is it required by law in the country of origin or destination? – Are there tests to verify that measures against tampering are properly applied and working properly? 	

IFS PAC secure number	IFS PACsecure requirement	Connec- tion with PACsecure PP require- ment number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
6.3	Personnel & Visitor Security				
6.3.1	Visitor policy shall contain aspects of packaging material 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.			<ul style="list-style-type: none"> - Do visitor/contractor access policies include controls to avoid that no members of the company are able to move freely without escorts inside the premises? - Are visitors and contractors informed of the packaging material product defense rules and their scope while inside company premises? - Does the company have defined means to ensure that contractors who will spend a long time inside the plants are properly identified, supervised and escorted inside critical areas? - Are there controls to ensure that the access for truck drivers who load or unload products/materials is restricted to defined areas inside and outside the building and company premises? Are there means to watch the movements of non-employees once they enter company premises? (E.g. cameras or guards at defined areas? Other procedures?) - If contractors and visitors are provided with access keys, are those keys programmed to limit the access to specified and selected areas? - If escorts are required to guide visitors and contractors at all times, are there arrange- ments to have defined guides at all shifts? - Are security/guards aware of how to deal in cases where there are no escorts available at any particular moment? 	

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IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
6.3.2	All employees shall be trained in packaging material 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.			<ul style="list-style-type: none"> - Does the annual training program include packaging material product defense? - How is packaging material product defense and associated controls explained to new employees? - Are there records that demonstrate that employees received packaging material product defense training? - Is training updated according to changes in the packaging material product defense program? - How are employees informed of major changes in the packaging material product defense program? - Does the system evaluate training effectiveness? - Does training include controls of knowledge acquired from the last version of the packaging material product defense training? - What controls are implemented at the time of hire/termination of an employee or creation/termination of a service by a contractor? - Are access controls updated at the time of termination of an employee or when the work is finished on the part of a contractor? 	

IFS PAC secure number	IFS PACsecure requirement	Connection with PACsecure PP requirement number	Text/Number of connected PACsecure PP (Prerequisite Program) requirement	What to check? What should be asked?	Example for KO/Major
6.4	External Inspections				
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.			<ul style="list-style-type: none"> – Is there a documented procedure that defines the criteria to follow in case an external organization requires access to the company's premises? – Are there clearly defined levels of authority to provide access to external organizations at all times? – Does the procedure define the means to proceed if or when a regulatory body requests access to the premises? – Are relevant functions aware of their responsibilities under such conditions? – Are levels of authority defined with respect to the kind of information that is allowed to be provided? – Are there means to ensure a complete record of activities done and details of the visit? 	

ANNEX 1: Glossary/definitions list

Definitions which are not mentioned within the glossary can be found in relevant regulations and directives. In relation to the terms used within this document and PACsecure documents, the following definitions apply and shall be respected.

Term	Explanation
Additive	Materials such as plasticizers, preservatives, slip agents, antistatic agents, processing aids, and others, added to a base material in order to achieve a specific result.
Adhesive	An adhesive substance (as glue or cement, or starch in paper industry).
Allergen (EU)	<p>Food causing an adverse reaction that is mediated by an immunological response. Defined allergens are:</p> <ul style="list-style-type: none"> – Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof – Crustaceans and products thereof – Eggs and products thereof – Fish and products thereof – Peanuts and products thereof – Soybeans and products thereof – Milk and products thereof (including lactose) – Nuts i.e. Almond (<i>Amygdalus communis</i> L.), Hazelnut (<i>Corylus avellana</i>), Walnut (<i>Juglans regia</i>), Cashew (<i>Anacardium occidentale</i>), Pecan nut (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nut (<i>Bertholletia excelsa</i>), Pistachio nut (<i>Pistacia vera</i>), Macadamia nut and Queensland nut (<i>Macadamia ternifolia</i>) and products thereof – Celery and products thereof – Lupin and products thereof – Molluscs and products thereof – Mustard and products thereof – Sesame seeds and products thereof – Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂. <p>(Commission Directive 2007/68/EC of 27 November 2007 amending Annex III a to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients.) Regulation (EU) No 1169 / 2011 of the European Parliament and of the council.</p>
Allergen (US)	<p>There are 8 major allergens recognized in the United States according to the 2009 U.S. Food and Drug Administration (FDA) Model Food Code, Definitions section, page 12.</p> <p>(1) "Major food allergen" means:</p> <ul style="list-style-type: none"> (a) Milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans (b) A Food ingredient that contains protein derived from a food, as specified in Subparagraph (1)(a) of this definition. <p>(2) "Major food allergen" does not include:</p> <ul style="list-style-type: none"> a) Any highly refined oil derived from a food specified in Subparagraph (1)(a) of this definition and any ingredient derived from such highly refined oil; or b) Any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labelling and Consumer Protection Act of 2004 (Public Law 108-282).
Aseptic technique	Precautionary measures taken to prevent contamination.
Assessor (for accreditation bodies)	Person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a Conformity Assessment Body.

Audit	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.
Audit time window	Period of time during which the unannounced audit may be performed. The date of reference for this time window is the audit due date (date of first certification audit). Within the IFS protocol, the time window is [-16 weeks; +2 weeks] of the audit due date. In case where initial audit will be performed directly unannounced, there will not be a specific time window.
Auditor	An individual who is qualified to provide audits, such as certified auditor. Note: An employee who is qualified and independent of the audited function typically conducts first-party/internal audit within the organization. A totally independent certified auditor who is not involved in the customer-supplier relationship conducts third-party audits.
Biological hazards	Parasites, bacteria, moulds, or viruses that have the ability to cause illness or death.
Blackout period	Period of time that the company may notify its certification body when the unannounced audit cannot take place (e.g. staff holidays, maintenance days, non-production days, etc.). This includes maximum 10 operational days, plus non-operating periods. Note: the company cannot provide 10 individual days, but periods related to days when the company cannot ask the auditor to perform the audit in optimum conditions (e.g. planned customer visit, holidays of quality manager, etc.).
Buyer/filler	A company who buys packaging materials from packaging material manufacturer and converter and fill the package with the product.
Calibration	Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material and the corresponding values realised by standards.
Carrier	An operator of a conveyance such as a truck, railcar, vessel, or aircraft used to transport goods.
CCP – Critical Control Point	A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
Chemical hazards	Chemical products (e.g. agricultural chemicals, cleaning agents, food and packaging additives, waxes and coatings, heavy metals, inks, solvents, etc.) that have the potential to cause illness or death especially when used in excess of regulatory limits.
Cleaning	The removal of soil, residue, dirt, grease or other objectionable matter.
Company	General organisation (whereas the site is a unit of the company).
Competent employee	An employee who is familiar with and capable of assessing the operation of a piece of equipment or process.
Contact surfaces	Surfaces that contact packaging product. This also includes any surface that might drip or drain onto a surface that contacts packaging product during the normal course of operations. Contact surfaces include equipment such as containers, tables and conveyor belts used in packaging operations. It does not include forklifts, hand trucks, or pallets that are used for handling wrapped packaging products.
Contamination	Introduction or occurrence of a contaminant in packaging material or environment. Contamination does include: physical, chemical, biological contamination. Contamination can also mean correlation of packages among themselves.
Control measure	(Food safety) action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. Acceptable levels may be derived from; regulatory requirements; industry standards; scientific information; customer requirements; risk assessments.

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Converter	A manufacturer that takes raw materials and converts them into a usable package or package component.
Converting time	The period in which a product may be processed/converted before being considered unsuitable for the purpose.
Corporate	Company.
Correction	Action to eliminate a detected non-conformity or deviation.
Corrective action	Action to eliminate the cause of a detected non-conformity or other undesirable situation.
CP – Control point	Identified by the hazard analysis as essential in order to control the likelihood of introducing or proliferation of food safety hazard in the product and/or the environment. A CP can be considered as an OPRP (Operational Prerequisite Program), as defined in ISO 22000.
Customer	A customer is a business company or person to whom products are sold either as finished product or as a semi-finished part of the finished product.
Deviation	Non-compliance with a requirement but there is no impact on food safety related to products and processes. In the IFS, deviations are requirements scored with a B, C or D and KO requirements scored with a B.
Establishment	Any building or surrounding area in which packaging material and/or product is handled manufactured, or converted, and is under the control of the same management.
Extrusion	The process of forming a thermoplastic film, container, or profile by forcing the polymer melts through a shaped orifice. The extruded plastic is immediately chilled.
Facility	Buildings and other physical structures used for or in connection with the manufacturing and converting of packaging material and product.
Factory inspection (versus Internal audits)	Factory inspection covers specific subjects and can be carried out by any appropriate person. That means regular visits in any areas, for any purposes, to check the conformity (hygiene, pest control, product control, fabrication, foreign material hazards, surrounding control etc.).
FIFO	“First In—First Out”: an inventory system of product rotation, where the oldest product is shipped first.
Flow diagram	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular packaging material item.
Food safety	Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.
Formula	Exhaustive description of quantity and quality of raw materials to be used to process the products, as required in customer specifications. Formula can also include technological parameters and specific “know-how” on the process.
FSEP	Food Safety Enhancement Program. The FSEP is the Canadian Food Inspection Agency’s (CFIA) approach to encourage and support the development, implementation and maintenance of Hazard Analysis Critical Control Point (HACCP) systems in all federally registered establishments of the meat, dairy, honey, maple syrup, processed fruit and vegetable, shell egg, processed egg and poultry hatchery sectors. Government and food industry developed FSEP jointly in 1991 in consultation with consumer groups. (http://www.inspection.gc.ca/english/fssa/polstrat/haccp/haccpe.shtml)
Glue	Any of various strong adhesive substances; especially: a hard protein chiefly gelatinous substance that absorbs water to form a viscous solution with strong adhesive.

GMO	An organism, with the exception of human beings, in which the genetic material has been modified otherwise than natural multiplication or natural recombination.
GMP – Good Manufacturing Practices	The practices that prevent and minimize the biological, chemical and physical contamination of packaging material and product during receiving, manufacturing, converting, storage and transportation, to ensure food safety.
GMP regulation (EU/US)	EU: (EC) No 2023/2006 of 22 December 2006 on good manufacturing practices for materials and articles intended to come into contact with food. US: 21 CFR 174 - 21 CFR 190.
HACCP (risk assessment)	A system which identifies evaluates and controls hazards which are significant for packaging material safety.
Hazard	A biological, chemical or physical agent in, or condition of, packaging material with the potential to cause an adverse health effect.
Hazard analysis	The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for packaging material safety and therefore should be addressed in the HACCP plan.
Head office assessment (for accreditation bodies)	Assessment of the Conformity Assessment Body Head Office.
Hygiene	Conditions and measures that are required to ensure that packaging material and product is safe.
Inert	Material without active chemical properties.
Initial IFS PACsecure audit	The Initial IFS PACsecure audit is considered the first audit as defined in the IFS PACsecure Standard.
Integrity Program	Program implemented by IFS in order to: <ul style="list-style-type: none"> – Monitor, as preventive actions performance of auditors and certification bodies as well as audited companies, – Manage, as corrective actions, any complaints addressed to IFS.
Internal audit	General process of audit, for all the activity of the company. Conducted by or on behalf of the company for internal purposes. Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.
Lamination	A process of plying layers of stock to a given thickness.
Lot	The packaging product manufactured during a period of time or according to a specific code.
Leak test	A testing process designed to find unintended holes or voids that allow air or fluid to pass through packaging materials. For labeled products, leak test is conducted prior to labeling in order to avoid concealing any leaks.
Microorganisms	Organisms too small to be seen by the naked eye that include yeasts, moulds, bacteria, and viruses.
Monitoring	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CP is under control. See also Codex Alimentarius, General principles of Food hygiene, Guidelines for the application of the HACCP system, section 9.
MSDS – Material Safety Data Sheet Safety Data Sheets (SDS)	The safety data sheet information is principally intended for use by professional users and must enable them to take the necessary measures as regards the protection of health, safety and the environment at the place of work. The safety data sheet may be supplied on paper or electronically, provided that the addressee has the necessary means of receiving it.

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	<p>Non-conformity</p> <p>Non-fulfilment of a specified requirement. Non-conformity can be given in non-respect of legislation, law, packaging material safety, internal dysfunctions and customer issues. In the IFS, defined non-conformities are Majors and KO's scored with a D.</p>
added	<p>Non-operating periods</p> <p>Periods when the production lines are not operating at all, e.g. planned maintenance work, bank holiday, company planned shutdown for holidays, etc.</p>
changed	<p>Packaging material defense/Product defense (food defense) (US)</p> <p>Food Defense is the collective term used by the US Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Department of Homeland Security (DHS), etc. to encompass activities associated with protecting the nation's food supply from deliberate or intentional acts of contamination or tampering. This term encompasses other similar verbiage (i.e., bioterrorism (BT), counter-terrorism (CT), etc.);</p> <p>The USDA Food Safety and Inspection Service define Food Defense as "the protection of food products from intentional adulteration by biological, chemical, physical or radiological agents."</p> <p>The definition also applies on packaging materials.</p> <p>The protection of products from intentional contamination or adulteration by biological, chemical, physical, or radiological agents for the purpose of causing harm.</p>
	<p>Pest</p> <p>Any animal or insect such as birds, rodents, cockroaches, flies, and larvae that may carry pathogens and can contaminate packaging material and product.</p>
	<p>Physical hazards</p> <p>Physical components (e.g. wood or glass chip, metal piece, etc.) and foreign matter that can cause illness or injury. This includes pests and their components.</p>
	<p>Potable air</p> <p>Air containing less than 1,000 viable colony-forming units of total micro-organisms per cubic meter of air. Air containing less than 200 viable colony-forming units of bacteria and 200 viable colony-forming units of fungi in a cubic meter of air. Users should check with authority having local jurisdiction for limits pertaining to chemical and other contaminants.</p>
	<p>Potable water (CA)</p> <p>Water that meets Health Canada's Canadian Drinking Water Guidelines. (http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/doc_sup-appui/index_e.html)</p>
	<p>Potable water</p> <p>Water suitable for human consumption without endangering health. It is immaculate concerning smell, taste and nature.</p>
	<p>Primary packaging</p> <p>Packaging coming into contact with the packed goods such as PET bottles, cups, plastic closures of packages.</p>
	<p>Procedure</p> <p>Specified way to carry out an activity or process. Procedures shall be implemented and the elaboration of procedures shall be done by documents or process description (e.g. flowchart).</p>
	<p>Product</p> <p>Result of a process or activities transforming inputs into outputs. Products include services. In the context of this Standard a product is to be considered a packaging material.</p>
	<p>Product development</p> <p>The creation of products with new or different characteristics that offer new or additional benefits to the customer. Product development may involve modification of an existing product or its presentation, or formulation of an entirely new product that satisfies a newly defined customer who wants a market niche. In the IFS PACsecure Standard, the requirements for chapter product development apply even if there is just a product modification, use of new wrapping materials or modifications of production processes.</p>

Product fraud (food fraud)	<p>The deliberate and intentional substitution, mislabelling, adulteration or counterfeiting of product, raw materials, product formula/configuration or packaging placed upon the market for economic gain. This definition also applies to out-sourced processes.</p> <p>Note 1: the scope of term “product fraud” comprises the negative influence/impact of packaging material used on food products, but also could be applicable to non-food products</p> <p>Note 2: raw materials includes additives, inks, adhesives, solvents, wrapping materials, rework.</p>	added
Product fraud (food fraud) mitigation plan	<p>A process that defines the requirements on when, where and how to mitigate fraudulent activities, identified by a product fraud vulnerability assessment. The resulting plan will define the measures and controls that are required to be in place to effectively mitigate the identified risks.</p> <p>The control measures required to be put into place may vary according to the nature of:</p> <ul style="list-style-type: none"> – the product fraud (substitution, mislabelling, adulteration or counterfeiting) – detection methodology – type of surveillance (inspection, audit, analytical, product certification) – source of the raw material, product formula/configuration and packaging. 	
Product fraud (food fraud) vulnerability assessment	<p>A systematic documented form of risk assessment to identify the risk of possible product fraud activity within the supply chain (including all raw materials, product formula/configuration, product, packaging and outsourced processes). The method of risk assessment may vary from company to company, however the systematic methodology for product fraud vulnerability assessment shall include as a minimum:</p> <ul style="list-style-type: none"> – The identification of potential product fraud activities, using known and reliable data sources. – The evaluation of the level of risk; both product and supply source. – The evaluation for the need for additional control measures. – Use of the results of the Product Fraud Vulnerability Assessment to develop and implement the Product Fraud Mitigation Plan. – Reviewed annually, or when there is increased risk identified by change to defined risk criteria. <p>The criteria used to evaluate the level of risk might be:</p> <ul style="list-style-type: none"> – History of product fraud incidents – Economic factors – Ease of fraudulent activity – Supply chain complexity – Current control measures – Supplier confidence. 	added
Product recall	Any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor.	
Product requirements	Product requirements includes: product safety, product quality, product legality, process and specification.	
Product withdrawal	Any measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer.	
Qualified employee	An employee who is qualified (such as certified auditor) and independent of the audited function conducts first-party/internal audit within the organization.	
Raw material	One of the parts of a mixture	
Raw material specification (RMS)	A document describing detailed product features, attributes and processing factors that enable the user or the document (i.e. supplier) to produce or supply material that will fulfil its intended use.	

Reviewer	<p>Person of the certification body in charge of assessing the IFS PACsecure audits reports before a certification decision is made.</p> <p>The tasks of the reviewer are, at least:</p> <ul style="list-style-type: none"> – To check the overall consistency of the audit reports. – To check if the audit reports are properly completed – To check if the findings are well described and if the justifications are relevant. – To check if the corrective actions proposed by the audited company have been validated by the auditor (or by a representative of the certification body) and are relevant. <p>The review shall be documented.</p>
Risk	A function of the probability of an adverse health effect and the severity of that effect consequential to (a) hazard(s) in packaging material.
Secondary packaging	Packaging, e.g. films that have no contact with the food.
Senior management	Executive management.
Services	See definition of product.
Site	A unit of the company.
Supplier Quality Assurance (SQA) Program	A program designed to ensure raw materials/other material suppliers are in compliance with product specifications and safety or quality requirements. The program often includes elements such as a supplier selection and approval process; supplier auditing and product testing.
System	Set of interrelated or interacting elements. System is a planned, sustainable structured course of action. Depending on the complexity, documentation is recommended. System includes: documentation, procedure description, control/monitoring, corrective action, site plan.
Tertiary packaging	Packaging/wrapping that is used to group secondary packaging together to aid handling and transportation and prevent damage to the products, for example, the pallet and shrink wrap used to transport a number of cardboard outer containing boxes filled with packaging material.
Traceability	Ability to trace and follow a material intended to be, or expected to be incorporated into a packaging material, through all stages of production, converting and distribution.
Validation	Confirmation through the provision of objective evidences that the requirements for the specific intended use or application have been fulfilled.
Verification	Confirmation through the provision of objective evidences that specified requirements have been fulfilled.
Witness assessment (by accreditation bodies)	Assessment of the Conformity Assessment Body when it is carrying out conformity assessment services within its scope of accreditation.
<p>changed</p> <p>added</p>	<p>Witness audit before applying to IFS examinations</p> <p>Initial witness audit</p> <p>The auditor who is witnessed shall be accompanied by an observer from the certification body during a complete audit in order to evaluate his/her competence. The observer shall not be part of the audit (as a team member). The observer shall fulfil the same requirements as for trainers or shall be an IFS PACsecure auditor, IFS Food auditor or IFS HPC auditor. This witness audit shall be a product safety audit and/or an audit under ISO/IEC 17065.</p> <p>Note: The witness audit can either be performed before or after passing the exams. Hence, for the latter, also an IFS audit can be used. In this case both, the auditor under observation (AUO) and the witnesser, have to cover the whole scope of the audit. The audit is uploaded with the witnesser as lead auditor as the "AUO" is not yet approved as IFS auditor (inserted as "AUO" in the participants list).</p> <p>On the application file of the auditor (sent afterwards to the IFS offices), the certification body shall specify the name of the company, audit date and name of the person who observed the auditor. On request, the certification body shall be able to provide minutes of the witness audit.</p>

Witness audit, to be performed every 2 years, for IFS PACsecure approved auditors	The auditor who is witnessed shall be accompanied by an observer from the certification body during a complete IFS PACsecure, IFS Food, IFS HPC, or another GFSI recognized packaging material safety scheme audit, in order to evaluate his/her competence. The observer shall not be part of the audit (as a team member). The observer shall fulfil the same requirements as for trainers or shall be an IFS PACsecure, IFS Food or IFS HPC auditor. For the observer, relevant product scope(s) approval, in relation to the products/processes of the audit, is not mandatory. The certification body shall specify the name of the observer in the participants' list of the IFS PACsecure audit report and shall be able to provide, on request, minutes of this witness audit.
Wrapping	See tertiary packaging.

Part 3: Requirements for Accreditation Bodies, Certification Bodies and Auditors

IFS accreditation and certification process

0 Introduction

IFS PACsecure certification is a product and process certification. All bodies involved shall comply with the international rules and IFS-specific requirements described in this document. Part 3 of the IFS PACsecure Standard deals mainly with accreditation bodies, certification bodies and auditors.

1 Requirements for the Accreditation Bodies

1.1 General requirements

The accreditation bodies shall fulfil the requirements of the ISO/IEC 17011 norm "Conformity assessment – General requirements for Accreditation Bodies accrediting conformity assessment bodies", and shall have signed the MLA (Multilateral Agreement) for Product Certification of the EA or IAF.

deleted

~~As soon as it will come into force,~~ The accreditation bodies shall also fulfil the GFSI Requirements for the Application of ISO/IEC 17011:2004, which is complementary of the below requirements.

In order to ensure interactive communication, the accreditation body shall appoint an IFS contact person within their organisation.

1.2 The training of the accreditation committee (or competent person)

In general, all accreditation body personnel engaged in IFS PACsecure accreditation activity shall have sufficient knowledge of the IFS PACsecure scheme, related normative documents and food or packaging industry.

Decisions on accreditation can only be made following a recommendation of a competent person or accreditation committee. The person in charge, or at least one member of the accreditation committee, shall

have taken part in an IFS PACsecure training course organised by IFS or shall be able to demonstrate equivalent knowledge level as confirmed by IFS. In case of a committee, the trained person provides the other members of the accreditation committee with the necessary information. This information is based on the main points of the IFS PACsecure training course with the main emphasis on Part 1 (IFS PACsecure audit protocol), Part 3 (requirements for accreditation bodies, certification bodies and auditors), Part 4 (audit report, certificate) and the auditors' approval process for IFS.

1.3 Competences of the assessor of the accreditation body

The assessor(s) of the accreditation bodies is responsible for the following:

- accompanying IFS PACsecure auditors during registered IFS PACsecure audits (witness assessment),
- assessing the head office of the certification body (head office assessment) according to the ISO/IEC 17065 rules and IFS-specific requirements.

In general, the assessor(s) shall meet ISO/IEC 17065 and IFS requirements.

Witness assessors shall, at a minimum:

- Have taken part in the IFS PACsecure training course, or shall be able to demonstrate an equivalent knowledge level as confirmed by IFS,
- Have taken part in a HACCP course or other course related to hazard analysis and assessment of associated risks,
- Have a minimum of two (2) years of experience in the packaging material industry sector.

Head office assessors shall, at a minimum:

- Have specific knowledge in the IFS PACsecure scheme,
- Have specific knowledge of the related normative documents.

1.4 Frequency of the assessments of certification bodies

For initial assessment, a head office assessment (with review of at least one full certification process) and at least one witness assessment shall be performed.

The certification body is allowed to perform maximum 5 audits before getting accreditation. In this case, at least one of the audits shall be

assessed by the accreditation body (witness assessment) and all audits (including at least one full certification process) shall be reviewed by the accreditation body during the initial headquarter assessment.

For renewal assessment, a head office assessment (with review of at least one full certification process) and at least one witness assessment shall be performed.

During the surveillance of the accreditation cycle:

- A minimum of one head office assessment a year,
- A minimum of one witness assessment every two (2) years

shall take place.

Remark: a flexibility of three (3) months at the maximum can be allowed for the interval between two (2) assessments, according to the accreditation body rules.

During head office assessments, the following documentation shall be sampled and assessed, as a minimum:

- At least 10% or two (2) IFS PACsecure auditor files, whichever is greater,
- At least two (2) site files or 2% of delivered audits, whichever is greater.

For consecutive witness assessments, the accreditation body shall, wherever possible, select two different certification body's IFS PACsecure auditors with different scopes.

1.5 Accreditation of an internationally-active certification body

The witness assessments shall cover the typical activities (including international activities and critical locations) of the certification body. If the accreditation body subcontracts an assessment, the subcontracted accreditation body shall be a signatory to the IAF MLA for Product Certification. IAF GD 3 Cross Frontier Policy shall apply.

1.6 Conditions for recovering accreditation after withdrawal or suspension

In case the accreditation body decides to withdraw or suspend accreditation, certification bodies shall stop performing IFS PACsecure audits and issuing IFS PACsecure certificates. To recover accreditation after withdrawal, the same conditions as for initial assessment apply. In case of accreditation suspension, IFS and accreditation body will jointly determine requirements to remove suspension.

1.7 Transfer of certification

In case one certification body decides to transfer its certification activities to another one, the new certification body shall verify all current IFS PACsecure certificates, in order to decide if further actions (e.g. withdrawal of recent certificates or additional IFS renewal audit) will be necessary.

2 Requirements for the Certification Bodies

Certification bodies intending to perform IFS PACsecure audits shall comply with the following rules. The prescribed tender procedure for certification bodies is supplied by IFS.

2.1 ISO/IEC 17065 IFS accreditation process

The certification body shall be accredited according to ISO/IEC 17065 for the scope of IFS PACsecure by an IAF or EA recognised accreditation body (see section 1). Certification bodies in the process of IFS accreditation to ISO/IEC 17065 may organise the witness assessment(s) before having achieved accreditation status. They shall demonstrate that they are actively applying for ISO/IEC 17065 accreditation.

Note: In case of withdrawal or suspension of the ISO/IEC 17065 accreditation of the scope of IFS PACsecure for the certification body, the whole certification process is stopped and the certification body is no longer allowed to issue any IFS PACsecure certificates. In particular, the certification body cannot issue IFS PACsecure certificates from the date of withdrawal or suspension, even for the audits which have been already performed but which are still in the certification process (review of the report, certification decision, etc.).

2.2 Signing of contract with the proprietor of IFS

After having applied and then gained IFS accreditation to ISO/IEC 17065, in order to be allowed to perform IFS PACsecure audits, the certification body shall sign a contract with IFS in which it commits to meet all IFS requirements. The certification body is not authorised to perform IFS PACsecure audits (except the first witness assessment(s) during the accreditation process) before having signed this contract.

2.3 Certification decision

The person in charge of assessing the audit reports (reviewer) shall be either an approved IFS PACsecure auditor, an IFS PACsecure trainer or shall fulfil the following rules:

- To have a food or packaging university degree and two (2) years professional experience in the food safety/packaging material safety and quality related professions
- To have attended (as auditor or observer) at ten (10) complete audits (related to other packaging material safety schemes) in the last five (5) years
- To have participated in a hygiene training course
- To have participated in IFS PACsecure Train-the-trainer course
- To be different of the person who performed the audit.

The review shall be documented.

The decision concerning the certification can only be made following the recommendation of a competent person or a certification committee. Furthermore, decision can only be made by a person different from the person who performed the audit. The competent person for the certification decision or at least one of the members of the certification committee shall be an IFS PACsecure auditor, an IFS PACsecure trainer or an IFS PACsecure reviewer.

According to ISO/IEC 17065, the final certification decision shall be made by the certification body and shall not be subcontracted.

2.4 Certification bodies' responsibilities for IFS PACsecure trainers and the IFS PACsecure auditors (including freelancers)

deleted |

Certification bodies have the following responsibilities:

added |

- **The certification body is obliged to ensure compliance with ISO/IEC 17065 norm and the IFS framework agreement.**
- To facilitate witness audits (by accreditation bodies and/or by Integrity Program).
- To ensure that at least one member of their staff is an IFS PACsecure trainer who has taken part in an IFS PACsecure Train-the-trainer course. The trainer is responsible for the in-house training of all auditors, intending to become IFS PACsecure auditors or who already are IFS PACsecure auditors. Persons intending to become IFS PACsecure trainers shall meet the requirements mentioned in 2.5.

Note: for a certification body which is starting IFS activities, this in-house training can be organised by IFS, on request.

- To ensure that the auditor is competent for the scope of the audit and its execution and is able to access and to apply relevant laws and regulations, based on IFS and internal certification body's requirements; the certification body shall maintain these competences (continuous supervision by the certification body) and shall monitor audit execution by on-site witness audit. Every auditor shall be monitored by an IFS PACsecure (or IFS Food, IFS HPC or other GFSI recognized packaging material safety) on-site witness audit at least once every two (2) years, and the results of this witness audit shall be documented. The observer shall be an IFS PACsecure, IFS Food or IFS HPC approved auditor or shall follow the same rules as for trainers (see section 2.5).
- To maintain records of auditor competences.
- To ensure that no auditor has either acted against IFS rules, for example acting as a consultant, or has been active in and/or on behalf of the company being audited during the previous two (2) years. That is to say, during the certification process, no other commercial and/or personal relationships are permitted between the auditee and the auditor.
- To ensure that no auditor shall perform more than three (3) consecutive IFS PACsecure audits of the same production site (only applies for complete audits, whatever the time between them; follow-up and extension audits are not concerned by this rule).
- ~~To ensure that an auditor is employed by only one IFS certification body for performing IFS PACsecure audits and this for a period of not less than 12 months. In special cases, IFS offices shall be contacted and may allow exceptions.~~
- **To ensure that all auditors have a valid contract with the certification body.**
- To sign an audit order for each audit, this includes a statement accepting all the above-mentioned requirements.
- To organise a 2-day training session for IFS PACsecure auditors once a year for the purposes of sharing experience, calibration and updating knowledge of relevant legal requirements, etc. The IFS PACsecure trainer shall lead a part of the training course.
- To perform an on-site witness audit of an auditor during a product safety audit and/or an audit under ISO/IEC 17065 accreditation to ensure the auditor's competence (see glossary) before he/she has applied for the IFS examinations. The certification body shall state the date, the name of the audited company where the on-site witness audit took place, and the name of the observer in the IFS examination application file. The minutes of the on-site witness audit shall be provided on request to the IFS in English, French or German. The observer for the on-site witness audit of an auditor applying for IFS examination shall comply with the same requirements as the trainers (see section 2.5) or shall be an IFS PACsecure, IFS Food or IFS HPC auditor.

changed

- To include the name of the observer in the Audit Portal when uploading the audit data, when it has scheduled specific on-site IFS witness audit(s) according to ISO/IEC 17065 on internal audits.

The certification body is responsible for choosing an auditor with the corresponding scope(s), language, competence(s), etc. for each IFS PACsecure audit.

2.5 Specific requirements for IFS PACsecure trainers

IFS PACsecure trainers shall have the following profile:

- Fulfil requirements for IFS PACsecure auditors as described in section 3.2 a), b), c) and d),
- Have audit experience to GFSI standards or other packaging material safety schemes,
- Have knowledge of packaging legislation,
- Have taken part in a IFS PACsecure Train-the-trainer course organised by IFS,
- Be fluent in writing and speaking the languages they will use during participating in training and leading training; they shall inform the IFS offices about the languages they are able to use when teaching.

The IFS PACsecure Train-the-Trainer course is organised by IFS.

In order to keep his/her knowledge of IFS PACsecure up to date, each IFS PACsecure trainer shall take part in a 2-day IFS PACsecure training course every two (2) years. These seminars are organised by IFS and shall be the basis for in-house training to all auditors.

IFS PACsecure trainers have the responsibility to:

- Train new IFS PACsecure auditors before applying to IFS PACsecure exams,
- Lead (a part or the whole) 2-day training session for IFS PACsecure auditors once a year, for the purposes of sharing experience, calibration and updating knowledge of relevant legal requirements, etc.

When a new version of the Standard is published, the certification body's trainer shall take part in the new IFS PACsecure course organised by IFS and carry out in-house training of all the already IFS PACsecure approved auditors, before performing audits based on new version. The duration of this in-house training shall be at least one day.

In case of publication of new doctrines, the trainer shall train all IFS PACsecure auditors before the doctrine comes into force.

3 Requirements for IFS PACsecure auditors

In general, the auditors shall meet the requirements of chapters 7.2 7.2.2 and 7.3.1 7.2.3 of ISO 19011.

changed

During an IFS PACsecure audit, auditors shall, according to IFS good auditing practices, use relevant samples of products, in order to investigate on-site the auditee's production processes and documentation and to check the fulfilment of IFS requirements. In particular, auditors shall perform, during the audit, a traceability test in the company.

IFS publishes guidelines which can provide further information on topics to be checked and/or requested to the audited company during the audit.

3.1 Conversion of auditors to get the IFS PACsecure version 1.1 auditor approval

Auditors being already qualified for PACsecure or other IFS schemes are allowed to audit against the IFS PACsecure version 1.1, without going through the full qualification process as mentioned in 3.2 and 3.3 if they fulfil the following requirements:

- If they are PACsecure auditors: they shall have experience in product/process certification (or attend a training on product/process certification organised by IFS, including verification of acquired knowledge) and additionally attend an IFS PACsecure training organised by IFS.
- If they are IFS HPC auditors approved for scope 3 (Housekeeping properties): they shall additionally attend an IFS PACsecure training organised by IFS.
- If they are IFS Food approved auditors, also qualified for a packaging standard related to safety and quality, like GMP FEFCO, ISO 22000 scope M or BRC IoP: they shall additionally attend an IFS PACsecure training organised by IFS.
- If they are qualified for a packaging standard related to safety and quality (e.g. BRC IoP, ISO 22000 scope M, etc.): they shall attend an IFS PACsecure training organised by IFS and, if relevant, additional training on product/process certification, organised by IFS.

3.2 Requirements for new IFS PACsecure auditors

3.2.1 Requirements before applying for the IFS PACsecure examinations

Before applying for IFS examinations, auditors shall have met the following requirements:

- They shall have signed a contract with the certification body (see ISO/IEC 17065 norm).

deleted

- They confirm to the certification body that, for a period of at least 12 months, they will perform IFS PACsecure audits only for the respective certification body. They may, however, work for several certification bodies on other standards. In special cases, IFS should be contacted and may allow exceptions.
- They shall have participated at the IFS PACsecure in-house course organised by the certification body **or the equivalent IFS training provided by IFS.**
- They shall have submitted all the relevant information about their competence to the certification body.
- The certification body shall have observed and confirmed the professional qualification and competence of the auditors.

3.2.2 General requirements for auditors when applying for IFS PACsecure examinations

Candidates applying for qualification as IFS PACsecure auditors shall meet the following requirements and provide evidence with the application documents. An outline CV is available from IFS.

a) Education in the food and packaging material sector

1) A food or packaging-related university degree (bachelor's and/or master's degree equivalents) and two (2) years professional experience in the packaging material industry in relation to packaging material production activities (quality, production, R&D, ...).

or

2) If the candidate started directly as an auditor after completing his/her food or packaging related university degree then the candidate shall have five (5) years professional audit experience in the packaging related industry.

or

3) If the candidate has a university degree but not a food or packaging-related one, (bachelor's and/or master's degree equivalents) then the candidate shall have five (5) years professional experience in the packaging material industry – in relation to packaging material production activities (quality, production, R&D, ...).

or

4) Professional education in food or packaging processing (high degree) and five (5) years professional experience in the packaging material industry – in relation to packaging material production activities (quality, production, R&D, ...).

b) General audit experience

A minimum of ten (10) complete audits shall be performed by the auditor in the packaging material processing industry during the previous two years. The audits shall have been carried out in different companies.

c) Food/Packaging hygiene (including HACCP/risk assessment) training
Qualified training on the basis of the Codex General Principles for Food Hygiene.

d) Training in auditing techniques based on Quality Management System or Packaging Material Safety Management System
Duration: one week/40 hours or equivalent.

e) Specific and practical knowledge for product scopes auditors apply for (see Annex 1 for product scopes)

At least two (2) years professional experience in the packaging material industry in relation to packaging activities, for each applied product scope.

or

At least ten (10) packaging safety audits and/or second party audits including quality and packaging material safety investigations with traceable origin and confirmed by the retailer or by the industry, per product scope. Ten (10) witness audits during IFS PACsecure audits, as observer, are also accepted to qualify the observer on the product scope. Audits shall have been carried out in different ~~companies~~ **production sites**.

changed

f) Language

~~Auditors must be fluent in English. If the auditor wishes to perform audits in language(s) different from his/her mother language, he/she shall be able to provide evidence for speaking fluently this/these other language(s).~~

changed

g) IFS PACsecure in-house training

IFS PACsecure in-house training materials shall be based on the materials provided by IFS. The auditor shall have taken part in the in-house training (covering IFS, packaging-related legislation, general hygiene requirements, GMP) undertaken by an authorised IFS PACsecure trainer and organised by the certification body. The minimum duration shall be two (2) days.

IFS is responsible for the technical validation of the auditors' application files before they take part in IFS examinations. If the auditor's CV does not meet the above-mentioned requirements, IFS may reject the auditor's examination application. If the auditor does not show sufficient evidence for the product scopes he/she is applying for, IFS may reject the applications for the product scopes concerned.

~~All CV's content shall be confirmed by a person from the accredited certification body who shall put his/her name and position on the bottom of the CV.~~

deleted

For auditors exclusively working for one certification body the CV of the auditor shall be confirmed by a person from the accredited CB who shall sign for confirmation with his/her name and position on the CV. Non-exclusive auditors have to confirm correctness and completeness of their given data. All auditors have to sign the IFS terms and conditions.

added

Note: IFS offices have the possibility to withdraw an IFS PACsecure auditor approval or not to accept him/her at the examination, if the information provided in the CV is false. This kind of breach will be also forwarded to the IFS Integrity Program.

3.3 IFS examination process (for new auditors, as specified in chapter 3.2)

Auditors who comply with the requirements mentioned in chapter 3.2 can take part in an IFS PACsecure written examination. If successful, the auditor is officially authorised to perform IFS PACsecure audits. The auditor is registered and a personal IFS PACsecure auditor certificate is issued. Starting from the day of passing the written examination, the auditor is allowed to perform IFS PACsecure audits for the product scopes he/she was authorized for by IFS offices until the end of the second calendar year. The IFS PACsecure auditor certificate mentions the duration of validity, ~~the name of the certification body~~ and the auditors' product scope(s).

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3.4 Maintenance of auditors' qualification (for both types of auditors, as specified in chapters 3.1 and 3.2)

The auditor cannot perform IFS PACsecure audits anymore when his/her IFS PACsecure auditor certificate expires. The certification body is responsible to maintain auditor's IFS approval so that there are no gaps during the auditor approval.

Auditors' approval shall be re-assessed before end of validity of the auditor certificates. For maintaining their approval, auditors shall fulfil the following requirements:

- have performed a minimum number of ten (10) IFS PACsecure audits (5 audits per year),
- have been trained internally by the certification body on packaging-related legislation, Standard requirements, audit practices, etc. (2 days per year),
- be monitored by an IFS on-site witness audit (once every two years) **by the certification body**. This audit can be performed at any time during the year of end of validity of auditor's certificate. Witness assessments performed by accreditation bodies during IFS PACsecure audits are accepted as witness audits,
- have taken part in an IFS PACsecure calibration training course (subsequent to passing the initial examination, the first mandatory calibration training shall be successfully completed in the second calendar year following the date on which the initial examination was successfully completed. Then, the re-approval shall be managed every two (2) calendar years, based on the same rule).

added |

Documented evidences shall be provided to IFS offices.

Example:

Date of initial written examination: 25th of October 2018

Date of end of validity for IFS PACsecure auditor certificate (initial approval): 31st of December 2020

Auditor is authorised to perform IFS PACsecure audits between 25th October 2018 and 31st December 2020.

In 2020, if the auditor has performed 10 IFS PACsecure audits (5 per year), if he/she has been trained internally, through a yearly 2 days course, has been witnessed, and has taken part in the IFS PACsecure calibration training, the new end validity date of IFS PACsecure auditor certificate (re-approval) is: 31st December 2022.

If any of these three rules are not fulfilled, the auditor shall participate again in the IFS PACsecure initial written examination.

3.5 Scope extension for IFS-approved auditors

Auditors may, during the validity of their IFS PACsecure auditor certificate, extend their product scopes. Scope extension may not be requested in the first 12 months after the initial IFS PACsecure auditor approval.

For extension of product scope(s), they shall provide the same evidence as for the initial approval, based on new experience (new from the initial application). At least ten (10) IFS PACsecure audits in the scope, as a trainee, can also be accepted as evidence. The auditor shall have participated in all steps of the audit (on-site audit, assessment and decision processes).

The auditors can only perform IFS PACsecure audits according to the scopes stated by IFS.

3.6 Audit team

3.6.1 General rules

In general, all members of the audit team shall be IFS approved auditors.

In case of auditing with teams, the following general regulations apply:

- An IFS PACsecure audit team consists of IFS PACsecure approved auditors whose product scopes comply with the activities of the audited site.
- A lead auditor shall always be appointed.
- Co-auditor(s) shall always be approved for at least one product scope of the audit scope. Two (2) hours of the audit duration are

deleted

not shareable; this additional time shall be allocated to the team, not to an individual auditor, for common tasks (e.g. opening and closing meeting, discussion about audit findings, etc.)

- The remaining time can be split as long as the auditor competencies for product scopes are not disconnected during the audit. ~~No “crossing over” is allowed. This means that, if the lead or co-auditor(s) do not have, individually, all product scopes which are necessary for the audit, they have to audit all parts of the audit related to product scope knowledge together.~~

It shall be clearly indicated in the audit time schedule which auditor did which part of the audit. Auditors without necessary scopes can only take part as trainees.

The minimum audit duration shall anyway be respected.

3.6.2 Specific rules for audit team and auditing 3 consecutive times

For audit teams an additional rule applies as regulation for consecutive audits. As an exceptional case, (if the certification body has no other possibility to combine an audit team in year 4–6, due to missing approval for product scope of their auditors) the following sequence of auditor planning is possible:

Year 1–3: Lead auditor A + co-auditor B

Year 4–6: Lead auditor B + co-auditor C

Year 7: Lead auditor A or C + co-auditor A or C.

ANNEX 1: Product scopes

1. Flexible packaging
2. Rigid plastic
3. Paper
4. Metal
5. Glass
6. Other natural materials

Multi component packaging materials (e.g. Tetra Pak) have to be assigned based on the material which is the main component of the material. The main component of multi component packaging materials shall be mentioned in the scope of the audit on the report.

Materials to be considered as “other natural materials” are, for example wood, clay, cork, jute, textiles, banana leaves, etc.

changed

Part 4: Reporting, auditXpressX™ Software and IFS Audit Portal

0 Introduction

changed

After an IFS PACsecure audit has been performed, a detailed and well-structured audit report shall be completed. ~~The language of the report shall be English.~~ **In general, the language of the report shall be the working language of the company. In special cases, where the native language of the retailers or purchasers is different from the language of the company, an English language version of the report could also be prepared.** The IFS PACsecure audit report shall be prepared according to the following format.

1 Reporting

1.1 Audit overview (Annex 1)

The first part of the audit report shall contain the following general information:

Audit details

The **cover page** of the audit report shall include:

- name and address of the certification body
- the logo of the certification body
- the certification body's accreditation details
- name of the audited company or site
- date of the audit.

These first pages shall give a summary of the most important audit report items and shall include:

- name and address of the audited site
- name and address of the company (if headquarters)
- EAN, UCC, Global Location Number (if available)
- COID, as defined in the IFS Portal
- audit date (in case of a follow-up audit the date of the follow-up audit shall additionally be defined)
- time of the audit

- previous audit date
- the name of the certification body and the auditor who performed the previous audit
- details of the version of the Standard
- audit scope (mandatory detailed descriptions of processes/products)
- numbers of product scopes
- list of key personnel present at audit **and, if applicable consultant present at audit** | added
- name of the lead auditor
- if applicable, additional name of the co-auditor
- if applicable, name of the auditor trainee
- **if applicable, name of the observer for this audit** | added
- **if applicable, name of the translator for this audit**
- result of the audit (in case of a follow-up audit, to specify that a follow-up audit has taken place and that the Major non-conformity has been solved)
- company profile: some compulsory general information about the company shall be provided, as follows:
 - The year of construction of the plant
 - The registration numbers of the company by authorities if available and/or existing (and GS1 number, if available)
 - The COID (IFS identification code number), in case of renewal audit
 - When the last investment was made in production, product oriented investments concerning quality and safety (construction changes, machines). Specify the kind of investment made in production area
 - The name and contact data (phone/fax/e-mail) of the contact person in case of emergency (e.g. withdrawal/recall)
 - Product groups and products per group produced in the company. **Also, indicate if products are food contact packaging materials and/or non-food contact packaging materials, according their intended use.** | added
 - Complete view of the company's processes
 - If the audited company also has trade products (already processed), specify the kinds products
 - How many employees are there, listed according to full-time and part-time workers (own employees, external companies), shift work

- The number and names of the sub-companies (sites) of the company (where are they situated, if they are IFS certified), precision about names and kinds of sub-contracted part(s) of the process
- The site area of the plant in square meters
- State if the company fulfils the requirements about use of IFS logo, as defined in IFS PACsecure audit protocol (Part 1)
- If the certification body has decided to decrease audit duration (see rules in chapter 5.3 of audit protocol), explanations about the reasons for decreasing
- If the site is certified according to other schemes, specify the schemes' names
- If there are seasonal breaks in production process, please specify time frame
- further explanations regarding scoring and frequency
- below the company profile: name of the person in charge of assessing the report (reviewer).

1.2 Audit report (Annex 2)

The audit report itself is structured as follows:

- the result of the audit with level and percentage
- observations on KO's and Majors (in case of a follow-up audit, additional explanation on which requirement the Major has been solved)
- general summary table for all chapters
- an overall summary of the audit (of all chapters)
- a list of all established deviations and non-conformities for each chapter (1 to 6)
- a description of follow-up of corrective actions from the previous audit
- a separate list (including explanations) of all requirements evaluated with N/A (not applicable)
- a detailed audit report.

1.3 Action plan (Annex 3)

The certification body/the auditor describes and explains all established deviations and non-conformities (KO's, Majors) in each chapter in the action plan, which has a specified format shown in the annex.

1.4 Minimum requirements for IFS PACsecure certificate (Annex 4)

After successful completion of the IFS PACsecure process, the certification body shall issue a certificate in English language. For the purposes of international recognition, and so as to be understandable, IFS PACsecure certificates awarded by the certification body shall include the following information at a minimum:

- the name and address of the certification body, including its logo
- the logo of the accreditation body or its name and registration number (requirement mentioned in the ISO/IEC Guide 65, G.12.7.); the logo of accreditation body shall be used in conformity with accreditation body's rules
- the name and address of the audited company
- the COID, as defined in the IFS Portal
- if the company is a subsidiary, the name of the company's headquarters
- audit scope (with mandatory detailed descriptions of processes/products) and including for instance trade products if applicable). If the list of the products is too long to be specified on the one page certificate, the list shall be specified in an annex and the IFS certificate shall make a reference to that annex.
- name and number of product scope(s)
- level achieved
- audit score in percentage, if required by the customer or by the audited company
- date of audit (last day of audit)
- date of follow-up audit if relevant
- next audit to be performed within the time period (renewal audit)
- certificate issue date
- certificate expiry date, i.e. 12 months after the date of issue the certificate (the certificate validity date shall remain the same each year as described in the audit protocol, Part 1 and Part 5 (for unannounced option).
- place and date of signature
- name and signature of the certification body's person(s) responsible for the certification decision as described in Part 3 of the Standard
- IFS PACsecure logo
- PACsecure logo
- **QR-code.**

| deleted

| deleted

| added

| added

Please note: The auditXpressX™ software includes a certificate format with the minimum required content, but each IFS ISO/IEC 17065 norm accredited certification body may use its own layout, providing that it includes these minimum requirements.

1.4.1 QR-code on the IFS certificate

1) QR-code on the IFS certificate via auditXpressX:

The QR-code will be implemented automatically when exporting the certificate via auditXpressX. The QR-code embodies a public link to the IFS Database which verifies the authenticity of the certificate. The link contains a key which verifies i.a. the date of issue of the certificate.

The color of the QR-code is, by default, the color of the Standard. Users may change the color and position of the QR-code by using the template.

2) QR-code manual upload into the IFS Database for auditXpressX non-users:

For certification bodies not using auditXpressX, the IFS Database will provide a separate page for the upload of the QR-Code into the IFS Database in order to generate a certificate. The QR-code can be created via "My Clients" by providing following data:

- a) COID
- b) Standard
- c) Date of issue of the certificate (important for the correlation in the IFS Database)
- d) Color: the color of the Standard is shown as a suggestion. The QR-code can alternatively be downloaded in black or in white.

3) Position on the IFS certificate

The QR-code should be either in the top right corner or centered on the bottom of the IFS certificate.

4) Verification of the certificate through the QR-code:

A security mechanism has been added to the QR-code verification, so that not too many QR-codes can be verified in a certain lapse of time from the same IP-address.

QR-code data:

The QR-code shows following data:

- The certificate is in the IFS Database: yes/no
- COID
- Name of the company
- Mailing address of the certified site
- GLN, if existent
- Name of the CB
- Standard
- Date of issue of the certificate
- Certificate valid until
- Certificate still valid (or, if so, locked)

added

2 auditXpressX™ Software

In order to increase the standardisation of IFS reporting, auditXpressX™ software has been developed. It offers the following advantages:

- easy collection of audit data through a user-friendly interface
- production of quick and error-free IFS audit reports
- automatic evaluation of the audit results by dynamic computation of all relevant items
- automatic generation of a standardised audit report
- temporary storage of interim audit data for later completion
- simple and secure export of completed audit reports to the IFS audit portal
- simple exchange of audit files between the auditors and their competent certification body
- offline working, i.e. no permanent Internet connection required
- an update option provides constant access to the most recent version of the IFS.

added

3 The IFS Audit Portal and the IFS Database (www.ifs-certification.com)

changed

Every IFS PACsecure audit shall be uploaded to the IFS Audit Portal by the certification body (uploading of report, action plan and certificate).

There are ~~3~~ **4** user groups which **can** have access to the IFS Database:

changed

- Certification bodies
- Certified companies
- Retailers and other users
- **Food safety authorities.**

added

The different groups' access rights are as follows:

Certification bodies:

- manage their certified companies and upload audit reports, action plans and certificates
- may suspend certificates in specific situations
- can manage all IFS PACsecure audit dates via the diary function, enabling retailers and companies to have a good overview of the scheduled audits. It is mandatory to upload in the diary function of the Audit Portal all audits dates, at latest 2 weeks before the audit.

- manage their accounts
- have the possibility to compare two consecutive audit reports and action plans, for internal auditor training and calibration purposes
- download the IFS logo(s).

Certified companies/suppliers:

- have access to their own audit data
- have the possibility to unlock retailers and other users for their achieved percentage, detailed audit report and action plan
- have the possibility to compare two consecutive audit reports and action plans, for improvement purposes
- download the IFS Logo(s)
- manage their certification bodies
- manage company personnel access (create sub-accounts) to the audit data
- search for other certified companies
- manage their suppliers using a “favourites” option **with “My Audits”**.

added

Access for the headquarters of certified companies

A “headquarter” access for certified companies can be set up which allows a company headquarter to administer all of their certified sites through a single access point.

Retailers and other users:

- search for certified companies
- manage their certified companies via a “favourites” option **with “My Audits”**
- ~~get information via e-mail in case of a certificate suspension of their favourite companies.~~

added

deleted

Food safety authorities

- **search for certified companies**
- **manage their certified companies via a “favourites” option with “My Audits”**.

added

The user manuals for the IFS Audit Portal are available on the respective secured area for each user group.

Security of the Database

The security system used for the database is based on international recognised and mostly used security systems. **Data protection is an important issue for the IFS Management GmbH. They fulfil all for the**

added

company applicable data protection regulation. The data policy of IFS Management GmbH is available on the website www.ifs-certification.com. ~~The retailer and certified companies access provide general information about all certified companies.~~ **The access provide general information about all certified companies.** If no further authorisation is granted by the certified companies both user groups will be able to see the following information only:

changed

- the company's name and address
- the certification body's name and address
- the auditor's name (including auditor scopes)
- the scope of the audit
- the date and duration of the audit
- the level achieved at the audit
- the IFS PACsecure certificate's date of issue and its validity.

By using their secure log-in access, the certified companies themselves can give the authorisation for access to the following detailed information:

- audit report and action plan.

~~The retailers and other users/certified companies~~ **user groups** automatically receive access to the unlocked data by the certified company after the data has been unlocked. Communication to retailers and other ~~users~~ **user groups** is via a secure Web process which guarantees that only authorised retailers and other users/certified companies can view specific data of the certified companies/suppliers.

changed

changed

Tool "My Audits"

The tool "My Audits" enables the different user groups to select their favourites from all certified companies which are listed in the IFS Database and to store them in a separate list.

For each certified company which is stored under "My Audits" as a favourite, the user can receive following notifications via e-mail:

- **Reminder 3 months before the expiration date of the certificate.**
- **The certificate is expired, and no valid certificate exists.**
- **A surveillance audit is recorded.**
- **If the certificate is withdrawn by the certification body before the expiration date.**
- **A certificate is edited.**
- **A new audit has not been entered until now. The current certificate expired 3 months ago.**

added

added

- Monthly e-mail of all new registered audits of the current month, of companies in the favourite list.
- Monthly e-mail about all audits which are expired of the current months.
- Receiving of the corrective action comparison per email to his favourites.
- A new audit date was scheduled for one of the companies in his favourites list.
- Receive e-mails in case suspensions of certificates have been decided by certification bodies based on non-conformities rated in Integrity on-site Checks
- Receive e-mails on IFS Global Markets status, if applicable
- Receiving e-mail if a company changes the responsible certification body.
- Receiving e-mail if the date of an audit in the diary was edited or deleted.
- Notification e-mail when two companies in IFS database were merged.

ANNEX 1

Cover page of the audit report

Logo of the certification body

**IFS PACsecure
Version 1.1**

Final Audit Report

Audited company: "Paper and Plastic Ltd"

Date of audit: 02. 12./03. 12. 2018

Name and address of certification body

Accreditation number of the certification body

| changed

First pages of the audit report

IFS PACsecure
Version 1.1, December 2017
Audit Overview

changed |

Audit details					
<i>Lead auditor:</i> Mr. Müller		<i>Date/time of current audit:</i> 02. 12. 2018 (09:00–18:00)		<i>Date/time of previous audit:</i> 07. 12. 2017 (09:00–18:00) 08. 12. 2017 (08:30–17:30)	
<i>Co-auditor:</i> Ms. Lehmann		<i>Date/time of current audit:</i> 03. 12. 2018 (08:30–17:30)		<i>CB and auditor of previous audit:</i> TEST GmbH/FrankTest	
<i>Trainee:</i> Mr. Schubert					
<i>Name and address of the company (or headquarter)</i> Perfect Packaging Example street 12345 Witzenhausen Germany			<i>Name and address of the audited site</i> Paper and Plastic Ltd Musterstraße 12346 Berlin Germany		
			<i>EAN Code/UCC Global Location Number COID</i>		
<i>Phone:</i> 0 12 34 56		<i>Fax:</i> 01 23 45 67 89		<i>Phone:</i> 0 12 34 57	
				<i>Fax:</i> 01 23 45 67 88	
Scope of audit					
Production of paper and PE foil Product scope(s): 1, 3					
Audit participants					
Name:	Position:	Opening meeting	Documentation review	Site assessment (Audit):	Closing meeting
Mr. Quality	Quality Manager	X	X	X	X
Mr. Manager	General Manager	X			X
Mr. Transport	Transport Manager	X		X	X
Final Result of Audit					
As a result of the audit performed on 02. 12. and 03. 12. 2018, "xyz" found that the processing activities of Paper and Plastic Ltd for the above-mentioned scope of production comply with the requirements set out in the IFS PACsecure, Version 1.1, at Foundation Level , with a score of XX%.					Next audit in 12 months
Company profile					
Compulsory information In case of reduction of audit duration, explanations of the reasons:					
<i>Reviewer:</i>					

Explanations regarding the audit report

Evaluation of requirements

Result	Explanation	Points
A	Full compliance	20 points
B (deviation)	Almost full compliance	15 points
KO requirement scored with a B	Almost full compliance	15 points
C (deviation)	Small part of the requirement has been implemented	5 points
D (deviation)	Requirement has not been implemented	-20 points

Major	When there is a substantial failure to meet the requirements of the Standard, which includes product safety and/or the legal requirements of the production and destination countries. A major can also be given when the identified non-conformity can lead to a serious health hazard. A major can be given to any requirement which is not defined as KO.	15% of the possible total amount of points is subtracted
KO requirement scored with a D	The KO requirement has not been implemented	50% of the possible total amount of points is subtracted

N/A	Not applicable Requirement not applicable for a company	N/A requirements will be excluded from the final scoring
------------	--	--

Scoring and awarding of certificates

Audit result	Status	Action company	Report form	Certificate
At least 1 KO scored with D	Not approved	Actions and new initial audit to be agreed upon	Report gives status	No
> 1 Major and/or < 75 % of the requirements are fulfilled	Not approved	Actions and new initial audit to be agreed upon	Report gives status	No
Max 1 Major and ≥ 75 % of the requirements are fulfilled	Not approved unless further actions taken and validated after follow-up audit	Send completed action plan within 2 weeks of receiving the preliminary report. Follow-up audit max. 6 months after the audit date	Report including action plan gives status	Certificate at foundation level, if the Major non-conformity is finally solved as controlled during the follow-up audit
Total score is ≥ 75 % and < 95 %	Approved at foundation IFS PACsecure level after receipt of the action plan	Send completed action plan within 2 weeks of receiving the preliminary report.	Report including action plan gives status	Yes, certificate at foundation level, 12 months validity
Total score is ≥ 95 %	Approved at higher IFS PACsecure level after receipt of the action plan	Send completed action plan within 2 weeks of receiving the preliminary report.	Report including action plan gives status	Yes, certificate at higher level, 12 months validity

ANNEX 2

IFS PACsecure Version 1.1, December 2017 Audit Report

Result:

The processing activities of company “Paper and Plastic Ltd” met the requirements of the IFS PACsecure, version 1.1.

The company passed with a score of XX% at:

Foundation (Higher) level
... %

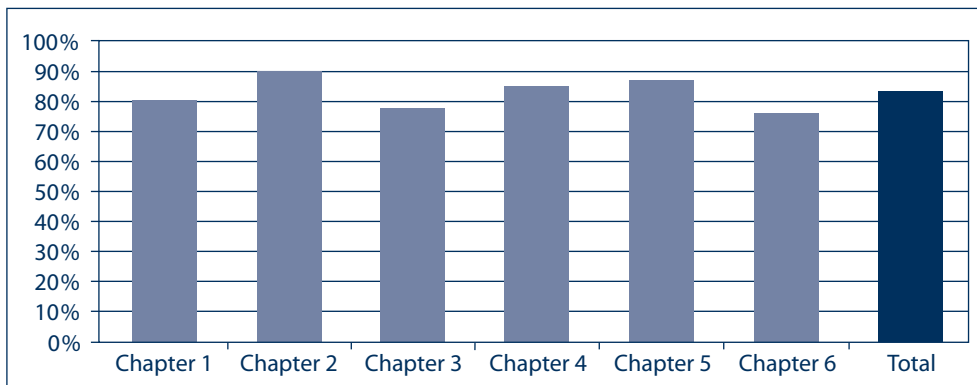
Date of renewal audit: between the XX/XX and the XX/XX.

Summary:

	Chapter 1	Chapter 2	Chapter 3	Chapter 4	Chapter 5	Chapter 6
	Senior management responsibility	Quality and packaging material safety management system	Resource management	Planning and production process	Measurements, analysis, improvements	Product defense plan and external inspections
KO	0	0	0	0	0	0
Majors	0	0	0	0	0	0
A	0	0	0	0	0	0
B	0	0	0	0	0	0
C	0	0	0	0	0	0
D	0	0	0	0	0	0
N/A	0	0	0	0	0	0

Observations regarding KO’s and Majors:

General summary table for all chapters:



Overall summary of the audit:

Description of follow-up of corrective actions from the previous audit:

Chapter 1: Senior management responsibility

Summary of all Chapter 1 deviations and non-conformities found:

N°	Reference	IFS requirements	Evaluation	Explanation
1.	1.1.1			
2.	1.1.2			

Report of the N/A evaluations

N°	Reference	IFS requirements	Evaluation	Explanation
1.				

Detailed audit report

N°	Reference	IFS requirements	Evaluation	Explanation
1.				
2.				

ANNEX 3

Action plan

Name and address of the audited company

The Corrective Action Plan must be returned to the certification body before: _____

Requirement number	IFS PACsecure requirement	Evaluation	Explanation (by the auditor)	Corrective action (by the company)	Responsibility/ Date/Status of implementation (by the company)	Release by the auditor

ANNEX 4

CERTIFICATE

Herewith the certification body

Name of the certification body

being an ~~ISO/IEC 17065~~ accredited certification body for IFS certification and having signed an agreement with the IFS owner, confirms that the processing activities of

Name of the audited company Address

COID
(Headquarter)

for the audit scope:
(detailed descriptions of processes/products ~~plus, if relevant, trade products~~)

Name and number of the product scope(s)

meet the requirements set out in the

IFS PACsecure Version 1.1, December 2017

at Foundation level/Higher Level

with a score of XX % (if required)

Certificate – register number: _____

Audit date: _____
(If relevant: date of follow-up audit)

Date of issue of certificate: _____

Certificate valid until: _____

Next audit to be performed within the time period: _____
(specify soonest and latest audit date, according to requirements of audit protocol, Part 1)

Date and place

Name and signature of
the responsible person
at the certification body

Address of the
certification body

Logo of the accreditation
body or its name and
registration number



Part 5: Audit protocol for unannounced audits

| added

0 Introduction

Due to increasing requirements of the market, the IFS Board and IFS International Technical Committee have made the decision to implement a process for performing unannounced audits against the IFS PACsecure Standard.

This document is an additional document to the IFS IFS PACsecure Standard and describes the protocol to perform unannounced audits.

The rules of this document apply from 1st April 2018, meaning that any audit scheduled after this date may be performed as an unannounced audit.

0.1 Unannounced audit protocol

Prior to scheduling and performing the audit, the company shall inform its certification body about the chosen option:

- IFS PACsecure announced audit (option “Announced”): the requirements defined in the current audit protocol of IFS PACsecure Standard apply.
- IFS PACsecure unannounced audit (option “Unannounced”): the information below describes the requirements which will apply. This option involves a full unannounced audit against the audit checklist of the IFS PACsecure requirements, which replaces the yearly scheduled audit. The audit date shall not be notified to the company in advance of the audit. This option is preferably aimed at renewal audits (i.e. for companies already IFS PACsecure certified), but may also apply for initial audits, if the company prefers starting directly with an unannounced audit.

For each renewal audit, the company shall inform its certification body about the chosen option.

1 Audit planning

1.1 Timeframe for registration for an unannounced audit

To get registered for an unannounced audit, the company shall notify its certification body at latest before the start of audit time window (see below). This applies both to companies keeping the same certification body and those changing certification body.

The registration date shall be stated in the contract between the certification body and the company.

Note: if the company does not inform the certification body before the start of audit time window, the option “Unannounced” cannot be chosen.

As the date of the audit shall not be made known to the company, the expected date shall not be communicated by the certification body in the diary function of the IFS audit portal.

The certification body shall tick the box “Unannounced audit” in the IFS audit portal. When the audit has been performed, the certification body shall provide the audit dates in the portal, at latest 2 working days after the first audit day. This will ensure that the portal users are informed that the audit has taken place and that the certification process is on-going.

1.2 Time window for performing the audit

The time in which the certification body shall perform the unannounced audit is [–16 weeks; +2 weeks] of the audit due date. The audit shall be performed during consecutive days.

Example:

Initial IFS PACsecure audit (announced): 1 November 2018

Renewal IFS PACsecure audit 1 (announced): 25 October 2019
(between 6 September 2019 and 15 November 2019, based on audit due date: 1 November, following IFS protocol for announced audits)

Renewal IFS PACsecure audit 2 (unannounced): between 12 July 2020 and 15 November 2020, based on audit due date 1 November, following IFS protocol for unannounced audits

Note: if the audit is scheduled by the certification body outside the defined time window, the audit will not be a valid IFS PACsecure unannounced audit and will be processed as an announced audit.

Blackout period:

When registering for an unannounced audit with its certification body, the company has the opportunity to identify maximum 10 operational days, plus not operating periods, when the site is not available for the audit.

These dates shall be notified to the certification body at the same time as the company is registered for the unannounced audit by its certification body and reasons shall be provided. Reasons may be challenged by the certification body or by the auditor during the audit.

Note: the company may only split the 10 operational days into a maximum of 3 periods (e.g. planned customer visit, holidays of Quality manager, etc.).

1.3 Other information to be provided by the company to its certification body

The company shall provide its certification body with the name(s) of the person(s) to be contacted on-site when entering the site the day of the unannounced audit, to facilitate the auditor entry.

As for an announced audit, the certification body may ask, before the start of the time window, for some company's documentation, in order to prepare the audit.

1.4 Audit scope

The same requirements as in the current IFS PACsecure Standard (part 1, chapter 4) apply to determine audit scope.

1.4.1 Specific audit process for multi-location companies with central management

If defined processes are centrally organized in a company with several production sites (e.g. purchasing, personnel management, complaint management, etc.):

- The central managing site—headquarters—shall be audited announced or unannounced. The audit shall always take place before the audit of each production site and shall be performed before the start of the unannounced audit time window of the production site audits.
- The production sites shall be audited unannounced.
- The audit of headquarters (announced or unannounced) and the unannounced audit of the production site(s) shall not be performed during consecutive days (e.g. if the headquarter is

located within one of the production sites, there shall be 2 different audits: an announced or unannounced audit for the centrally organized processes and an unannounced audit for the production site.)

- All audits, including headquarters', shall be performed within a maximum timeframe of 1 year.

1.5 Audit duration

The same requirements as in the current IFS PACsecure Standard (part 1, chapter 5.3) apply to calculate audit duration.

1.6 Audit time schedule

As it is not relevant to send an audit time schedule for an unannounced audit in advance, the auditor shall present, on the day of audit, a provisional audit time schedule, which may have to be adapted during the audit.

2 Preparation of the audit

Before being audited, the company shall review all requirements of the IFS PACsecure Standard in detail and, if existing, IFS doctrine and erratum. On the day of the audit, the current version of the Standard shall be available at the site being audited. The company is responsible for acquiring the current version of the Standard.

If the audit is not an initial audit, and if the company has changed certification body, the company shall also inform the certification body, so that the auditor can check the corrective action plan from the previous audit (the certification body shall anticipate the report release by the company).

3 On-site audit performance

3.1 Start of the unannounced audit

The company should prepare a minimum set of documents to be provided to the auditor.

When entering the company, the auditor will ask to meet the person(s) whose names were provided by the company at the time of registration.

Note: If company denies access to the auditor (apart from “force majeure”), the currently valid IFS certificate shall be suspended by the certification body, within a maximum of 2 working days after the audit date (notification will be received by customers having placed the company in their favorites’ list in the audit portal) and this information will be visible in the company history in the audit portal. The company shall be invoiced by the certification body for the total cost of the audit. Moreover, the next audit can only be scheduled announced and shall preferably be performed by the same certification body.

After arrival and introduction, the auditor may briefly review the documents prepared by the company and shall immediately start the audit on the location (production area). The opening meeting and documentation audit shall be undertaken later during the audit.

As for announced audits, it is not possible to include in the scope of the IFS PACsecure certification products scope and processes which are not operating during the audit, unless those production lines involve the same HACCP study (or risk assessments), the same products scope and processes as the lines, which are audited when operating.

If, during the unannounced audit, some lines are not operating and involve different HACCP plans (or risk assessments), product scopes and processes, an additional audit of the lines, when operating, is mandatory. When performing the audit, two options are possible:

- If it is possible, the auditor can ask the company to run the production line(s) later during the first audit day or the following audit day(s), so that the line(s) is/are assessed later during the unannounced audit.
- If it is not possible for the company to start the production line(s) during the audit, the auditor shall come back to audit the line(s) when operating, during an extension audit (if the company wants to include these products into the audit scope and/or an exclusion is not possible). The extension audit shall be performed announced.

3.2 Evaluation of requirements

The same requirements as in the current IFS PACsecure Standard (part 1, chapter 5.5) apply for the evaluation of requirements

4 Audit report

The same requirements as in the current IFS PACsecure Standard (part 1, chapter 5.7) apply to the IFS audit report.

The option “Unannounced” will be clearly stated in the audit report.

5 Conditions for issuing audit report and certificate

The same requirements as in the current IFS PACsecure Standard (part 1, chapter 5.8) apply for issuing the certificate.

The option “Unannounced” will be clearly stated on the IFS certificate.

6 Awarding the certificate

The same requirements as in the current IFS PACsecure standard (part 1, chapter 6) apply for issuing the certificate.

The certificate validity date remains the same each year and is determined by the date of the initial audit.

Example:

Initial IFS PACsecure audit (announced): 1 November 2018

Certificate valid until: 26 December 2019

Renewal IFS PACsecure audit 1 (announced): 25 October 2019
(between 6 September 2019 and 15 November 2019, based on audit due date: 1 November)

Certificate valid until: 26 December 2020

Renewal IFS PACsecure audit 2 (unannounced): between 12 July 2020 and 15 November 2020, based on audit due date 1 November

Certificate valid until: 26 December 2021

Note: if a company would like to include new product(s) in the scope of the certificate whereas the audit has already been performed, the same rules as described in Part 1, chapter 3 & 4 apply.

7 Further requirements from the current IFS PACsecure Standard applying to the unannounced audit protocol

All requirements from the Parts 1, 2, 3 and 4 which are not detailed in this Part of the Standard apply to the unannounced audit protocol.

ANNEX 1

Cover page of the audit report

Unannounced audit

Logo of the certification body

**IFS PACsecure
Version 1.1, December 2017**

Final Audit Report

Audited company: "Paper and Plastic Ltd"

Date of audit: 02./03.12.2018

Name and address of certification body
Accreditation number of the certification body

First pages of the audit report

IFS PACsecure Version 1.1, December 2017 Unannounced audit overview					
Audit details					
<i>Lead auditor:</i> Mr. Müller <i>Co-auditor:</i> Ms. Lehmann <i>Trainee:</i> Mr. Schubert		<i>Date/time of current audit:</i> 02.12.2018 (09:00–18:00) 03.12.2018 (08:30–17:30)		<i>Date/time of previous audit:</i> 07.12.2017 (09:00–18:00) 08.12.2017 (08:30–17:30) <i>CB and auditor of previous audit:</i> TEST GmbH/Frank Test	
<i>Name and address of the company (or headquarter)</i> Perfect Packaging Example street 12345 Witzenhausen Germany			<i>Name and address of the audited site</i> Paper and Plastic Ltd Musterstraße 12346 Berlin Germany		
			<i>EAN Code/UCC Global Location Number COID</i>		
Phone: 0 12 34 56		Fax: 01 23 45 67 89		Phone: 0 12 34 57	
				Fax: 01 23 45 67 88	
Scope of audit					
Production of paper and PE foil					
Product scope(s): 1, 3					
Audit participants					
Name:	Position:	Opening meeting	Documentation review	Site assessment (Audit):	Closing meeting
Mr. Quality	Quality Manager	X	X	X	X
Mr. Manager	General Manager	X			X
Mr. Transport	Transport Department	X		X	X
Final Result of Audit					
As a result of the audit performed on 02.12.2018 and 03.12.2018, "xyz" found that the processing activities of Paper and Plastic Ltd for the above-mentioned scope of production comply with the requirements set out in the IFS PACsecure, Version 1.1, at Foundation Level , with a score of XX%.					Next audit between XX.XX and XX.XX OR unannounced
Company profile					
Compulsory information In case of reduction of audit duration, explanations of the reasons:					
<i>Reviewer:</i>					

Explanations regarding the audit report

Evaluation of requirements

Result	Explanation	Points
A	Full compliance	20 points
B (deviation)	Almost full compliance	15 points
KO requirement scored with a B	Almost full compliance	15 points
C (deviation)	Small part of the requirement has been implemented	5 points
D (deviation)	Requirement has not been implemented	-20 points

Major	When there is a substantial failure to meet the requirements of the Standard, which includes food safety and/or the legal requirements of the production and destination countries. A major can also be given when the identified non-conformity can lead to a serious health hazard. A major can be given to any requirement which is not defined as KO.	15% of the possible total amount of points is subtracted
KO requirement scored with a D	The KO requirement has not been implemented	50% of the possible total amount of points is subtracted

N/A	Not applicable Requirement not applicable for a company	N/A requirements will be excluded from the final scoring
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Scoring and awarding of certificates

Audit result	Status	Action company	Report form	Certificate
At least 1 KO scored with D	Not approved	Actions and new initial audit to be agreed upon	Report gives status	No
> 1 Major and/or total score < 75%	Not approved	Actions and new initial audit to be agreed upon	Report gives status	No
Max 1 Major and total score ≥ 75%	Not approved unless further actions taken and validated after follow-up audit	Send completed action plan within 2 weeks of receiving the preliminarily report. Follow-up audit max. 6 months after the audit date	Report including action plan gives status	Certificate at foundation level, if the Major non-conformity is finally solved as controlled during the follow-up audit
Total score is ≥ 75% and < 95%	Approved at foundation IFS PACsecure level after receipt of the action plan	Send completed action plan within 2 weeks of receiving the preliminarily report.	Report including action plan gives status	Yes, certificate at foundation level, 12 months validity
Total score is ≥ 95%	Approved at higher IFS PACsecure level after receipt of the action plan	Send completed action plan within 2 weeks of receiving the preliminarily report.	Report including action plan gives status	Yes, certificate at higher level, 12 months validity

ANNEX 2

IFS PACsecure Version 1.1, December 2017

Unannounced audit report

Result:

The processing activities of company "Paper and Plastic Ltd" met the requirements of the IFS PACsecure, version 1.1, December 2017

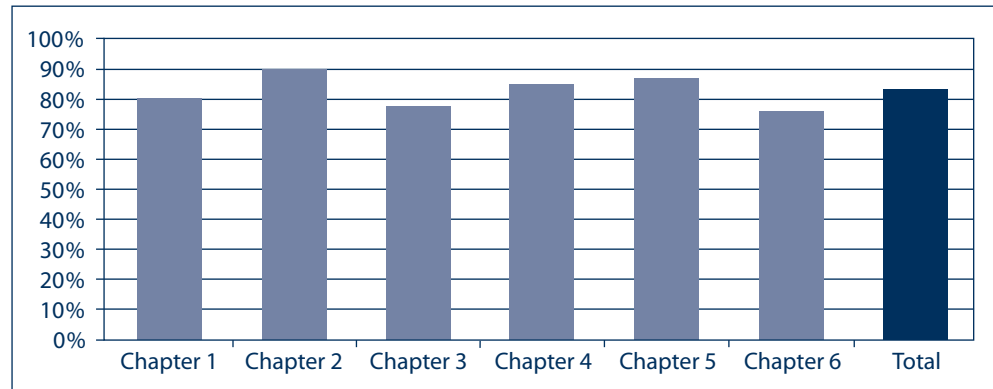
The company passed with a score of XX% at:

Foundation (Higher) level
... %

Date of renewal audit: between the XX/XX and the XX/XX or unannounced audit.

Summary:

	Chapter 1	Chapter 2	Chapter 3	Chapter 4	Chapter 5	Chapter 6
	Senior management responsibility	Quality and packaging material safety management system	Resource management	Planning and production process	Measurements, analyses, improvements	Product defense plan and external inspections
KO	0	0	0	0	0	0
Majors	0	0	0	0	0	0
A	0	0	0	0	0	0
B	0	0	0	0	0	0
C	0	0	0	0	0	0
D	0	0	0	0	0	0
N/A	0	0	0	0	0	0

Observations regarding KO's and Majors:**General summary table for all chapters:****Overall summary of the audit:****Description of follow-up of corrective actions from the previous audit:****Chapter 1: Senior management responsibility****Summary of all Chapter 1 deviations and non-conformities found:**

N°	Reference	IFS requirements	Evaluation	Explanation
1.	1.1.1			
2.	1.1.2			

Report of the N/A evaluations

N°	Reference	IFS requirements	Evaluation	Explanation
1.				

Detailed audit report

N°	Reference	IFS requirements	Evaluation	Explanation
1.				
2.				

ANNEX 3

Unannounced audit

Action plan

Name and address of the audited company

The Corrective Action Plan must be returned to the certification body before: _____

Requirement number	IFS PACsecure requirement	Evaluation	Explanation (by the auditor)	Corrective action (by the company)	Responsibility/ Date/Status of implementation (by the company)	Release by the auditor

ANNEX 4

UNANNOUNCED AUDIT CERTIFICATE

Herewith the certification body

Name of the certification body

being an accredited certification body for IFS certification
and having signed an agreement with the IFS owner,
confirms that the processing activities of

Name of the audited company Address

COID
(Headquarter)

for the audit scope:
(detailed descriptions of processes/products)

Number and name of the product scope(s)

meet the requirements set out in the

**IFS PACsecure
Version 1.1, December 2017**

at Foundation level/Higher Level

with a score of XX% (if required)

Certificate – register number: _____

Audit date: _____
(If relevant: date of follow-up audit)

Date of issue of certificate: _____

Certificate valid until: _____

Next audit to be performed within the time period: _____
(specify if unannounced or announced, according to requirements of related audit protocol)

Date and place

Name and signature of the responsible
person at the certification body

Address of the certification body

Logo of the accreditation
body or its name and
registration number

