IFS PACsecure

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Standard for assessing product and process compliance in relation to the safety and quality of packaging material

VERSION 2

JULY 2021

ENGLISH

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Acknowledgements

IFS would like to thank all participants who responded to the stakeholder consultation carried out in 2021. Your input and opinions were a big support to IFS for the improvement of the IFS PACsecure Standard. We appreciate the time you have taken to positively respond to it.
IFS is grateful to the members of the IFS PACsecure Technical Working Group, IFS National Working Groups and the IFS International Technical Committee.

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As part of the review process of the IFS PACsecure Standard, test assessment have been also performed for version 2. We would like to thank the following companies for their involvement

- 1st Solution CTC GmbH, Germany
- DQS CFS, Chile
- Alfons haaf polyäthylen-werk, Germany
- Faret S.A, Chile

In case of any queries regarding the interpretation of IFS Standards and Programmes, please contact standardmanagement@ifs-certification.com

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0 Introduction

0.1 History of the International Featured Standards

In 2003, the German retail federation – Handelsverband Deutschland (HDE) – and its French counterpart – Fédération des Entreprises du Commerce et de la Distribution (FCD), drew up a common food safety and quality standard to enable the assessment of food suppliers. The assessment provided a uniform approach towards food suppliers. This was the first variant of the IFS Food Standard, designated to certify suppliers producing private label food products for retail.

IFS Management GmbH stands for International Featured Standards and is a company owned by FCD and HDE. It encompasses a package of global safety and quality standards and programs that provide transparency and comparability along the entire post-farm supply chain. IFS Standards are applicable to a variety of operations and activities in the food and non-food sector. All IFS Standards follow a risk-based approach, which gives users the flexibility to implement the requirements into their business based on the specific risks in regard to the products and processes.

Based on the IFS experience, the IFS PACsecure Standard is one of the IFS Standard family covering another part of the supply chain.

0.2 IFS Objectives, mission and vision

The aim of IFS Certification is to assess whether the processes of a manufacturer are able to produce products that are safe, legal and in compliance with customer specifications. That is why both product safety and quality are essential components of all IFS Standards. The IFS Assessment is product and process focussed and ensures that the development of high-quality products is assured through correspondingly functioning processes.

IFS Standards are uniform global safety and quality standards that provide transparency and comparability along the entire post-farm supply chain. In this way, IFS strives to meet all the challenges of globalisation, in addition to the constantly growing significance of the private labels the retailers are responsible for. An IFS Certification enables the reduction of costs of long repetitive audits and additionally supports company management by means of uniform reports and a modern, user-friendly database.

The mission of IFS clearly states that IFS Standards go beyond product safety with the aim to "deliver trusted products", which fulfil the expectations of the buying company. With the objective that an IFS Certificate demonstrates that the company has implemented a functional product safety and quality management system, IFS together with its huge network is continuously increasing and optimising its portfolio of standards, assessment protocols and supporting tools and documents. Therefore, IFS has defined "Providing trusted standards and services to cooperate within the supply chain to improve product integrity" as its goal for today and for the future. Continuous improvement is not only the objective of certified companies; it is also applicable to IFS.

0.3 About the IFS PACsecure Standard

The packaging materials are used to contain, protect, preserve, inform / identify and / or manipulate products along the supply chain. In addition, there are certain packaging components and/ or packaging materials with specific and relevant functions such as extending the useful life and / or improving the condition of the products, monitoring the condition of the packaged products, among others. As a consequence, the packaging materials have an impact on product integrity, whether they are used as part of the consumer unit, or as a mean to handle the product across the supply chain.

Due to the impact of packaging materials in the delivering of trusted products, the IFS and its stakeholders determined the need to develop a standard to ensure packaging materials comply with safety, quality and legal requirements according to their intended use on products.

The aim of this IFS Standard is to assess the quality and safety of packaging materials and the compliance with customer requirements. It is also is intended to be used as a tool to support businesses to meet new requirements on quality, transparency and efficiency, and to improve product integrity along the entire supply chain.

The first version of the IFS PACsecure Standard was developed on October 2012, as result of the joint effort of IFS, PAC Packaging Consortium (former the Packaging Association of Canada) and the technical working group consisting of leading food and packaging companies in North America. The later versions of the standard are now managed by a joint effort of the PAC Packaging Consortium through their technical expertise and know-how in the packaging industry, the IFS and its global network.

The IFS PACsecure Standard is recognised internationally by the Global Food Safety Initiative (GFSI). It is built upon general aspects of a product safety and quality management system. However, the main emphasis is to instil confidence in the products and processes, meaning that safety, quality, legality and compliance with specified customer requirements are ensured via an on-site evaluation and documentation review and inspection.

The IFS PACsecure Standard version 2 has been revised by the following international working groups: PACsecure Technical Working Group, National Working Groups, International Technical Committee and the IFS Technical Team Working Group. Representatives of retailers, food service, packaging industry, food industry, consultants, certification bodies, packaging experts and PAC Packaging Consortium were part of these outstanding working groups that combined input from Europe, North and South America and Asia.

It will be possible to perform IFS PACsecure version 2 Assessments from 3rd of January 2022. From 3rd of May 2022, IFS PACsecure version 2 will be mandatory.

0.4 Coverage of the IFS PACsecure Standard

The IFS PACsecure is applicable for the production, processing and / or conversion of packaging components and / or packaging materials, intended to be used as primary or secondary packaging.

For more details on the IFS Assessment scope, see chapter 2.2, Part 1.

For clarification of the scope determination between IFS PACsecure and other IFS Standards, see ANNEX 1.

0.5 Content of the IFS PACsecure Standard

The content of the IFS PACsecure Standard is laid out as follows:.

Part 1 – IFS PACsecure Certification protocol

Part 2 – List of IFS PACsecure Assessment requirements

Part 3 – Requirements for accreditation bodies, certification bodies and auditors.

Part 4 – Reporting, auditXpressX™ software and IFS Database.

The IFS PACsecure Standard is accompanied by another normative document, the IFS PACsecure Doctrine. The IFS PACsecure Doctrine provides additional rules and clarifications on the interpretation of some IFS PACsecure requirements. Both normative documents shall be implemented following the defined date of implementation after publication. Each IFS Database user will receive notifications via the IFS Database in case of any new publication, review, applicability and / or amendments of current and potential new normative documents.

0.6 Review of the IFS PACsecure Standard

The IFS Technical Team and its working groups need to demonstrate control over the content and quality of the IFS PACsecure Standard and review it annually, to ensure its compliance with their requirements. The working groups are composed of all participants involved in the assessment process: the representatives of retailers, packaging industry, food industry, food service, consultants, certification bodies, packaging experts and PAC Packaging Consortium. The objective of the working groups is to share experiences, discuss and decide on changes or alignments to the IFS PACsecure Standard, the requirements of the assessment report and training needs.

PART 1
IFS PACsecure Certification protocol

0 Purpose and content

This part provides a detailed description of procedures to be followed before, during and after an IFS PACsecure Assessment. Moreover, it explains the principles of the IFS PACsecure Certification process, including requirements to be applied by assessed companies and certification bodies.

1 The IFS PACsecure Certification process

Companies are required to prepare well in advance for an IFS PACsecure Certification, which comprises of the different steps that are displayed in ANNEX 2.

The IFS Assessment is a crucial part of the certification process, as the company and its production processes will be challenged against all specified requirements laid down in Part 2, in order to assess whether the products and production processes comply.

As an IFS Certification is a product and process certification, an IFS Assessment is always focussed on the following fundamental points:

a. Product and process based approach

The product and process approach includes the assessment of compliance with customer related specification(s) and the legal compliance of the products, depending on the country of production and the country of destination.
IFS PACsecure Assessment is always specific to one production site. All products and processes of the relevant production site shall be included in the scope of the assessment.
During the IFS PACsecure Assessment, the auditor shall collect objective evidence to evaluate the compliance of the products and the operating processes with the assessment requirements (see Part 2).
The main characteristic of the IFS PACsecure Assessment includes:

- **Product sampling:** One of the key elements for conducting the IFS PACsecure Assessment is to follow an assessment trail which emphasises the collection of evidence to assess product(s) and related operating processes through selected samples. The selection of samples shall be risk based but can also follow another criteria. The aim is to make a representative selection of all products and processes included in the certification scope to gain maximum information about the production site and its products.
  The use of relevant product samples is a vital element and allows the IFS Auditor to follow a uniform path by conducting an on-site evaluation and documentation and a record review and inspection, to obtain all necessary evidence. In addition, auditors shall perform a traceability test on the sampled product(s) during the assessment.

Note: IFS has published guidelines (e.g. IFS Good Assessment Practices (GAP) guideline), which provide further information on topics to be checked and / or requested from the assessed company during the IFS PACsecure Assessment.

- **Overall on-site evaluation:** At least 50 % of the total IFS Assessment duration shall be allocated to the on-site evaluation (within the production areas of the physical site) in order to allow the auditor sufficient time to comprehensively audit and inspect the products and the processes. For further information, see the IFS PACsecure Doctrine.

  The on-site evaluation of the production site shall include (but may not be limited to) the following areas and / or activities:

  - Production / conversion processes
  - Receipt, storage and dispatch areas
  - Good Manufacturing Practices (GMP)
  - Product development
  - On-site laboratory facilities, if exists
  - Maintenance facilities, if exists
  - Staff and sanitary facilities
  - External areas.

- **Operating process evaluation:** Whilst observing and following running production lines, the IFS Auditor shall execute, as minimum, the following activities:

  - Collect information on key process parameters, such as critical control points (if existing), control measures, as well as their monitoring in order to cross-check them with the hazard analysis and risk assessment system information
  - Observe and interview employees
  - Inspect the products and processes characteristics
  - Take samples for cross-checking
  - Review formulas / configurations used during the production / conversion process
  - Observe actual finished product dispatch or raw material delivery
  - Assess the implemented product safety and quality management system in practice.

- **Documentation and record review and inspection:** The on-site evaluation is followed by a comprehensive documentation and record / review, including cross-checking of related documents. This part of the assessment aims at verifying the information collected from the on-site evaluation and the evaluation of further requirements.

The above-mentioned activities are important parts of the assessment trail, in which auditing and inspection techniques are applied alternately by the auditor, in order to evaluate the production site's compliance in depth.

b. Auditor qualification

The IFS Auditor's specific expertise is the crucial basis for the assessment of the production site. Having IFS Auditors approved for specific product scope(s) is vital to guarantee a high degree of quality and reproducibility of the assessment findings. For more information, see Part 3.

c. Annual certification cycle

The production site will go through a full IFS PACsecure Certification process including a comprehensive IFS PACsecure Assessment every year. This includes the assessment of the full IFS PACsecure checklist (Part 2) and the verification of corrective actions from the last IFS Assessment, if applicable. Detailed information about the certification cycle is explained in chapter 4.3, part 1.

d. Certification by certification bodies accredited to the ISO / IEC 17065:2012 norm

Reliability of the certification is guaranteed through accredited, internationally recognised, independent, third-party certification bodies. In addition to the accreditation, the certification bodies shall have signed a contract with IFS Management GmbH and shall follow specific rules described in part 3 of the IFS PACsecure Standard.

e. Surveillance and harmonised rules by the IFS Standard owner

As part of the Quality Assurance activities, IFS has implemented procedures for the surveillance of the performance of IFS approved certification bodies, IFS Auditors and IFS certified companies: the IFS Integrity Program ensures the quality and integrity of the implementation of IFS Standards. The different measures are undertaken following a risk-based approach as well as the management of complaints which have been raised by stakeholders. The company shall be informed by its certification body about the procedures and rules of the IFS Integrity Program. Detailed information about the Integrity Program is explained in chapter 5, part 1.

2 Before the IFS PACsecure Assessment

Before starting the certification process, the company shall read the current versions of the two (2) normative documents: the IFS PACsecure Standard and the IFS PACsecure Doctrine.

In order to prepare the initial assessment, the company may perform a voluntary pre-assessment to evaluate its current status and level. The pre-assessment cannot include any recommendations and a different auditor shall perform the pre-assessment to the one who performs the subsequent IFS Assessment.

2.1 Making a contract with a certification body

In order to undertake an IFS PACsecure Assessment, the company shall appoint an IFS approved certification body, accredited to the ISO / IEC 17065:2012 norm for the IFS PACsecure Standard. The list of all IFS international certification bodies that have a valid contract with IFS is available by country on the IFS Website (www.ifs-certification.com).

Making a contract with a certification body is an important step, therefore the company shall ensure that the following items are addressed:

a. Contract

A contract shall exist between the company and the certification body, detailing the scope of the assessment, the duration and the report details. It shall also contain the mandatory notification from the company of changes that may affect their ability to conform to the certification requirements.

The assessment scope shall be agreed between both parties before the assessment takes place. Detailed information about the assessment scope is explained in chapter 2.2, part 1 and ANNEX 3.
The contract shall make a clear reference to the IFS Integrity Program and shall also mention that information about the company and its employees is stored in the IFS Database in line with the General Data Protection Regulation. Detailed information about the Integrity Program is explained in chapter 5, part 1.

b. Communication with the certification body concerning the detailed activities / processes of the production site

To assist the IFS PACsecure Auditor in preparing for the assessment, the company shall clearly inform the certification body of the following topics:

- All products on-site and related processes covered by the scope of the IFS PACsecure Assessment, including decentralised structures.
- Partly outsourced process(es), fully outsourced product(s), and traded product(s), if existing.
- Overview of exported products, including the different destination countries the products are sold to.
- Under exceptional circumstances, any request for exclusion of products. This will be carefully verified by the certification body in order to review if the exclusion is possible.
- Evaluation of the history of certification status of IFS or any other GFSI recognised standards, for example type of certification, assessment scope, last unannounced assessment, if a certificate has been suspended in the past, etc.

For additional information about outsourced processes and exclusions, see chapter 2.2.1, Part 1 and ANNEX 4.

c. Notifications to the certification body

During the certification cycle, the senior management shall ensure that the certification body is informed about any changes that may affect their ability to conform to the certification requirements (e.g. recall, alert on products, organisation and management, modification to the products or the production method, contact address and production sites, new address of the production site etc.). The details shall be defined and agreed between both parties.
As required in Part 2, chapter 1, requirement 1.2.6: In case of any changes that may affect the company's ability to conform to the certification requirements (changes in legal entity name and / or production site location, product recall(s) and / or withdrawal(s) by official order for product safety and / or product fraud reasons and / or any visit from health authorities which results in notifications and / or penalties issued by authorities) the certification body shall be informed within three (3) working days.

d. Language of the assessment

The IFS PACsecure Assessment shall be carried out in the working language of the production site. If there is a need for translation (for limited defined situations), the certification body shall provide an interpreter not affiliated with the company. For further information about the usage of an interpreter, see the IFS PACsecure Doctrine.

2.2 Scope of the IFS PACsecure Assessment

IFS PACsecure is applicable for the production, processing and / or conversion of packaging components and / or packaging materials, intended to be used as primary or secondary packaging for:

- food products,
- cosmetics and personal hygiene products,
- household products,

and in general, for any product which is under the scopes of the IFS Standards.

Note: The IFS PACsecure is also applicable for packaging materials intended to be used only as secondary packaging in the following products:

- Medical devices "class I" that are not sterilised, coated and / or medical impregned.
- Over-the-counter drugs / pharmaceutical products.

In both cases, this applies only for products that can be sold to final users / consumers without any prescription, or pharmacist / health professional consultation.

The standard can only be used when packaging components and / or packaging materials are produced, processed, converted and / or printed by the company. For clarification of the scope determination between IFS PACsecure and other IFS Standards, see ANNEX 1.

Certification is always site-specific in relation to the actual processes of the site and cannot be applied to different sites or locations under one certification.

The IFS PACsecure product scopes (from 1 to 7) shall be used to determine the assessment scope and shall be included on the IFS PACsecure Certificate and in the IFS PACsecure Assessment Report. The IFS PACsecure products scopes are laid down in ANNEX 3.

The scope of the assessment shall:

- Include the full activities of the company, including all production / conversion processes and products manufactured by the production site.
- Provide a clear and unambiguous description of all process(es) / product(s) manufactured by the production site and covered by the IFS PACsecure Certification.
- Exclude words like sales, storage, transport, distribution, R & D, development / design, etc., as these topics are always evaluated within the IFS PACsecure Assessment in case the site performs them.
- The word "labelling" should be written in the scope in case it is essential to describe the processes of the company (e.g. only relevant processing step of the company).
- Detail the different types of products. General explanations e.g. "production of glass" is not allowed, as this does not provide sufficient information.
- Include information about the intended use of products (primary and / or secondary packaging materials).
- Be clearly and unambiguously stated in the assessment report and on the certificate.

- Exclude references to product certifications, claims or labels that are under specific regulations (e.g. Organic, FSC, BPA free, among others) in order to avoid confusion on the scope of the IFS PACsecure Assessment and certification.
- Exclude brand information, as it does not provide a detailed description of the product category. It can only be mentioned in the company profile of the IFS Assessment Report.

The agreed scope shall be mentioned by the auditor and agreed upon during the opening meeting of the IFS PACsecure Assessment.

The assessment shall be specific to the production site where all the processing / conversion of the product(s) is undertaken. Where decentralised structures exist and the assessment of a certain location is insufficient for gaining a complete overview of the company's processes, then all other relevant facilities shall also be included in the assessment. Full details shall be documented within the assessment report. For more information about different types of production sites and which information to give in the assessment report and certificate, see the chapter 2.2.2, Part 1.

The exclusion of production process(es), including storage and transport, is not allowed.

Exclusion of product(s) is in general not allowed but may be accepted under specific conditions. The applicable rules that shall be followed and fulfilled for these specific conditions are detailed in ANNEX 4.

2.2.1 Outsourced processes and IFS PACsecure Assessment scope

Specific rules for the management of partly outsourced processes, fully outsourced products and traded products shall be followed.

a. Partly outsourced process

A partly outsourced process is defined in the IFS PACsecure Standard as a production step or part(s) of production / conversion process (including wrapping and labelling) that is carried out off-site by a third-party on behalf of the IFS PACsecure certified production site. This also includes processes which are partly outsourced by a sister company within the same company group.

When the assessed site has outsourced part(s) of the production / conversion process, control over such processes shall be ensured in order not to compromise product safety, legality, quality and authenticity. The auditor shall evaluate whether these are controlled.

The requirements applicable for the management of partly outsourced process(es) are described in Part 2 (requirements 4.4.6, 4.4.7 and 4.4.8). In addition, the following rules apply:

- In the assessment report of the assessed site (assessment overview): a detailed description of the partly outsourced processes and related certification status of the appointed third-party shall be provided. If the appointed third-party is IFS PACsecure certified, their COID (IFS identification code number) shall also be mentioned.
- The following sentence shall be added to the certificate of the assessed site in the assessment scope, beneath the description of products and processes: **"Besides own production, the company has partly outsourced processes"**.
- Storage and / or transport activities carried out by a third-party are not considered as partly outsourced processes and shall be evaluated according to the relevant chapters of the IFS PACsecure checklist (4.14 and 4.15), especially to the requirements 4.14.5 and 4.15.6.

- Rules regarding partly outsourced processes apply to both customer branded products and the company's own branded products.
- If the requirements for partly outsourced processes are not fulfilled, this may lead to a deviation or a non-conformity for the IFS PACsecure assessed production site.

b. Fully outsourced product

A fully outsourced product is a product manufactured, wrapped and labelled under the own company brand or customer brand by a different company than the assessed one. The following rules apply in regard to these kinds of products:

- These products shall not be included in the certification scope, as they are out of the IFS PACsecure Certification scope.
- The description of the certification status from the manufacturer of the fully outsourced products shall be added to the certificate and in the company profile section of the assessment report.
- The following sentence shall be added to the certificate of the assessed site in the assessment scope, beneath the description of products and processes: **"The company has own broker activities which are/are not IFS Broker certified"**

c. Traded product

A traded product is a product manufactured, wrapped and labelled by and under a different company name to the company being IFS PACsecure certified. The following rules apply in regard to these kinds of products:

- These products shall not be included in the certification scope, as they are out of the IFS PACsecure Certification scope.
- The description of the certification status from the manufacturer of the traded products shall be added to the certificate and in the company profile section of the assessment report
- The following sentence shall be added to the certificate of the assessed site in the assessment scope, beneath the description of products and processes: **"The company has own broker activities which are/are not IFS Broker certified".**

2.2.2 Realisation of the IFS PACsecure Assessment in the case of different types of production sites

The IFS Assessment is production site specific, which means that one production site is subject to one assessment and one certificate.

IFS has defined the following four (4) types of production sites:

1. **Single production site**
2. **Multi-location production sites**
3. **Multi-legal entity production site**
4. **Production site with decentralised structure(s).**

The management of COID, assessment, report and certificate issuing for each type of production site is explained in the following.

1. Single production site

A single production site is a production site which fulfils the following conditions:

- It is not centrally managed by a head office / central management
- It has only one legal entity
- It has no decentralised structure(s).

This type of sites shall have one COID, one assessment, one certificate and one report.

2. Multi-location production sites

A multi-location production sites refer to a company with multiple production sites at different locations, which may have a head office / central management.
A multi-location production site can individually choose to be certified as part of multi-location production sites, as a single production site or not to be certified.
In the case of multi-location production sites with or without head office / central management, the following rules apply:

a) Company with head office / central management

a[1] If the head office / central management has processing activities, it shall be assessed and subjected to an own IFS PACsecure Certificate and assessment report.
If the head office / central management does not have processing activities but is assessed, it cannot be subjected to an own IFS PACsecure Certificate and assessment report.
In both cases described above, the following rules apply:

- All COIDs of the production sites shall be linked to the head office / central management.
- The assessment of the head office / central management shall always take place before the assessment of each production site.
- Each site shall be assessed separately, within a maximum period of 12 months from the head office / central management assessment.
- All Assessments shall be performed under the responsibility of one certification body.
- All KO requirements shall be assessed at all production sites, even if some of them are (partly) managed at the head office / central management.
- Each site shall get an individual certificate and report.
- If a non-conformity has been raised during the assessment of the head office / central management, all assessed production sites are also affected, and the certificates of these production sites shall be suspended.
- After a positive follow-up assessment of the head office / central management, suspension of certificates of the production sites can be lifted. Depending on the type of non-conformity which has been issued in the head office / central management, a new assessment of the production sites may also be necessary.

a[2] If the head office / central management does not have processing activities and is not assessed, the company shall ensure that all necessary information and responsible personnel are available from the head office / central management (when necessary), to ensure that the auditor can assess centrally managed processes properly during the assessment of each production site (e.g. a representative from the head office / central management attends the assessment of the production sites, head office / central management documents are available on-site at production sites, etc.). This shall be defined by the certification body based on information provided by the company before the assessment takes place.

Note: The information that shall be provided in the IFS Assessment Report in relation to multi-location production sites is detailed in part 4, chapter 1.1 "IFS Assessment Report".

b) Company without head office / central management

If a company has several independent production sites at different physical locations, without any head office / central management, then each production site shall have one COID, one assessment, one certificate and one report.

3. Multi-legal entity production site

a) In the case a production site has multiple legal entity at one physical location with the same scope, the following rules apply:

- Each legal entity shall have its own COID.
- One assessment shall be performed.
- The report and the certificate shall be duplicated for each legal entity.
- The COIDs of each legal entity shall be linked in the IFS Database.
- If the certificate of one legal entity is suspended, the certificates of linked legal entity / ies shall be suspended too, unless the certification body can demonstrate that the other legal entity / ies is / are not affected.

b) In the case a production site has multiple legal entities at one physical location, but with different scopes, the following rules apply:

- Each legal entity shall have its own COID.
- Each legal entity shall have its own report and certificate.
- If a contractual relationship between the legal entities exists, the COIDs of each legal entity shall be linked in the IFS Database.
- All assessments shall be performed by one certification body.
- If the certificate of one legal entity is suspended, the certificates of all legal entities shall be suspended too, unless the certification body can demonstrate that the other legal entities are not affected.
- The assessment duration shall be calculated separately for each COID. When a head office / central management can be appointed, the assessment duration rule for multi-location applies (see chapter 3.1, part 1).

4. Production site with decentralised structure(s):

A decentralised structure is a facility (for example a workshop or a warehouse) owned by the company where part(s) of the processes and operations of the production site take place. When the assessment of the production site is insufficient for gaining a full view of the company's processes, then all other relevant facilities shall also be included in the assessment. The scope and full details shall be documented in the assessment overview of the assessment report.

If the decentralised structure is a warehouse with logistics activities situated at the same physical location as the production site, the company has the option to either include it in the IFS PACsecure Assessment scope or to perform a combined IFS PACsecure / IFS Logistics Assessment. For further information about the scope determination between IFS PACsecure and IFS Logistics, see ANNEX 1.

2.3 Type of IFS PACsecure Assessments

Different types of Assessments shall be conducted, depending on the certification status of the company.

2.3.1 Initial assessment

The initial assessment is the full and thorough assessment of a production site, ideally resulting in the issue of a certificate. During the assessment, all IFS PACsecure requirements shall be assessed by the auditor.

An initial assessment can be:

- a production site's first IFS PACsecure Assessment, or
- the assessment performed after an interruption of the certification cycle (see the chapter 4.3, Part 1), or
- the assessment performed after a failed recertification assessment due to:
  - a D evaluation of a KO requirement (Knock Out non-conformity) and / or more than one Major non-conformity, or
  - a total scoring of below 75%, or
  - a failed follow-up assessment, or
  - an exceeded maximum period to execute the follow-up assessment.

If an initial IFS PACsecure Assessment is failed due to a KO requirement scored with "D" and / or more than one Major non-conformities, or if the total scoring is below 75%, the IFS PACsecure Assessment Report shall be uploaded into the IFS Database and this assessment cannot be considered as a pre-assessment (please, see chapter 4.2.1.1, where the conditions for issuing the IFS Assessment Report and the IFS Certificate are explained in detail).

2.3.2 Recertification assessment

A recertification assessment is the assessment performed to renew the existing IFS PACsecure Certification. The period in which a recertification assessment shall be performed is shown on the certificate.

A recertification assessment is a full and thorough assessment of a production site, ideally resulting in the issue of a new certificate. During the assessment, all IFS PACsecure requirements shall be assessed by the auditor. Particular attention shall be paid to the deviations and non-conformities identified during the previous assessment, as well as to the implementation and effectiveness of corrections and corrective actions laid out in the company's action plan.

Assessed companies shall always inform their certification body if they have already been IFS certified in the past. The auditor shall read the IFS Assessment Report and verify the action plan of the previous assessment, even if another certification body issued the report or if the previous assessment took place more than one year ago.

If C and / or D scorings of requirement(s) are still present from one assessment to the next, or if the scorings deteriorate, the auditor shall assess in accordance with the chapter 5.11 of the assessment checklist, Part 2.

The link between two consecutive assessment ensures a continuous improvement process.

A recertification assessment can be performed either announced or unannounced; however, the unannounced option is mandatory at least once every third IFS Certification Assessment.

Production sites are responsible for maintaining their certification. All IFS PACsecure certified companies will receive a reminder from the IFS Database three (3) months before certification expiration. The certification bodies shall contact their customers in advance to set a date for an announced assessment or to register them for an unannounced assessment.

If the assessment is not an initial assessment and if the company changes certification body, the company shall also inform their new certification body so that the auditor can check the action plan from the previous assessment.

2.3.3 Follow-up assessment

A follow-up assessment is required in a specific situation where the results of the assessment (initial or recertification) did not allow a certificate to be issued due to one Major non-conformity scoring and a total scoring of 75% and above.

The follow-up assessment is an on-site assessment focused on the implementation of corrections and corrective actions regarding the Major identified in the previous main assessment to verify whether the company has solved the Major non-conformity.

The follow-up assessment shall generally be performed by the same auditor who performed the assessment where the Major non-conformity was identified.

The follow-up assessment shall be performed no earlier than six (6) weeks and no later than six (6) months after the previous assessment. If a follow-up assessment is not performed within six (6) months of the date of the previous assessment, then a full new initial assessment shall be performed.

If the company decides not to perform a follow-up assessment but to start again with a full new assessment, then the new assessment shall be scheduled no earlier than six (6) weeks after the assessment where the Major non-conformity was issued (for further information, see chapter 4.2.1.1, Part 1).

Possible outcomes of the follow-up assessment are:

- The Major non-conformity has been solved by the company; therefore, the result is deemed positive. In this case, the site has passed the IFS Certification Assessment and a certificate shall be issued at foundation level only.
- The Major non-conformity is still valid; therefore, the result is deemed failed. In this case, the site has not passed the IFS Certification Assessment and a full new assessment (initial assessment) will be necessary.

The management of the follow-up assessment process is explained in part 1, chapter 4.2.1.1, and different steps related to the follow-up assessment in ANNEX 5.

2.3.4 Extension assessment

If new processes or products different to those included in the scope of the current IFS Assessment are implemented between two (2) certification assessments (e.g. seasonal products), the certified company shall immediately inform its certification body, who shall perform a risk assessment to decide whether and when an extension assessment should be performed or not. The results of this risk assessment, based on good manufacturing practices and product safety and quality risks, shall be documented.

If the certification body decides that an extension assessment is needed, it is not necessary to perform a full new assessment but an on-site extension assessment during the validity period of the existing certificate (on-going certification cycle).

An extension assessment shall always be performed as long as the hazard analysis / risk assessment system (especially the CCP's, if existing) and / or products are different from the one(s) assessed during the "main" assessment.

Extension assessment shall also be performed to observe production lines which were not working during the "main" assessment and / or if a significant change to the production process(es) and / or its environment has been made.

The certification body is responsible for determining relevant requirements to be assessed and the relevant assessment duration necessary to assess these requirements thoroughly.

The extension assessment report is generated as a single report and shall be provided as an annex to the current IFS Assessment Report. The uploading of an extension assessment is free of charge.

Conditions for passing the extension assessment are the same as for initial or recertification assessment, but they will only be focused on specific requirements that have been assessed. The original assessment score does not change.

If the extension assessment demonstrates compliance, the certificate shall be updated with the new scope and uploaded to the IFS Database together with the extension IFS Assessment Report. The updated certificate shall keep the same expiry date as the current certificate.

When an extension assessment has been performed, the recertification assessment shall include the processes assessed during the extension assessment (all in one certificate).

In the event of a Major non-conformity, a D evaluation of a KO requirement or a total scoring below <75% after an extension assessment, the full assessment (including the main one) is failed, and the current certificate shall be suspended.

In case of seasonal products, an extension assessment shall be performed to assess products and processes which could not be assessed while operating during the main assessment. The certifi-

cate shall specify all the assessed products and processes. During the following year, there will be one recertification and one extension assessment, in order to cover all products and processes.

For further information about extension assessments, see the IFS PACsecure Doctrine.

2.4 IFS PACsecure Assessment options

Before scheduling and performing the IFS PACsecure Assessment, the company shall decide whether the assessment shall be conducted on an announced or unannounced basis, ensuring that at least one unannounced IFS PACsecure Assessment is performed every three (3) years.

The information on whether if the assessment was unannounced or announced shall be visible on the certificate, on the cover page and in the section "assessment overview" of the IFS Assessment Report.

2.4.1 Announced assessment option

The announced assessment is conducted at a time and date agreed between the company and the selected certification body. It shall be preferably performed on consecutive days and shall be justified in the assessment report, in case of other. The recertification assessment shall be scheduled at earliest eight (8) weeks before the assessment due date (anniversary date of the initial assessment) and at latest two (2) weeks after the assessment due date.

2.4.2 Unannounced assessment option

This option is preferably aimed at recertification assessments but may also apply to initial assessments if the company prefers starting directly with an unannounced assessment. This option only applies to initial and recertification and not to extension and follow-up assessments.

It is mandatory that at least one unannounced IFS PACsecure assessment is performed every three (3) years. Based on this rule, in case the certification cycle is interrupted where an unannounced assessment was due, the next certification assessment (=initial assessment) has to be conducted unannounced.

It is the certification body's responsibility to make sure the rules for unannounced assessment are fulfilled, also in the case that the company (COID) changes its certification body. The certification body shall discuss assessment options with the sites and notify them which year an unannounced assessment will take place. If the company was formally certified to any other GFSI recognised standard, the certification body will need to be aware of the audit/assessment history in order to maintain the unannounced certification frequency. In the case of different IFS Standards, the unannounced certification frequency counts separately.

The following rules apply when the unannounced option is chosen:

- It shall take place without the company being notified of the date in prior, to ensure the unannounced character of the assessment. The certification body shall not inform the date of assessment in the diary function of the IFS Database and shall tick the box "Unannounced assessment" in the IFS Database.
- The assessment shall be performed on consecutive days.

- For unannounced initial assessments:
  - The time window for the assessment can be chosen.
  - The certificate validity is calculated from the last day of the assessment date within the chosen time frame.
  - The fixed registration deadline is four (4) weeks before the time window starts.
  - The time window will remain the same for the following years.
- For unannounced recertification assessments:
  - The time window is calculated as follows: [– 16 weeks before assessment due date; + two (2) weeks after assessment due date].
  - The fixed registration deadline is four (4) weeks before the time window starts.
  - The time window will be the same for all years.
- The company shall provide the certification body with the name(s) of the on-site person(s) to be contacted on the production site.
- For multi-location production sites with a head office / central management:
  - Head office / central management shall either be assessed through an announced or unannounced assessment.
  - The assessment of the head office / central management shall always take place before the assessment of each production site and shall be performed before the start of the unannounced assessment time window of the production site(s).
  - An unannounced assessment shall be performed at the production sites.
  - When the head office / central management is assessed through an announced assessment:
    - The announced assessment of the head office / central management and unannounced assessment of the production site shall not be performed on consecutive days. For example, if the head office / central management is located within one of the production sites, there shall be two (2) different assessments: an announced assessment for the centrally organised processes and an unannounced assessment for the production site.
  - When the head office / central management is assessed through an unannounced assessment:
    - unannounced assessments of the head office / central management and the production site can be organised to take place on the same day. For example, if the head office / central management is located within one of the production sites, there can be one assessment: an unannounced assessment for centrally organised processes and for the production site. This assessment shall start with the production processes.
  - All assessments, including that of the head office / central management, shall be performed within a maximum time frame of 12 months.
- When the unannounced assessment has been performed, the certification body shall provide the assessment dates in the IFS Database, at latest, two (2) working days after the first assessment day. This will ensure that the users of the IFS Database are informed that the assessment has taken place and that the certification process is on-going.

If a company denies the auditor access (apart from "force majeure"), the currently valid IFS Certificate shall be suspended by the certification body within a maximum of two (2) working days of the assessment date. All users with access to the IFS Database and with the respective company in their favourites list will receive an email notification from the IFS Database, informing them that the current certificate has been suspended. This information will be visible in the company's history in the IFS Database. The company shall be invoiced by the certification body for the total cost of the assessment.

2.5 Planning an IFS PACsecure Assessment

Before being assessed, the company shall review all requirements of the IFS PACsecure Standard and the IFS PACsecure Doctrine:

- For an announced assessment, the first assessment day shall be entered by the certification body into the IFS Database via the diary function at least two (2) weeks (14 calendar days) before the first day of the assessment.
- For an unannounced assessment, the certification body shall be notified by the company of the registration for this assessment at latest four (4) weeks before the start of the assessment time window, in order to register it on the IFS Database. This applies to production sites with the same certification body and for those changing certification bodies.
- For the unannounced assessment, there is a possibility to select a blackout period where the company has the opportunity to identify a maximum of ten (10) operational days when the production site is not available for assessment, as well as non-operating periods. The ten (10) operational days can be split into a maximum of three (3) periods. These, together with the non-operating periods, shall be notified to the certification body latest four (4) weeks before the start of the unannounced assessment time window and cannot be changed at a later stage. The certification body has to decide if the unannounced aspect of the assessment is fulfilled. Reasons shall be provided and may be challenged by the certification body or by the auditor during the assessment.
- If a company produces seasonal products and has registered for the unannounced assessment option, the expected seasonal production dates shall be notified to the certification body and the time window [– 16 weeks, + two (2) weeks] does not apply. These companies are not permitted to provide a blackout period to the certification body. The unannounced assessment shall take place at any time during this seasonal production period. The company still has to follow the registration process for the unannounced assessment and the date of the assessment shall be within the assessment time window.

For further information about the registration process for unannounced assessments, please see the IFS PACsecure Doctrine.

2.5.1 Drawing up an assessment time schedule

The certification body shall provide the company with the assessment time schedule, where the assessment duration shall be indicated.

The assessment time schedule shall:

- Include appropriate details concerning the scope covered and the complexity of the assessment.
- Be sufficiently flexible to respond to any unexpected event which may arise during the on-site evaluation part of the assessment.

- Take the review of the assessment report and action plan from the previous assessment into consideration.
- Specifies the company's products or product ranges that are to be assessed.
- Clearly indicate which auditor performs which part of the assessment if performed by an assessment team. Information about the assessment date and time for each auditor shall be provided in the IFS Database.
- Clearly indicate when and which part of each standard has been assessed if the IFS Assessment is performed in combination with another standard / norm.

If the announced option has been chosen, the time schedule shall be sent to the site before the assessment, to ensure the availability of responsible persons on the day of the assessment.

If the unannounced option has been chosen, it shall be shared during the opening meeting. It might also be modified or adapted due to the availability of the participants to be assessed and the current processing and / or conversion times.

3 IFS PACsecure Assessment realisation

The realisation of the IFS PACsecure Assessment shall always take into account the following elements:

- The assessment shall take place at a time when the products included in the assessment scope are being processed.
- The production lines shall be operational during the IFS Assessment.

If production lines are not operating during the IFS Assessment, they shall not be included in the scope of the assessment unless they have the same hazard analysis / risk assessment system, and they involve the same products and conversion / production processes as the ones included in the assessment scope.

If the non-operating production lines involve a different hazard analysis / risk assessment system and different product and / or conversion / production processes, two (2) options are possible:

- The production line(s) can run later during the assessment and are included in the scope of the "main" assessment.
- The production line(s) cannot run later during the assessment. In this case, the company has the option to include these processes and products via an extension assessment (for further information on extension assessment, see chapter 2.3.4, Part 1).

3.1 Assessment duration

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 assessment. They include:

- the size of the site
- the type of production / conversion process
- the assessment scope

- the number of production lines involved
- the number of personnel employed at the site
- the number of non-conformities found in the previous assessment.

In all cases, the minimum assessment duration shall be two (2) days (16 hours). The time for assessment preparation and reporting shall not be included in the assessment duration.

One assessment day is equivalent to eight (8) hours (without lunch break) and shall never exceed ten (10) hours.

The determination of the final assessment duration is the responsibility of the certification body.

The assessment duration does not include the time for assessment preparation and reporting, which shall take, at a minimum:

- Two (2) hours for assessment preparation
- Four (4) hours for writing of the IFS Assessment Report.

The rules to increase or decrease the IFS PACsecure Assessment duration are detailed in the IFS PACsecure Doctrine.

3.2 Assessment performance

The assessment shall be scheduled based on the following steps:

- Opening meeting.
- Evaluation of existing the Product Safety and Quality Management System; achieved by checking documentation (hazard analysis / risk assessment system, quality management documentation, etc.).
- On-site evaluation: detailed observation of all on-site production areas, production lines and production / conversion processes, which includes interviews with the working personnel and the gathering of information on key process parameters, such as the monitoring of critical control points (if existing) and control measures to be cross-checked with the hazard analysis / risk assessment system information.
- Documentation and record review and inspection: evaluation of documents and procedures, cross-checking of documents and records based on investigations and findings from the on-site evaluation.
- Final conclusions drawn from the assessment.
- Closing meeting: end of the assessment.

The company shall assist and cooperate with the auditor during the assessment. As part of the assessment, personnel from different levels of management and operative levels shall be interviewed. The most senior manager on the date of the assessment shall be present at the opening and closing meetings so that any deviations and non-conformities can be discussed.

Through the on-site assessment, the IFS Auditor shall make detailed notes regarding all evaluations against the IFS PACsecure Standard. These notes shall be used as the basis for the IFS Assessment Report.

During the closing meeting, at the end of the assessment, the auditor (or lead auditor in the case of an assessment team) shall present all findings and discuss all deviations and non-conformities (Major and / or D evaluation of a KO requirement) which have been identified during the assessment.

IFS requires certification bodies / auditors to provide a mandatory document which confirms the actual presence of the auditor(s) and assessed company representative(s) during the assessment. This document:

- shall be signed by a representative of the assessed production site at the end of each assessment day
- shall be signed by the auditor(s) (lead auditor, co-auditor) at the end of each day
- In case of an interpreter, technical expert, trainee, auditor in progress, auditor under observation and / or witness auditor having been present during the assessment, they shall be included in the mandatory document and shall sign it at the end of each assessment day
- shall state the start and end time of each day.

This document shall be part of the assessment documentation and shall be available upon request at the office of the certification body.

3.2.1 IFS Scoring System

In order to determine whether compliance with a requirement of IFS PACsecure has been met, the auditor has to evaluate all requirement of the checklist (Part 2). which are classified either as regular or as KO requirements.

The IFS Scoring System covers a scoring range based on the level of compliance of the requirement, from full compliance to a deviation and / or non-conformity.

In the IFS PACsecure Standard, there are six (6) scoring possibilities. Points are awarded for each requirement according to the following chart (chart 1):

Chart 1: IFS Scoring System

Result	Explanation	Points
A	Full compliance.	20 points
B (point of attention)	Point of attention as it may lead to a future deviation.	15 points
C (deviation)	Part of the requirement is not implemented.	5 points
D (deviation)	The requirement is not implemented.	–20 points
Major (non-conformity)	A Major non-conformity can be given to any regular requirement (which is not defined as a KO requirement). Reasons for Major rating are: • There is a substantial failure to meet the requirements of the standard, which includes but is not limited to product safety and / or the legal requirements of the production and / or destination countries. • A process is out of control which might have an impact on product safety.	Major non-conformity will subtract 15 % of the possible total amount; the certificate cannot be issued.
KO requirement scored with a D (non-conformity)	The requirement is not implemented.	KO non-conformity will subtract 50 % of the possible total amount; the certificate cannot be issued.

The auditor shall provide explanations in the assessment report:

- for requirements defined as compulsory fields, even if the requirements are scored with A,
- for all requirements scored with "B" (point of attention), "C" or "D" (deviations),
- for all requirements scored with "Major" or "KO=D" (non-conformities),
- for KO requirements, even if the requirements are scored with A.

If the auditor raises a Major and / or a KO non-conformity, the certificate cannot be issued.

KO requirements

There are specific requirements in the IFS PACsecure Standard which are named KO requirements. These requirements are essential and address key topics to be ensured by the production site to reach compliance. If the auditor identifies that the company does not fulfil at least one of these requirements during the assessment, this results in a non-certification.

In the IFS PACsecure Standard, the following ten (10) requirements are defined as KO requirements:

1) 1.2.2 Governance & Commitment
2) 2.2.3.8.1 Monitoring system of each CCP
3) 3.2.2 Personal hygiene
4) 4.2.1.2 Raw material specifications
5) 4.2.2.1 Product formulas / configuration
6) 4.12.2 Foreign material risk mitigation
7) 4.18.1 Traceability
8) 5.1.1 Internal audits
9) 5.9.2 Procedure of withdrawals and recalls
10) 5.11.2 Corrective actions

Scoring of KO requirements is explained in the following chart (chart 2).

Chart 2: Scoring of a KO requirement

Result	Explanation	Points
A	Full compliance.	20 points
B (point of attention)	**Point of attention as it may lead to a future deviation.**	**No "B" scoring is possible**
C (deviation)	Part of the requirement is not implemented.	5 points
D (= KO non-conformity)	The requirement is not implemented.	KO non-conformity will subtract 50 % of the possible total amount, the certificate cannot be issued.

Important notes:

- A "B" scoring is not possible for KO requirements: only A, C or D (= KO non-conformity) scorings are possible.
- If a KO non-conformity is rated during an IFS PACsecure Assessment, the assessment is failed. For more information, see ANNEX 6.

Not applicable (N / A)

When the auditor decides that a requirement is not applicable for a production site, the auditor has to evaluate it as N / A (not applicable) and shall provide an explanation in the IFS Assessment Report.

It is not possible to evaluate a KO requirement as N / A, except for KO requirements on monitoring system of each CCP (KO N°2) and product formulas / configuration (KO N° 5).

If there are a significant number of requirements which are deemed as not applicable, using a total point score for the assessment may be misleading. Therefore, the IFS Scoring System is based on a percentage of the total available score and this is ultimately used to decide the status of the production site i.e., foundation or higher level.

4 Post IFS PACsecure Assessment actions

4.1 Action plan

The auditor and / or certification body shall issue a provisional IFS Assessment Report and a provisional action plan with the findings addressed to the company. This plan shall be used as a basis for drawing up corrections and corrective actions by the company for the determined deviations and non-conformities, see ANNEX 7.

4.1.1 Company's completion of the action plan

The company shall provide the following in the action plan:

- proposed corrections and corrective actions for all deviations (C, D), KO requirements scored with a C and for non-conformities (Major or D evaluation of a KO requirement) listed by the auditor
- responsibilities and implementation deadlines for both corrections and corrective actions (see chart 3).

Chart 3: Timescale for corrections and corrective actions

TIMESCALE	
Corrections	**Corrective actions**
As soon as possible. Evidence of implementation shall be provided to the certification body within a maximum of four (4) weeks after the receipt of the provisional IFS Assessment Report and the provisional action plan for completion.	Relevant for a sustainable and successful implementation (may take longer than the deadline for issuing the certificate, need to be reasonably justified by the company). Implemented before the recertification assessment at the latest.

The company shall forward the action plan to the certification body within maximum four (4) weeks of having received the provisional IFS Assessment Report and the provisional action plan. If this deadline is not adhered to, the company shall undergo a full initial or recertification assessment.

The action plan shall be validated by the auditor and the reviewer during the certification decision process.

An IFS Certificate shall not be issued unless all corrections are implemented.

In the case of one Major non-conformity and a total scoring < 75 % or several Major and / or KO non-conformity / ies, the certificate will not be issued, the IFS Assessment Report shall be uploaded in the IFS Database and a new assessment shall be organised (see part 1, chapter 4.2.1.1 and ANNEX 8).

4.1.2 Validation of the action plan

The auditor or a representative of the certification body shall validate the evidence for corrections as well as the relevance of the proposed corrective actions and the timeline.

If the evidence of the corrections and / or proposed corrective actions are not valid or inadequate, and / or if the dates of implementation are not relevant, the auditor / representative of the certification body shall return the action plan to the company for completion in due time.

When the evidence for corrections as well as corrective actions proposed by the company are considered valid / adequate and dates of implementation are appropriate; the release of each correction and corrective action listed in the action plan, as well as the date of release by the auditor (or a representative of the certification body), shall be noted in the respective column of the action plan, before preparing the final IFS Assessment Report.

If the action plan is not released in due time, certification may not be issued. The evidence shall be stored by the certification body for a period of three (3) years.

4.1.3 Technical review

A technical review of the report shall be conducted by a nominated reviewer from the certification body (see glossary, ANNEX 12). In the case of unclarity or doubts about the findings and the related scorings, these need to be clarified between the auditor of the IFS Assessment and the reviewer.

Based on the result of the technical review, the nominated reviewer recommends the issuance of an IFS PACsecure Certificate or not.

4.2 Issuing the IFS Certificate

Based on the result of the technical review the certification body is responsible for making the final decision whether to issue the IFS PACsecure Certificate or not. The decision is made by (a) person(s) other than those who have carried out the assessment.

4.2.1 Scoring and conditions for issuing the IFS Assessment Report and IFS Certificate

Chart 4: Scoring and issue of certificate

Assessment result	Status	Company actions	Report form	Certificate
Total score is ≥ 95 %	Passed at IFS PACsecure higher level following the receipt of the action plan	Send completed action plan and evidence of corrections implemented within a maximum of four (4) weeks of receiving the provisional report	Report including action plan provides status	Yes, certificate at higher level, 12-month validity. The certificate shall only be issued when the corrections are closed
Total score is ≥ 75 % and < 95 %	Passed at IFS PACsecure foundation level after receipt of the action plan	Send completed action plan and evidence of corrections implemented within a maximum of four (4) weeks of receiving the provisional report	Report including action plan provides status	Yes, certificate at foundation level, 12-month validity. The certificate shall only be issued when the corrections are closed
Total score is ≥ 75 % AND Maximum one (1) Major	Not passed, unless further actions taken and validated in a follow-up assessment	Send completed action plan and evidence of corrections implemented within a maximum of four (4) weeks of receiving the provisional report. Follow-up assessment performed at a maximum of six (6) months after the assessment date	Report including action plan provides status	Certificate at foundation level only if the follow-up assessment result is deemed positive. The certificate shall only be issued when the corrections are closed and the report has been updated with the the follow-up assessment information
Total score is < 75 %	Not passed	Actions and new initial assessment to be agreed upon (no earlier than six (6) weeks after the assessment where the final score was < 75 %)	Report provides status	No

Assessment result	Status	Company actions	Report form	Certificate
> one (1) Major and / or total score is < 75 %	Not passed	Actions and new initial assessment to be agreed upon	Report provides status	No
At least one KO requirement scored with D	Not passed	Actions and new initial assessment to be agreed upon	Report provides status	No

Note:
Total number of points
= (total number of PACsecure requirements (points) – requirements evaluated as N / A (points)) × twenty (20)

Final score (in %)
= number of points awarded / total number of points

4.2.1.1 Specific management of the assessment process if one or several Major non-conformity / ies has / have been issued or if one or several KO requirement(s) has / have been scored with D during the assessment.

a. If one or several Major non-conformity / ies has / have been issued and / or one or several KO requirement(s) is / are scored with D during the assessment, the following rules apply:

- The current IFS Certificate shall be suspended in the IFS Database by the certification body as soon as possible, and at latest two (2) working days after the last day of the recertification assessment.
- The report shall be uploaded to the IFS Database.
- In the IFS Database, the certification body shall provide explanations in English about the reasons for suspending the current certificate. The explanations about the identified non-conformity / ies shall specify the number of requirements involved and shall provide the same details as those described in the action plan.

Note: All IFS Database users with the respective company in their favourites list will receive an e-mail notification (with explanations about the identified non-conformity / ies) from the IFS Database, informing them that the current certificate has been suspended.

b. If more than one Major non-conformity has been identified with a total score is below 75 %, the following rules apply:

- The IFS Assessment Report where one Major non-conformity with a result below 75 %, or several Major non-conformity / ies has / have been identified shall always be uploaded in the IFS Database after receiving the action plan (only for administrative purpose, but will not be visible, see ANNEX 8).
- A full new assessment shall be performed no earlier than six (6) weeks after the assessment where the Major non-conformities were issued (ANNEX 8).

c. If one Major non-conformity has been identified and the total score is equal or above 75%, a follow-up assessment shall be performed, and the following rules apply:

- In case of an unannounced assessment, the follow-up assessment shall be announced.
- If during the follow-up assessment, the assessment result is deemed positive, then:
  - The site has passed the IFS Certification Assessment, and a certificate at foundation level shall be issued. The company cannot be certified at higher level even if the final total score is equal or above 95 %.
  - The certificate shall include the date of the follow-up assessment.
  - The same validity date of the certificate remains in the certification cycle, as described in 4.3 (the longest certificate valid due date is calculated from the last day of the initial assessment date + eight (8) weeks – 1 day + 1 year).
- If during the follow-up assessment, the assessment result is deemed failed, then:
  - The site has not passed the IFS Certification Assessment; therefore, a certificate cannot be issued.
  - A full new assessment (initial assessment) will be necessary and shall be scheduled no earlier than six (6) weeks after the follow-up assessment (ANNEX 5).
- After performing the follow-up assessment, the IFS Assessment Report shall be updated with the outcome of the follow-up assessment. The certification body shall mention the following details in the updated IFS Assessment Report:
  - in the "date" section: specify the date of the follow-up assessment in addition to the assessment date when the Major non-conformity was identified,
  - in the "final result of the assessment" section: specify that a follow-up assessment has taken place and if the Major non-conformity has been solved or is still valid,
  - in the applicable section of the assessment overview: information on the solving/not solving of the Major non–conformity that triggered the follow-up assessment,
  - in the requirement scored with "Major": the score and explanation related to the non-conformity updated.
- The updated IFS Assessment Report shall be uploaded in the IFS Database by the certification body.

d. If one or several KO requirement(s) has / have been scored with D, the following rules apply:

- The assessment shall be completed, and all requirements shall be evaluated in order to give the company a full overview about its situation.
- The action plan should be completed (recommended) for improvement purposes.
- The IFS Assessment Report where one or several KO requirement(s) has / have been scored with D shall always be uploaded in the IFS Database (only for administrative purpose but will not be visible).
- After this situation, a full new assessment shall be performed, no earlier than six (6) weeks after the assessment where a / some KO requirement(s) was / were scored with D (ANNEX 6).

4.2.1.2 Deadlines for issuing the IFS Certificate.

If the assessment is not performed in due time, all IFS Stakeholders with access to the IFS Database and with the respective company in their favourites list will receive an e-mail notification.

The time between the date of the assessment and the issue of the certificate is determined by the certification body. A maximum of two (2) weeks shall be allocated for the auditor to send the provisional report and provisional action plan for completion to the company. A maximum of four (4) weeks shall be allocated for the company to provide evidence that corrections have been implemented and respond to the deviations and non-conformities (i.e., draw up the action plan).

If the auditor and the nominated reviewer recommend the IFS PACsecure Certification after positive validation of the evidence of implementation of corrections, the certification body can take the decision to issue the certificate. The IFS Assessment Report, the action plan and the certificate shall then be uploaded in the IFS Database.

The timeline is six (6) weeks (as a target time) or eight (8) weeks (as a maximum time) between the date of assessment and the upload of the assessment report in the IFS Database / issue of the certificate. For more information, see ANNEX 2.

4.3 Certification cycle

The certification shall be valid from the date of issue stated on the certificate. Companies are responsible for maintaining their certification.

For an **announced** assessment, the validity of the IFS PACsecure certificate is defined as follows:

- it starts from the date of issue of the certificate,
- it ends on the last day of the initial assessment date + eight (8) weeks –1 day + 1 year.

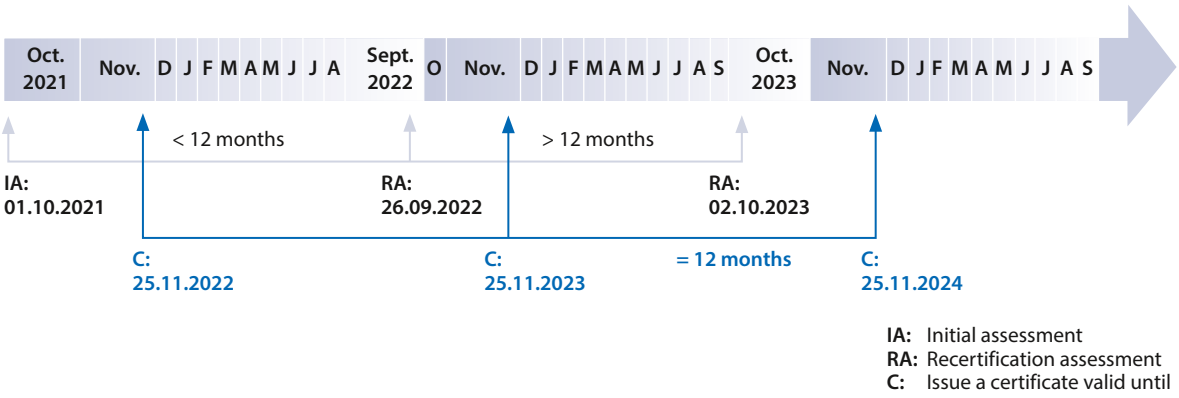
The time window to schedule the announced recertification assessment is calculated as follows:

- [– eight (8) weeks; + two (2) weeks] from the last day of initial assessment.

From the example listed in the chart (chart 5):

- Initial assessment date: 1st of October, 2021
- Date of issue of certificate: 26th of November, 2021
- Certificate valid until: 25th of November, 2022
- Recertification assessment date: 26th of September, 2022
- Certificate valid until: 25th of November, 2023 (independently from the recertification assessment date)
- Time window to schedule the recertification for an **announced** assessment: [6th of August – 15th of October].
- Time window to schedule the recertification for an **unannounced** assessment: [11th of June – 15th of October].

Chart 5: Certification cycle



IA: Initial assessment
RA: Recertification assessment
C: Issue a certificate valid until

The validity of the IFS Certificate remains the same each year and is determined by the date of the initial assessment.

The time window to schedule the recertification of an unannounced assessment is calculated as follows:

- [– 16 weeks before assessment due date; + two (2) weeks after assessment due date].

If the announced recertification assessment is not scheduled on time, or if the steps of the certification process were not completed in time, this will lead to a break in certification and only a new initial certificate can be issued.

The date of the recertification assessment be calculated from the initial assessment date and not from the date of issue of the certificate. In this way, even if the recertification assessment date changes every year and does not completely correspond to the anniversary date, the certificate validity date remains the same each year and gaps are avoided between two (2) consecutive certificates. If the assessment is scheduled earlier (but still within the assessment time frame), the company does not lose some weeks of its certificate validity.

The certificate shall always be edited on the basis of a certification decision and after several steps of certification decision according to ISO / IEC 17065:2012 norm (ANNEX 2).

The previous assessment report remains visible in the IFS Database for a further three (3) months (after the end of certificate validity). If the recertification assessment takes place later than the above-mentioned time window, the certification of the company will not be visible anymore. If the company has no further active certificates, the COID will be automatically set to an inactive status in the IFS Database.

4.3.1 Information about the conditions of withdrawal / suspension of a certificate

Withdrawal of a certificate by the certification body is only permitted in case of any information indicating that the products / processes may no longer comply with the requirements of the certification system. The only exception to this rule may be related to the non-payment for the current assessment by the certified company. The contract between the certification body and the assessed company shall take the certification cycle into account.

If certification is reinstated after suspension, the certification body shall make all necessary modifications to formal certification documents, public information, authorisations for use of brands, etc., in order to ensure all appropriate indications exist and that the products / processes continue to be certified.

If a decision to reduce the scope of certification is made as a condition of reinstatement, the certification body shall make all necessary modifications to formal certification documents, public information, authorisations for use of brands, etc., in order to ensure the reduced scope of certification is clearly communicated to the client.

4.4 Distribution and storage of the assessment report

Assessment 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, accreditation bodies and GFSI Integrity Program). The consent for distribution of the IFS PACsecure Assessment Report shall be made 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 IFS PACsecure Assessment Report. The assessment report and associated documentation including the auditor's notes shall be stored safely and securely for a period of five (5) years. The fully detailed access conditions to information about the assessment reports are available in Part 4.

Supplementary action

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

5 IFS Integrity Program

The IFS Integrity Program, launched in early 2010, includes different measures to assure the quality of the IFS Standards by reviewing IFS Assessment Reports of certified companies and also by using several measures to analyse and improve the performance of certification bodies and auditors. The IFS Integrity Program strengthens the reliability of the IFS Standards by surveilling their implementation in practice.

The main procedures of the IFS Integrity Program are described in Annex 4 of the IFS Framework Agreement on the IFS Assessment and certification between IFS Management GmbH and the certification body. These procedures have been developed through regular meetings of the IFS Quality Assurance Working Group, which is composed of international members. Annex 4 of the IFS Framework Agreement shall be signed by all certification bodies that have concluded a contract with IFS Management GmbH. Auditors performing IFS Assessments shall accept the IFS Integrity Program procedures to assure a qualitative performance of IFS Assessments. Certification bodies are obliged to inform their customers applying for an IFS Assessment certificate about the content of the current version of Annex 4 of the IFS Framework Agreement. The IFS Integrity Program is mainly involved in the following activities:

5.1 IFS complaint management

Retailers or any other interested parties have the right to forward any possible complaint or 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.

The IFS Integrity Program will gather all necessary information in order to investigate the cause of the complaint and to establish if there are deficiencies in meeting IFS requirements by certified companies, accredited certification bodies or IFS Auditors. Appropriate steps will be taken to fully investigate a complaint, which may include requesting a certification body to carry out internal investigations and to provide a statement on the outcome of the investigations to IFS.
Finally, the IFS Quality Assurance Management department will decide which approach would be 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 organise an Integrity witness audit for an IFS Auditor involved in the complaint case (in this case, an Integrity auditor assesses an IFS Auditor during one of her / his next regular IFS Assessments).

Based on the complaint, the Integrity On-Site Check will mainly be performed on an unannounced basis (announcement 30 minutes before the start of the Integrity On-Site Check). In some special cases, the Integrity On-Site Check might also be performed on an announced basis (generally announced about 48 hours before).

5.2 Risk based approach and monitoring of IFS Quality Assurance

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

In order to care for the correct implementation of all procedures described in IFS Standards and respective regulatory documents, the IFS Integrity Program carries out regular office audits at certification bodies (Integrity certification body office audits). During these office audits, work performance of IFS Auditors and certification bodies are checked by means of examples of several reports and by database analysis. If special topics have to be clarified during these Integrity certification body office audits, this could also lead to Integrity witness audits of IFS auditors or to Integrity On-Site Checks at companies certified by the respective certification body.

Additionally – taking the risk-based approach into account – reports of certified companies are analysed and read by IFS Quality Assurance Management staff. The IFS Quality Assurance Working Group has defined different criteria for the risk-based approach. These analyses are an ongoing monitoring procedure of the IFS Quality Assurance Management, taking into account both economic criteria (e.g. number of issued certificates in certain countries) and quality criteria (e.g. assessment results, assessment times etc.). As previously described, Integrity On-Site Checks will mainly be performed on an unannounced basis and might be performed on an announced basis in some special cases. Integrity witness audits of IFS Auditors may also be performed using this risk-based analysis approach of IFS Quality Assurance Management.

Additional information about above-mentioned chapters 5.1 and 5.2:
Companies with a valid IFS Certificate have to accept an unannounced / announced Integrity On-Site Check and have 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.

Witnessing IFS Auditors from certification bodies commissioned by Integrity auditors during regular IFS Assessments also have to be accepted.

Integrity On-Site Checks, Integrity witness audits and Integrity certification body office audits carried out as part of the Integrity Program are conducted by Integrity auditors employed or commissioned by IFS Management GmbH. Integrity auditors are completely independent from the assessed companies and the IFS certification bodies.

5.3 Sanctions

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

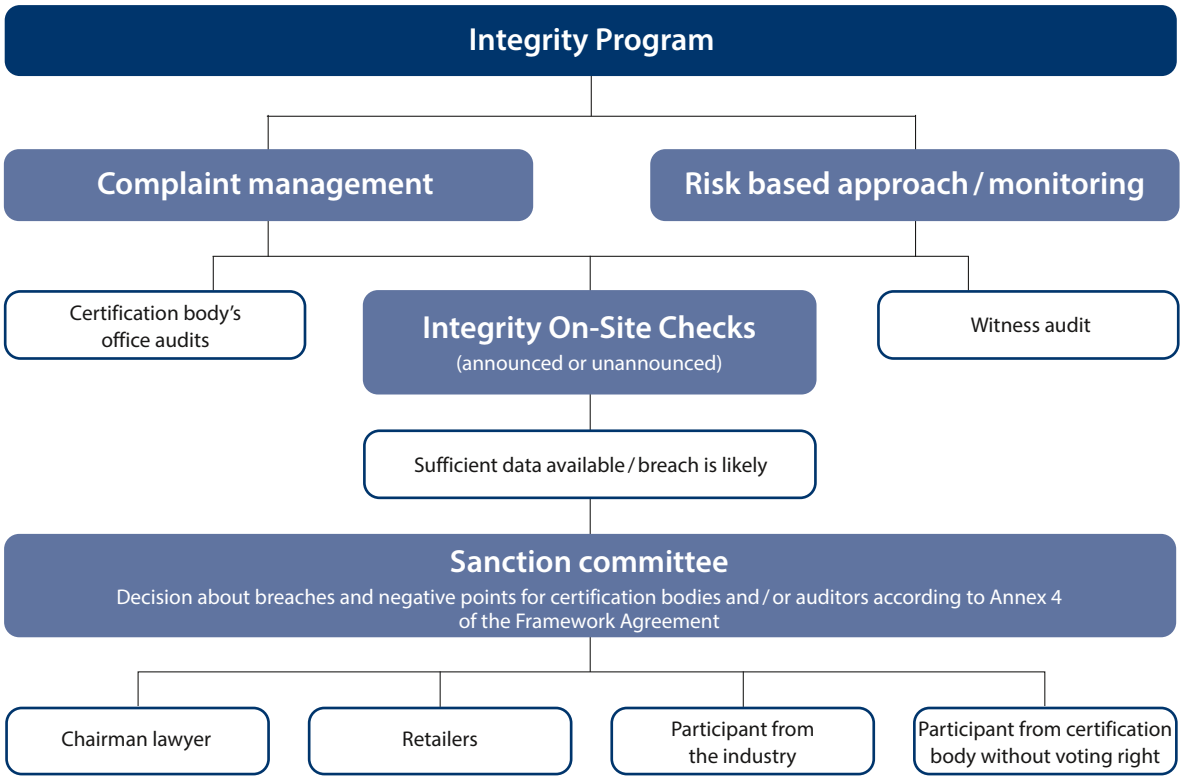
Topics concerning administrative faults of certification bodies based on database investigations can be directly assessed by the IFS Quality Assurance Management but have to be confirmed by the chairman (lawyer) of the sanction committee.

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 the breach. For each final breach ruling, a certification body and / or an auditor may get a certain amount of "negative points". These "negative points" are accumulated, but the period of limitation is two (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 the IFS Integrity Program activities is to improve the performance of certification bodies and / or auditors by requesting corrective actions, for example attending further training in the case of a decided breach.

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

All these procedures concerning breaches, penalties and "negative points" are laid down in Annex 4 of the IFS Framework Agreement between IFS and each certification body (chart 6).

Chart 6: Summary of IFS Integrity Program activities



6 IFS Logos

The copyright of IFS PACsecure and the registered trademark is fully owned by IFS Management GmbH. The IFS Logos shall be downloaded via the secured section of the IFS Database.
Furthermore, the terms and conditions below shall be communicated to the assessed company by the certification body and checked by the auditor during the assessment. The results of this check shall be described in the company profile of the assessment report as a compulsory field. If the auditor identifies that the company does not fulfil those terms and conditions, IFS shall be informed accordingly.

Terms and conditions for using the IFS Logos and communication about the IFS PACsecure Certification / application

These terms and conditions apply for all IFS Logos.

Form, design and colour of the IFS Logos

Only the latest version of the IFS Logos shall be used. When used, the IFS Logo(s) shall comply with the form and colour of the scale drawing. If used in documents, black and white print is also permitted. Companies shall only use the logo of the standard(s) they are certified for.
The general IFS Logo can only be used to express that the certification body or the IFS Consultant supports IFS certified companies, or that the certification body offers certification for more than one IFS Standard. All other forms of use shall be agreed with IFS.
The IFS PACsecure Logo can be used in print, electronic form and in films, as long as the form and format are fulfilled. The same conditions apply to the use of the logo as a stamp.

Restriction of comments and interpretations

When an IFS PACsecure certified production site, an IFS PACsecure supporting company or an IFS PACsecure Certification body publishes documents bearing the IFS Logo(s), comments and interpretations referring to IFS shall be clearly identifiable as such.

Use of the IFS PACsecure Logo in promotional material

The IFS PACsecure Logo shall not be displayed on the product itself, on product wrapping, or any kind of advertising document likely to reach the end-consumer (e.g. intercompany sales packaging, public exhibitions for end-consumers, product specific brochures for end consumers, etc.). The logo can only appear on a website section related to quality management or to quality and safety in general. It shall not be used for any kind of business-to-consumer marketing. It shall be clear that all information concerning certification clearly refers to IFS.
The IFS Logos shall not be used in presentations that have no clear connection to IFS.

An IFS PACsecure certified production site, which accepts IFS Certificates from its suppliers or service providers (brokers, logistics service providers or wholesalers) or an IFS certification body may use the general IFS Logo for promotional reasons and publish information about IFS Certification. If they have no certification of their own, it shall be clearly stated that the company supports or works with IFS certified companies. Any kind of use that gives the impression that the company itself is certified is not accepted.

Further restriction on the use of the IFS PACsecure Logo

The IFS PACsecure Logo shall not be used in any way that may imply that IFS Management GmbH is responsible for the certification decision. In case of suspension or withdrawal of the IFS PACsecure Certificate, the assessed production site and company have to immediately stop including the IFS Logos on their documents and / or website. In case of exclusion regarding the Assessment scope, the details about exclusions shall be available upon request. The IFS PACsecure Logo can be used, but the following claim shall be written at the bottom: "some products are excluded from the scope of the IFS PACsecure Assessment and exclusion details can be provided upon request".

Communication of the IFS PACsecure Certification

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

PART 2
List of IFS PACsecure Assessment requirements

0 General clarifications

0.1 About the guidance for industry and auditors

- The purpose of the guidance is to help companies and auditors with the interpretation of the requirements, thus providing a general approach to what is expected.
- The content is focused on examples of questions for each requirement, as the intention is for each company to be able to reflect on the purpose / objective of the requirement and determine how to implement them, according to the situation, processes and products of each site.
- The guidance is not mandatory; therefore, it is not expected that the auditor asks the same questions, as the auditor has to adapt the assessment to the situation of each site.

0.2 About the requirements:

- Requirements with a "*" require compulsory information for the IFS PACsecure Assessment Report (see ANNEX 10).

No.	IFS PACsecure Requirements	Guidance
1	**Governance & commitment**	
1.1	**Policy**	
1.1.1*	The senior management shall develop, implement and maintain a clear corporate policy, which shall include, at a minimum: • customer focus • product safety culture • product requirements • sustainability The corporate policy shall be communicated to all employees.	• How and where is corporate policy documented? • What are the contents of the corporate policy? • How was corporate policy communicated to all employees? • Does the corporate policy include a commitment regarding product safety culture? • What kind of mechanisms are used to verify that the policy is understood and applied within the organisation? • Is the policy available for relevant interested parties as appropriate? ***Additional explanation*** *Sustainability is included in the IFS PACsecure even if it´s a product safety and quality standard, in order to initiate / develop in companies the awareness on this topic.*
1.1.2	The corporate policy shall be broken down into measurable objectives, with responsibilities and timelines defined. These shall be known by the relevant departments / parts and shall be effectively implemented	• Is the content of corporate policy adapted to measurable objectives? • What product requirement objectives are addressed and how are the objectives attained? • Are the objectives clearly formulated and measurable? • What is the time frame to attain the objectives? • Who is responsible for the attainment of objectives? • What kind of mechanisms are used to measure whether the objectives have been attained?
1.1.3	All relevant information related to product requirements shall be communicated effectively to the relevant personnel promptly.	• How is relevant information related to product requirements transmitted to concerned persons?
1.2	**Corporate structure**	
1.2.1*	The structure of the company, hierarchy, and job positions shall be available, documented, and shall be known by the relevant personnel. The personnel responsible for the product safety and quality management shall have a direct reporting relationship to the senior management.	• How is the organisation structured? • Is an organisation chart available? • What is the version and date of issuing of the current organisational chart? • Who is(are) the person(s) responsible for product safety and quality management report? • To whom does the personnel responsible for product safety and quality management report?

No.	IFS PACsecure Requirements	Guidance
1.2.2* KO No. 1	**The senior management shall ensure that employees are aware of their responsibilities related to the product safety and quality management system and product requirements. Clearly identified and documented mechanisms shall be in place to monitor the effectiveness of their operation.**	• How does senior management ensure that employees know their responsibilities related to product requirements? • Are the employees aware of how they contribute to the effectiveness of the product safety and quality management system? • Are the employees aware of the implications of not conforming with product requirements or with the product safety and quality management system requirements? • How does the senior management take accountability for the effectiveness of the product safety and quality management system?
1.2.3	The senior management shall provide sufficient and relevant resources to meet the product and process requirements, including those related to the product safety and quality management system.	• How were the necessary resources defined? • How does the company ensure the all critical functions are covered by competent personnel at all times? • How is it ensured that contact can be made in certain situations?, e.g. senior management in crisis situation? • In what manner (coordination / communication) and in what form (resources) is the hazard analysis / risk assessment team supported by the senior management? • Is the hazard analysis and risk assessment team well known throughout the company? How has it been communicated?
1.2.4	The senior management shall ensure that all processes (documented and undocumented) are known by the relevant personnel (including new / permanent personnel and temporary / seasonal workers), and are applied consistently.	• What criteria are used to ensure process control? • What is done to ensure that all processes are known by the relevant personnel (incl. permanent staff and temporary / seasonal workers) and are applied consistently? • In case of new procedures / changes into existing procedures, what actions are taken to ensure that processes are known by the relevant personnel?

No.	IFS PACsecure Requirements	Guidance
1.2.5*	The senior management shall have a system in place to ensure that the company is kept informed of all relevant legal and regulatory requirements, scientific and technical developments, industry codes of practice, product safety and quality issues, and that they are aware of factors that can influence product defence and product fraud risks.	• Which legal and regulatory requirements and / or industry codes of practice are relevant for the company? • What kind of system is used by the company to be informed and updated on relevant information? • If changes occurs, who checks the implementation of these changes? • How does the senior management ensure that all relevant legal and regulatory product requirements are in place and known by the relevant persons? • How does the senior management ensure that purchased products, services and manufactured products comply with all relevant legal and regulatory requirements?
1.2.6*	The senior management shall ensure that the certification body is informed of any changes that may affect the company's ability to conform to the certification requirements. This shall include, at a minimum: • any legal entity name change, • any production site location change. For the following specific situations: • any product recall, • any product recall and / or withdrawals by official order for product safety and / or product fraud reasons, • any visit from health authorities which results in notifications and / or penalties issued by authorities, which are related to the IFS PACsecure Standard scope the certification body shall be informed within three (3) working days.	• Has the company had changes about the legal entity name or production site location? If so, Did the company inform the certification body? • Has the company had voluntary recalls, and / or recall / withdrawals by official order, and / or notifications / penalties issued by authorities? If so, Did the company inform the certification body within the timeframe? • What is the name of the authorities and when was the last visit?

No.	IFS PACsecure Requirements	Guidance
1.3	**Customer focus**	
1.3.1	A process shall be in place to identify the fundamental needs and expectations of customers. The feedback from this process shall be taken as input for the company's continuous improvement.	• How are customer needs and expectations identified? • How often are these identified? • What were the results of the last feedback process? • How were these results considered for continuous improvement? • Do identified needs influence the production process?
1.4	**Management review**	
1.4.1*	The senior management shall ensure that the product safety and quality management system is reviewed at least annually, or more frequently if significant changes occur. Such reviews shall include, at a minimum: • a review of objectives and policies, including elements of product safety culture • results of audits and site inspections • positive and negative customer feedback, including customer audit results • process compliance and changes / improvements • authenticity and conformity issues • status of corrections and corrective actions • notifications from authorities.	• How often is the product safety and quality management system reviewed and evaluated? • Who compiles the required data for the management review? • Does the management review include all listed topics? • Are the product safety culture objectives reviewed during the annual management review? • How does senior management ensure the suitability and effectiveness of the product safety and quality management system in case of changes?
1.4.2	Actions resulting from the management review shall be clearly aimed at supporting improvement. The management review shall assess follow-up actions from previous management reviews and any changes that could affect the product safety and quality management system. The management review shall be fully documented.	• Who traces the actions from a management review and how? • What conclusions did the senior management draw from the last management review? • Which actions from the previous management review were implemented? • Is it possible to determine an aim to support the improvement from the existing data?

No.	IFS PACsecure Requirements	Guidance
1.4.3	The senior management shall identify and regularly review (e.g. by internal audits or on-site inspection) the infrastructure and work environment needed to conform to product requirements. This shall include, at a minimum: • buildings • supply systems • machines and equipment • transport • staff facilities • environmental conditions • hygienic conditions • workplace design • external influences (e.g. noise, vibration). The results of the review shall be considered, with due consideration to risk, for investment planning.	• How often is this review performed? • When is infrastructure and work environment evaluated? • Does the infrastructure evaluation include internal flows (work, materials, waste, personnel, water, etc.)? • What was the result of the evaluation? • Who evaluated the infrastructure and work environment? • What risks were identified according to the results of the assessment? • What are the related investments for the near future?

No.	IFS PACsecure Requirements	Guidance
2	**Product safety and quality management system**	
2.1	**Quality management**	
2.1.1	**Document management**	
2.1.1.1	The product safety and quality management system shall be documented and implemented, and shall be kept in one secure location. This is applicable for physical and / or digital documentation systems.	• Where is documentation concerning the product safety and quality management system retained? • Are the documents related to the product safety and quality management system securely stored?

No.	IFS PACsecure Requirements	Guidance
2.1.1.2*	A documented procedure shall exist for the control of documents and their amendments. All documents which are necessary for compliance with the product requirements shall be available in their latest version. The reason for any amendments to documents, critical to the product and process requirements, shall be approved by authorised personnel, and recorded.	• What rules exist regarding document control? • Do the documents have an identification system? • How is the identification system structured? • How can a revision be identified? • Are there defined responsibilities? • Are changes and modifications traceable? • How is it possible to recognise that documents (e.g. specifications) are valid and up-to-date? • How is it ensured that only valid documents are in circulation? • Are the reasons for any amendments to documents reviewed, approved by authorised personnel, and recorded? • How do employees access the documents? ***Additional explanation*** *Control of documents comprises: distribution, access, retrieval, usage, storage, preservation, control of changes, retention, disposition and management of obsolete documents to prevent misuse.*
2.1.1.3	All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times.	• Are all documents legible? • Are the documents unambiguous? • Are the documents structured comprehensibly? • Are the documents located in the right place? Also, after office hours? • How are the documents made available to the employees? • How are document changes communicated to relevant employees? • Are there any distribution lists for documents? ***Additional explanation*** *Some examples of documents are: procedures, records (including batch-related manufacturing data), manuals, work instructions, reports, employee training records, plans, lists, etc. These can exist in different formats (e.g. in paper, recorded audio and/or video, and/or in any kind of format in digital media).*

No.	IFS PACsecure Requirements	Guidance
2.1.2	**Records and documented information**	
2.1.2.1	Records and documented information shall be complete, legible, genuine, and available on request. They shall be easily accessible; maintained in a way that subsequent manipulation or amendment is prohibited; securely stored and protected from loss, intentional adulteration and / or misuse.	• Are records plausible? • Are records legible? • How and where are records filed? • How is quick access to the records ensured? • Are records securely stored and protected from loss, intentional adulteration and / or misuse? • What kind of assurance is given that records cannot be subsequently manipulated? • Are the records reviewed by a supervisor?
2.1.2.2*	All records and documented information shall be kept in accordance with legal requirements and customer requirements. If no such requirements exist, records and documented information shall be kept for a minimum of one year after the specified converting time. For products which have no specified converting time, the duration of record and documented information keeping shall be justified and this justification shall be documented.	• Where are records stored? • Who stores records? • How long are records kept? • Are customer requirements defined in relation to record-keeping duration? • On what basis were record storage times defined? • For products with no specified converting time, is the record storage time definition justified? • How is data-backup carried out?
2.1.2.3	Any amendments to records shall only be carried out by authorised persons.	• How are amendments to records carried out? • Who is authorised to make amendments? • How are amendments authorised?
2.2	**Product safety and quality management**	
2.2.1	**Hazard analysis and risk assessment system**	
2.2.1.1	Before developing a hazard analysis and risk assessment system, the company shall assess the implementation of legal and regulatory requirements, good manufacturing practices (GMP's), and industry guidelines when applicable to its scope of activity and relevant for product requirements.	• What kind of legal / regulatory requirements, good manufacturing practices (GMP's), and industry guidelines are relevant for the scope of activity and product requirements? • Has the company assessed the adequate implementation of relevant legal / regulatory requirements, (GMP's), and industry guidelines? • What was the result of the assessment? If gaps were identified, have the necessary corrective actions been implemented?

No.	IFS PACsecure Requirements	Guidance
2.2.1.2	The basis of the company's product safety and quality management system shall be a fully implemented, systematic, comprehensive and documented hazard analysis and risk assessment system, based upon the Codex Alimentarius principles or on other applicable and recognised industry guidelines. It shall take into account any legal and regulatory requirements of the production and destination countries which may go beyond such principles or guidelines. The hazard analysis and risk assessment system shall be specific and implemented at each production site.	• The company's hazard analysis and risk assessment system is based on what principles? • Does every site / plant have a separate hazard analysis and risk assessment system? • What specific legal and regulatory requirements are taken care of in the hazard analysis and risk assessment system? • Are the applicable legal and regulatory requirements related to the production and destination countries included?
2.2.1.3	The hazard analysis and risk assessment system shall cover all raw materials, wrapping materials, products or product groups as well as every production / conversion process (including outsourced process) from incoming goods up to the dispatch of finished products, including product development.	• Does the hazard analysis and risk assessment system cover raw materials, wrapping materials, products or product groups as well as every process (including outsourced process) from incoming goods up to the dispatch of finished products? • Which processes are performed? • If the company has outsourced processes and / or product development, are these included in the hazard analysis and risk assessment?
2.2.1.4	The company shall ensure that the hazard analysis and risk assessment system is based upon scientific literature, or technical verified information related to the manufactured products and processes, or expert advice obtained from other sources, which may include: • trade and industry associations, • independent experts, • and regulatory authorities. This information shall be maintained in line with any new technical and scientific process development.	• Is the hazard analysis and risk assessment system based upon scientific literature and / or technical verified specifications related to products and processes, and / or expert advice obtained from other sources? • How is new technical and scientific process development taken care of? • Does a contract exist with an independent expert? • Does the hazard analysis and risk assessment system meet all applicable legal and regulatory requirements of the country in which it is established, including the required and applicable risk assessments and supporting documentation?

No.	IFS PACsecure Requirements	Guidance
2.2.1.5	The hazard analysis and risk assessment system shall be regularly reviewed, at least annually, and / or in the event of changes to raw materials, wrapping materials, production / conversion process, formulas / configuration, products, infrastructure and / or equipment, to assure that product requirements are complied with.	• Is the hazard analysis and risk assessment system reviewed at least annually? • How are product development / product modification and the hazard analysis and risk assessment system interconnected? • Have changes occurred since the last review? If so, What were the changes? Was the hazard analysis and risk assessment system reviewed due to the changes?
2.2.2	**Hazard analysis and risk assessment team**	
2.2.2.1	**Assemble hazard analysis and risk assessment team** The hazard analysis and risk assessment team shall be multidisciplinary and include operational staff. Personnel appointed as hazard analysis and risk assessment team members shall have specific knowledge of hazards and risks associated to products and processes.	• Who are members of the team? • Which personnel / departments are included in the team? • How was qualification for team membership verified? • What hazards are connected to the products and processes?
2.2.2.2	Those responsible for the development and maintenance of the hazard analysis and risk assessment system shall have received adequate training in the application of the hazard analysis and risk assessment principles. An internal team leader shall be designated.	• Were those responsible trained in the application of the hazard analysis and risk assessment principles? • When was the last training course held? • What were the contents of the training course? • How was the knowledge verified?

No.	IFS PACsecure Requirements	Guidance
2.2.3	**Hazard analysis and risk assessment**	
2.2.3.1	**Describe product** A full description of the product including all applicable relevant information on product requirements shall exist, such as: • composition (raw materials, rework, reprocessing, recycled materials, plant based materials, functional additives, etc.) • physical, sensory, chemical, functional and microbiological characteristics • legal requirements in regard to product safety and quality • methods of treatments • wrapping and labelling • durability (converting time) • conditions for storage, method of transport and distribution	• Does a complete product description exist for each product? • What is included in the product description? • Is the information provided in the product description / specification updated and verified according to product requirements? • Are converting times justified?
2.2.3.2	**Identify intended use** The intended use of the product shall be described in relation to the expected use of the product by the customer, and also by consumers when: • Products are intended to be sold to consumers • There is no subsequent transformation process that changes the characteristics and / or intended use of the product after it is sold to the customers. When consumers shall be considered, possible misuse and vulnerable groups shall be taken into account.	• What is the intended use of the product(s) by the customers? • When consumers are considered, What is the intended use of the product(s) by the consumers? Has misuse and vulnerable groups been taken into account? • Are there any restrictions for usage? ***Additional explanation*** *Examples of products with no changes after they are sold to the customers: pizza boxes, hamburger clamshell, etc.*

No.	IFS PACsecure Requirements	Guidance
2.2.3.3	**Construct flow diagram** A flow diagram shall exist for each product, or product group, and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall be dated, and after the determination of control measures, clearly identify each CCP and other control measures. In the event of any changes, the flow diagram shall be updated.	• Are flow charts available for all products? • Are the flow charts dated? • Are other control measures, and CCPs, if existing, identified in the flow chart? • Are flow charts up-to date?
2.2.3.4	**On-site confirmation of the flow diagram** The hazard analysis and risk assessment team, or their defined representatives, shall verify the flow diagram by on-site verifications at all operation stages and shifts. Where appropriate, amendments to the diagram shall be made.	• Was the flow chart verified on-site?
2.2.3.5	**Conduct a hazard analysis and risk assessment for each step**	
2.2.3.5.1	A hazard analysis and risk assessment shall be conducted for all possible and reasonably expected physical, chemical (including radiological and allergens) and biological hazards. The hazard analysis and risk assessment shall include the hazards linked to the materials in contact with the product, wrapping materials, work environment, and also any other relevant risk related to product requirements.	• Does a hazard analysis and risk assessment exist for each step? • Are all hazard and relevant risks included? • Which biological, physical and chemical hazards (including radiological and allergens) can be expected? • How was the hazard analysis performed?
2.2.3.5.2	The hazard analysis and risk assessment shall consider the likelihood of adverse effects for the consumer and the potential severity of these adverse effects. Consideration shall be given to specific control measures applied which are relevant for controlling each hazard and risk identified.	• Does a hazard analysis for all product groups including harm and likelihood exist? • Which controls are relevant in regard to the hazards and risks identified.

No.	IFS PACsecure Requirements	Guidance
2.2.3.6	**Determine Critical Control Points (CCP) and other control measures**	
2.2.3.6.1	The determination of relevant CCP's and other control measures shall be facilitated by the application of a decision tree or other tool(s) which demonstrates a logical reasoned approach. The determination of relevant CCP's and other control measures shall be justified and documented.	• How were the CCPs and other control measures determined? • Which CCPs and other control measures were defined? • How many CCPs and other control measures exist? • Are the determination of CCP's and other control measures justified and documented?
2.2.3.7	**Establish limits for each CCP and other control measures**	
2.2.3.7.1*	For each CCP, the appropriate critical limits shall be defined and validated to clearly identify when a process is out of control. Validation of limits defined for each CCP shall be documented.	• Is a critical limit defined for each CCP? • What critical limits are defined? • How were the limits determined? • Have the limits been validated? **Note:** In case no CCP has been determined, this requirement can be scored as N / A.
2.2.3.7.2	For other control measures defined, appropriate limits shall be determined.	• Is a clear limit defined for the other control measures defined? • How were the limits determined?
2.2.3.8	**Establish a monitoring system for each CCP and other control measures**	
2.2.3.8.1* KO No. 2	**Specific monitoring procedures in terms of method, frequency of measurement or observation, and recording of results, shall be established for each CCP to detect any loss of control at that CCP. Each defined CCP shall remain under control. Monitoring and control of each CCP shall be demonstrated by records. The operative personnel in charge of the monitoring of CCP's shall have received specific training / instruction. Records of CCP monitoring shall be verified by a responsible person within the company and maintained for a relevant period.**	• How are CCPs monitored? • Are the CCPs under control? • How is the monitoring of each CCP documented? • Are methods, frequency of measurement or observation, and result of monitoring documented? • Who is responsible for monitoring of the CCPs? • Has the person responsible for monitoring been trained in relation to these activities? • Is the person responsible for monitoring aware about what should be done in case the limits are not under control? • Who is responsible for the verification of CCPs monitoring records? • How long will records be stored? • Where are the records stored? **Note:** In case no CCP has been determined, this requirement can be scored as N / A.

No.	IFS PACsecure Requirements	Guidance
2.2.3.8.2	Control measure other than CCP shall be monitored, recorded and controlled by measurable or observable criteria. Records of monitoring shall be maintained for a relevant period. The operative personnel in charge of the monitoring of these control measures shall have received specific training / instruction.	• How are other control measures monitored? • Are the other control measures under control? • How is the monitoring of other control measures documented? • Are method, frequency of measurement or observation, and result of monitoring documented? • Who is responsible for monitoring of the other control measures? • Has the person responsible for monitoring been trained in relation to these activities? • Is the person responsible for monitoring aware about what should be done in case the limits are not under control? • How long will records be stored? • Where are the records stored?
2.2.3.9	**Establish corrective actions**	
2.2.3.9.1	In the event that the monitoring indicates that a particular CCP or a control measure other than CCP related to product safety is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any action taken relating to non-conforming products and identify the root cause for the loss of control.	• What corrective actions exist? • When was a corrective action carried out? • Where are corrective actions documented? • Who documents the taken corrective actions?

No.	IFS PACsecure Requirements	Guidance
2.2.3.10	**Establish verification procedures**	
2.2.3.10.1*	Procedures of verification shall be established to confirm that the hazard analysis and risk assessment system is working correctly. Verification of the hazard analysis and risk assessment system shall be performed at least once per year. Examples of verification activities include: • results of internal audits and site factory inspections • analyses • sampling • complaints by authorities and customers • deviations The results of this verification shall be incorporated into the hazard analysis and risk assessment system and shall be communicated to and reviewed by the senior management.	• How often is the system verified? • What was the date and result of the last verification? • What kind of activities were considered in the last verification? • Does the system reflect the results of the verification? • On what date was the system last changed?
2.2.3.11	**Establish documentation and record keeping**	
2.2.3.11.1	Documentation related to the hazard analysis and risk assessment system shall be in place. Examples of documentation include: • hazard analysis and risk assessment • determination of CCPs and other control measures • determination of critical limits • processes, procedures • results of hazard analysis and risk assessment system verification. Records examples: • outcome of CCPs and other control measures monitoring activities • training records of the operative personnel in charge of the monitoring of CCPs and other control measures • observed deviations and implemented corrective actions.	• What hazard analysis and risk assessment system related documents exist? • Do these documents include processes, procedures and results?

No.	IFS PACsecure Requirements	Guidance
3	**Resource management**	
3.1	**Human resources**	
3.1.1	All personnel performing work that affects product safety, quality and legality shall have the required competence, appropriate to their role, as a result of education, work experience and / or training.	• How are the competencies determined? • How is it assured that new employees have the right capabilities for the job?
3.1.2	The responsibilities, competencies, including deputation of responsibility, for each job position that has an impact on product requirements shall be clearly defined, documented and in place. Assignment of key roles shall be defined. Employees shall be able to demonstrate that they understand their responsibilities.	• Where are the described competencies, responsibilities and deputation of responsibility for each job position? • Do deputation regulations exist for all important functions? • How is the deputation of responsibilities organised? • How does the company ensure that all tasks related to product safety and quality are assigned to specific employees and that they are properly fulfilled by these employees? • How do employees know their responsibilities?

No.	IFS PACsecure Requirements	Guidance
3.2	**Personal hygiene**	
3.2.1*	Based on hazard analysis and assessment of associated risks, the requirements for personal hygiene shall consider, at a minimum, the following topics: • coverage of hair and beards • protective clothing (including their condition of use in productive areas and staff facilities) • hand washing, disinfection and hygiene • eating, drinking and smoking • actions to be taken in case of cuts or skin abrasions • fingernails, personal belongings (including medicines), and prohibition to use jewellery • notification of infectious diseases and conditions impacting product safety via a medical screening procedure, subject to legal restrictions in the country of operation. The requirements relating to personal hygiene shall be documented and in place.	• Do the rules regarding personal hygiene include all topics listed and are they based on a hazard analysis? • What kinds of hair restraints are needed and in which areas? • What kind of protective clothing is used? If disposable garments are used, when and where are they used? How are they disposed of? • How is protective clothing handled during breaks / intervals (e.g. in catering areas, changing rooms, etc.)? • Is smoking allowed? If so, where is it allowed? • Which are the infectious diseases and conditions that shall be notified? • How is it ensured that personnel, contractors and / or visitors know and are aware of the notification? • What is defined in the medical screening procedure? • How should lesions be treated / covered? ***Additional explanation*** • *Examples of protective clothing: suits, overalls, smocks, jackets, aprons, sleeves, among others. It also includes disposable garments (e.g. shoe covers, coveralls) and personal protective elements (e.g. hard hats, earplugs, face masks with filters, reusable gloves).* • *Fingernails include the usage of varnishes, acrylic nails, etc.* • *Jewellery includes watches, earrings, necklaces, piercings, wedding bands, etc.* • *Personal belongings include medicines, keys, mobile phone, etc.* • *Some examples of the result from the hazard analysis and assessment of associated risks are*: *(1) The usage of glove is required. If so, control activities shall be in place to prevent product contamination due to its misuse (e.g. glove colour shall contrast with product colour, check gloves condition)* *(2) The usage of headgear is required. Considerations: If so, control activities shall be in place to prevent product contamination due to its misuse (e.g. check if the headgear covers the hair completely)* *(3) The usage of wedding bands is allowed as an exception (after evaluation and justification). If so, relevant control activities shall be in place to avoid product contamination due to the exception.*

No.	IFS PACsecure Requirements	Guidance
3.2.2* KO No. 3	**The requirements for personal hygiene shall be in place and applied by all relevant personnel, contractors and visitors.**	• How are the hygiene requirements communicated to personnel, contractors and visitor? • How is it assured that personnel, contractors and visitors know, understand and follow the relevant hygiene rules?
3.2.3	Compliance with personal hygiene requirements shall be checked regularly.	• How are employees monitored during work? • Is employee compliance to hygiene rules checked on a regular basis?
3.2.4	Cuts and skin abrasions shall be covered by a colored plaster / bandage which contrasts with the product color. Where appropriate: • plasters / bandages shall contain a metal strip • single use gloves shall be worn.	• What color is the plaster and where is it used? • When metal detectors are used, Does the bandage contain a metal strip? Is the metal detector able to detect the bandage? • What is an employee required to observe in case of a hand injury?
3.2.5*	Suitable protective clothing shall be available and in sufficient quantity for each employee.	• Is protective clothing given to the personnel? If so, how many? • What are the rules regarding protective clothing? • How often is an employee supposed to change his / her protective clothing?
3.2.6	When required, all protective clothing shall be thoroughly and regularly laundered. The company shall determine if clothing shall be washed by a contract laundry, on-site laundry or by the employee, and the decision shall be justified by risk assessment. Defined requirements shall ensure, at a minimum: • sufficient segregation between dirty and clean clothing at all times • avoidance of contamination until use The effectiveness of the laundering conditions defined shall be appropriately monitored.	• What kind of protective clothing and is it laundered? At what frequency? • How is protective clothing laundered? • Is the decision on who washes the protective clothing determined by a risk assessment? • In case of employees laundering their protective clothing at home, are there any instructions for this activity (e.g. laundry conditions, how to transport protective clothing to the site) • How is dirty and clean protective clothing segregated? • How is the contamination of clean protective clothing avoided? • How is the effectiveness of the laundering monitored?
3.2.7	In case the personnel, contractors and / or visitors have infectious diseases and / or conditions that may have an impact on product safety, actions shall be taken to minimise contamination risks.	• How shall personnel and visitors behave in case of the presence or suspicion of an infectious disease? • What kind of actions are taken when these issues are notified by the personnel, contractors and / or visitor? • Have restrictions for external personnel been implemented? • How is it ensured that personnel and visitors know the guidelines?

No.	IFS PACsecure Requirements	Guidance
3.3	**Training and instruction**	
3.3.1*	The company shall implement documented training and / or instruction programs with respect to the product and process requirements and the training needs of the employees based on their job and shall include: • training objectives • training contents • training frequency • employee's task • languages • qualified trainer / tutor There shall be a procedure or program in place to prove the effectiveness of the training and / or instruction programs, in relation to the accomplishment of the training objectives.	• Who is responsible for training? • Which training were conducted last year? • Is there any evidence for training carried out in-house and externally? • Are evidence of the trainer qualification kept? • How are foreign / temporary employees trained / instructed? • Who participates in the training sessions? • How does it identify the training needs? • How often are training sessions held? • How is the effectiveness of the training and / or instruction programs checked? • When training and / or instruction programs are not effective, what kind of corrective actions are taken?
3.3.2*	The documented training and / or instruction shall apply to all personnel, including seasonal and temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained / instructed in accordance with the documented training / instruction programs.	• Are prospective employees (including seasonal and temporary workers) trained / instructed upon employment? • Which employees are trained / instructed upon employment? What is the content of these instructions? • Is an introductional training plan implemented for all relevant employees?
3.3.3	Records shall be available of all training / instruction events, stating: • list of participants (this shall include their signature) • date • duration • contents of training • name of trainer / tutor.	• When did the last training take place? • Are all training evidences comprehensive? • Do all records contain all necessary information?

No.	IFS PACsecure Requirements	Guidance
3.3.4	The contents of training and / or instruction shall be regularly reviewed and updated when necessary. Special considerations shall be given as a minimum to these specific topics: • product safety culture • product safety, quality and legal requirements • product fraud, • product defence, • product / process modifications, • complaints and non-conformities related to product compliance and its impact on customers (and consumers, if applicable) • feedback from the previous documented training / instruction program.	• Who is responsible for the review and update? • How are the training contents reviewed and updated? • When was the latest training content review and update done? • Are the listed topics included in the contents of training and / or instruction?
3.4	**Staff facilities**	
3.4.1*	The company shall provide suitable staff facilities, which shall be proportional in size, equipped for the number of personnel and designed and operated so as to minimise product safety risks. Such facilities shall be kept in a clean and good condition.	• How many employees are there? • Do they have access to a cafeteria? • Are there locker-rooms? • Where are the restrooms? • Are there bathing facilities? • Are there locker-rooms for employees and visitors with separation for outdoor and protective clothing? • Do locker-rooms give direct access to processing areas? ***Additional explanation*** *Examples of staff facilities are: changing room, smoking area, dining room, etc.*
3.4.2	The risk of product contamination by food, drink and / or foreign material from staff facilities shall be evaluated and minimised. Consideration shall be given to food and drink from vending machines, canteen and / or brought to work by personnel.	• May employees bring food and other material from home? • May employees take medicine to their work place? • Does a hazard analysis exist regarding foreign material from staff facilities?

No.	IFS PACsecure Requirements	Guidance
3.4.3	Changing rooms shall be located to allow direct access to the areas where products are handled. If this is not possible, control activities justified by risk assessment shall be in place to minimise product contamination risks. Where necessary, outdoor clothing and protective clothing shall be stored separately.	• Do locker-rooms give direct access to processing areas? • Does a risk assessment exist for changing rooms with no direct access to processing areas? • Are there locker-rooms for employees and visitors with separation for outdoor and protective clothing?
3.4.4	Toilets shall neither have direct access nor pose a contamination risk to an area where products are handled. The toilets shall be equipped with hand washing facilities. Sanitary facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.	• Do toilets not have direct access nor pose a contamination risk to an area where products are handled?
3.4.5*	Hand hygiene facilities shall be provided and shall address, at a minimum: • sufficient number of wash basins, • suitably located at access points to and / or within production areas, • sole use for cleaning hands only. Where similar equipment is needed in further areas (e.g. storage area), these shall be based on hazard analysis and assessment of associated risks.	• Are there enough hand hygiene facilities available at the entrance to processing areas and in staff areas?
3.4.6	Hand hygiene facilities shall provide: • running potable water at an appropriate temperature, • appropriate cleaning and disinfection equipment, • appropriate means for hand drying.	• Are all hand hygiene facilities provided with appropriate cleaning and disinfection equipment and appropriate means for hand drying? • Are all hand washing facilities provided with running potable water at an appropriate temperature?

No.	IFS PACsecure Requirements	Guidance
3.4.7	Where the processes require a higher standard of hygiene, the hand washing equipment shall provide in addition: • hand contact-free fittings, • hand disinfection, • waste container with hand contact-free opening.	• Are all areas where extended hygiene requirements are necessary due to risk assessment, equipped with hand contact-free fittings, hand disinfection and waste container with hand contact-free opening?
3.4.8	Based on hazard analysis and assessment of associated risks, a program shall be in place to control effectiveness of hand hygiene.	• Does the company have a program to control the effectiveness of hand hygiene? • Is this program based on hazard analysis and risk assessment in relation to products and processes?
3.4.9	Where it is justified by risk assessment, cleaning and disinfection facilities shall be available and used for boots, shoes and further protective clothing.	• Are there cleaning facilities for boots and protective aprons?

No.	IFS PACsecure Requirements	Guidance
4	**Operational processes**	
4.1	**Contract agreement**	
4.1.1	The requirements defined between the company and its customers shall be established, agreed upon and reviewed concerning their acceptability before the supply agreement is concluded. All requirements related to product safety and quality within defined agreement with customers, and any revision of these clauses, shall be communicated to and implemented by each relevant department.	• Who conducts the requirements review? • What assurances are given that customer requirements and specifications are in accordance with each other? • Do written supply agreements with customers exist? • Do specific customer requirements for purchased products exist? • How is it ensured that customers are informed about product changes? • In relation to the defined agreement, how are requirements related to product safety and quality communicated to relevant departments? ***Additional explanation*** *Some examples of topics that could be included in agreements are:* • *Handling or controlling of customer property,* • *Usage of and protection of trademarks and logos* • *Post-delivery activities associated with the products and service* • *Gang printing and usage of digital printing* • *Batched production and holding of product in stock* • *Specific requirements about raw materials, product formula / configuration, technological requirements, wrapping and / or labelling, product validation, outsourced processes, etc.* • *Definition of critical parameters to be controlled (e.g. in case of printing activities, text related to legal compliance in food safety).* *In regard to the customer property, the controls should comprise, as the minimum, its identification, verification and protection. Also, in case of loss, damage, or any issue over this property, the company shall inform the customer and take corrective actions.*
4.1.2	In accordance with customer requirements, the senior management shall inform their affected customers as soon as possible of any issue related to product safety or legality, including non-conformity / ies identified by competent authorities.	• How is it ensured that customers are informed about any issue related to product safety or legality?

No.	IFS PACsecure Requirements	Guidance
4.2	**Specifications and formulas / configurations**	
4.2.1	**Specifications**	
4.2.1.1	A procedure to control the creation, approval and amendment of specifications and formulas/ configurations shall be in place and shall include, where required, the acceptance of the customer(s). Where required by customers, specifications, formulas/configurations shall be formally agreed. This procedure shall include: • the review and update of specifications in case of changes related to raw materials, formulas/configurations process, wrapping material, legal and/or customer requirements, when applicable. • how to communicate the information and its changes inside the company and, when applicable, to the customer. • the management of customers' specifications and the protection of its information, when existing.	• What minimum content has been determined for specifications? • Who writes, amends, checks and approves specifications and formulas/configurations? • Do customers require a formal agreement on product specifications? If so, what products are concerned? • How are finished product specification updated? • How are customer specifications checked for correct entry into the company's systems, and protected to prevent loss of information? • How is the information and its changes communicated inside the company and, when applicable, to the customer? • If existing, how are customer specifications and the protection of this information managed?
4.2.1.2* KO No. 4	**Specifications shall be available and in place for all raw materials. Specifications shall be up to date, unambiguous and be in compliance with legal requirements and, if existing, with customer requirements.**	• Are specifications available for all raw materials? • What assurance is given that specifications are followed? • What assurance is given that specifications are in conformance with legal requirements and, if existing, with customer requirements? • How is it identifiable that specifications are up to date?
4.2.1.3*	Specifications shall be available and in place for all finished products. They shall be up to date, unambiguous and be in compliance with legal and customer requirements.	• Are specifications available for all finished products? • What assurance is given that specifications are followed? • What assurance is given that specifications are in conformance with legal requirements and, if existing, with customer requirements? • How is it identifiable that specifications are up to date?

No.	IFS PACsecure Requirements	Guidance
4.2.1.4	Specifications and / or their components shall be available on-site for all relevant personnel.	• How are the specifications or their components shared with the relevant personnel? • Is the content of specifications available on-site for the relevant personnel? • Who has access to specifications?
4.2.1.5*	A procedure shall be in place to verify and ensure, when applicable: • the fulfilment of specific customer requirements related to the exclusion of certain methods of treatment or production (e.g. GMOs), or the absence of specific components or ingredients (e.g. free-from Bisphenol A, phthalates, allergens, etc.). • the clearness, accuracy and truthfulness of claims according to the intended use of products, by means of scientific evidence and the relevant tests / analysis.	• Does the customer have specific requirements related to the exclusion of certain methods of treatment or production, or the absence of specific components or ingredients? • Have these specific requirements been included in specifications? • Has the company implemented procedures to verify and ensure these specific customer requirements? • How are claims verified and ensured by the company? • What kind of tests / analysis and scientific evidence are available to support claims? **Note:** In case there are no specific customer requirements, nor claims, the requirement can be scored as N / A. ***Additional explanation*** *Some examples of claims are: recycled material; plant-based material; functional additives; specific functions like shelf life extension, improvement of product conditions, track and/or trace of parameters in products, among others.*

No.	IFS PACsecure Requirements	Guidance
4.2.2	**Formula / configuration**	
4.2.2.1* **KO No. 5**	**Where there are customer agreements related to:** • **product formulation / configuration** • **process and technological requirements** • **labelling** • **wrapping** **they shall be complied with.**	• What assurance is given that specified formula / configuration is followed? • How is compliance with technological requirements checked? **Note:** If no specific technological requirements and / or formulas are agreed between the company and the customer, the formula of the supplier is the basis. In this case the requirement can be scored as N / A. ***Additional explanation*** • *"Technological requirements" are applicable to processes; therefore, comprises all the activities and parameters connected to the manufacturing process and the application of this specific technology (e.g. offset, flexography, dry transfer and other technologies used in printing process).* • *Examples of customer agreement about wrapping and labelling are when the customer uses automatic lines which requires a specific wrapping and labelling configuration; or wrapping with an additional condition (e.g. gas injection to remove oxygen), among others.*

No.	IFS PACsecure Requirements	Guidance
4.3	**Product development, product modification, and / or modification of production / conversion processes**	
4.3.1	For each new development of products, a hazard analysis and assessment of associated risks shall be conducted. In the case of modification of products, of production / conversion processes and / or formulas / configuration, the company shall review the hazard analysis and risk assessment to ensure the fulfilment of product requirements. When applicable, necessary changes shall be made.	• Are hazard analysis and assessment of associated risks available for new developments? • Are the hazard analysis and risk assessment (related to chapter 2) reviewed in case of modifications? ***Additional explanation*** *Some examples where the company should review the hazard analysis and risk assessment are:* • *A company that produces generic labels with the artwork provided by the customers, but the customer will modify one of the generic labels due to the inclusion of critical information (e.g. specific legal text). Topics like artwork modification, control of printing (e.g. misprinting of the legal text) among others, should be reviewed.* • *A company which produces corrugated cardboard will modify the additives of adhesives for enhancing the drying properties of corrugated boards. Topics like the drying rate and production speed in the conversion process, control of adhesive formula, among others, should be reviewed.*
4.3.2*	The product development, product modification and modification of production / conversion process shall result in specifications about formulation / configuration, wrapping requirements, production / conversion processes (including printing) and process parameters related to the fulfilment of product requirements. Factory trials and product test / analysis shall be established to ensure product requirements are complied with. The progress and results of the product development / modification and modification of production / conversion process shall be recorded.	• Are specifications developed about formulation / configuration, wrapping requirements, production / conversion processes (including printing) and process parameters related to the fulfilment of product requirements? • What factory trials and product test / analysis are made while a product is developed and / or a process is modified? • Is the developed product submitted to trial runs and product testings? • Are records of progress and results of the product development / modification and modification of production / convertion process available?

No.	IFS PACsecure Requirements	Guidance
4.3.3*	When the company has printing processes, a system to manage the development, modification and usage of artwork shall be implemented and maintained. This system shall comprise the following elements, at a minimum: • responsibilities and activities related to the management of artwork and customer-approved reference material between the company and customer. • approval of final artwork, of product concepts, of printing specifications and the identification of critical information, by the customer, when applicable. • Usage and storage conditions of approved artwork master, customer-approved reference material and printing materials, in order to avoid their degradation, misuse and loss. • management of renewal, changes and obsolescence of artwork masters, customer-approved reference material and printing materials, including their disposal.	• Does the company have printing activities? • Does the company maintain a system to manage the development and / or modification of artwork? • Who is responsible for the management of artwork and customer-approved reference material, if applicable? • Who is responsible for the final artwork, product concepts and for the identification of critical information by the customer? How is this approval carried out? • How is the critical information of the customer identified? • What kind of control activities are in place to ensure the approved artwork, printing equipment, and printing specifications corresponds to the product to be printed? • How are managed the renewal, changes and obsolescence of artwork masters, customer-approved reference material and printing materials? ***Additional explanation*** *Some examples of critical information are: food ingredient list(s), allergens, claims, identification code, among others.*
4.3.4	Conversion time tests or validation through physical, sensory, chemical, functional and microbiological evaluation shall be carried out and consideration shall be given to product formulation / configuration, wrapping material, manufacturing, and declared conditions. In accordance with this evaluation, the conversion time shall be established.	• Are conversion time tests executed? • What kind of evaluations and validations are carried out? • How is the conversion time determined? • How are converting recommendations and / or product use information established? • How are converting requirements taken into consideration during product development?
4.3.5*	A procedure shall be in place to ensure that the finished product complies with current legislation of the production and destination countries, and customer requirements.	• What kind of procedure has been implemented to ensure product legislation compliance? • Export goes to which countries? • Which countries have special requirements?

No.	IFS PACsecure Requirements	Guidance
4.3.6	Recommendations for handling (e.g. storage conditions) and / or use of products (e.g. conversion time, intended use, etc.) shall be established, where appropriate.	• Has the company established any recommendations for handling the products? If so, how were they implemented? • Has the company established any recommendations regarding the usage of products? If so, how were they implemented?
4.3.7	In the event of changes to process characteristics or product formulation / configuration, including rework and / or wrapping materials, the company shall ensure that the product requirements are complied with. Labelling shall be reviewed and adapted when necessary.	• How are the changes controlled? • Who is responsible to authorise the changes? • How are the process characteristics reviewed to assure that product requirements are fulfilled? • What kind of actions are taken to prevent adverse impacts? • Who is responsible for label review?
4.4	**Purchasing**	
4.4.1*	The company shall control purchasing processes to ensure that all externally sourced raw materials, semi-finished products, wrapping materials and services, which have an impact on product safety and quality, conform to defined requirements.	• How is it ensured that purchased products and services conform to specifications?
4.4.2*	A procedure for the approval and monitoring of suppliers shall be in place. The approval and monitoring procedure shall contain clear assessment criteria, such as: • audits performed by an experienced and competent person • certificates of analyses • supplier reliability • complaints • required performance standards.	• Does an approval procedure exist for new suppliers? • How does the company inform the suppliers about the approval requirements? • How does the company handle the non-approved suppliers and ensure that no goods / services are procured from them? • How are supplies monitored? • Are suppliers graded? • How is the qualification of suppliers ensured? • Which criteria are included in the supplier assessment? • How often are assessments made? • Which supplier has analysis certificates? • How is supplier reliability assessed and measured? • Does the supplier reliability include complaints and non-conformities? • What kind of performance standards are requested?

No.	IFS PACsecure Requirements	Guidance
4.4.3*	The results from the supplier assessments shall be reviewed regularly and this review shall be justified by risk assessment. There shall be records of the reviews and the consequential actions of the assessment shall be documented.	• Who reviews the results of supplier assessments? • How often are the results of supplier assessments reviewed? • What actions are taken after a review of the results for supplier assessments?
4.4.4	The purchased raw materials, semi-finished products and wrapping materials shall be checked in accordance with the existing specifications and justified by risk assessment for their authenticity. The schedule of these checks shall take at a minimum, defined product safety and quality risks. The frequency and scope of sampling shall be based on: • the impact of the raw materials, semi-finished product and wrapping materials on the finished product • the supplier's status	• How does the company check the conformity of the products purchased? • How is the authenticity of products checked? • Does a sampling plan exist? • How is the frequency and scope of the sampling plan determined? • How is the supplier status identified? • What kind of impact does the supplier status have on the determination of frequency and scope of sampling plan?
4.4.5	The purchased services shall be checked in accordance with the existing specifications. The schedule of these checks shall take into account, at a minimum: • the defined service requirements, • the supplier status according to its assessment • the impact of the service on the finished product.	• How is the impact of the service on the finished product determined? • How does the company check the conformity of the services purchased? • At what frequency are the purchased services checked? • How is the supplier status identified? • What kind of impact does the supplier status have on the schedule of checks?

No.	IFS PACsecure Requirements	Guidance
4.4.6	Where a company outsources a part of product processing / conversion (including wrapping and / or labelling), the company shall have it documented in the product safety and quality management system and ensure control over such processes to guarantee that product safety and quality are not compromised. Control of such outsourced processes shall be identified and documented. There shall be evidence that, when required, the customer has been informed and has agreed to such outsourced process.	• Does the company have an outsourced process(es)? • Is the outsourced process(es) included in the product safety and quality management system? • What are the hazards / risk identified in the hazard analysis and risk assessment for the outsourced process(es)? • What are the specific controls defined to control each hazard and relevant risks identified for the outsourced process(es)? How are the controls carried out and documented? • At what frequency are the controls for the outsourced process(es) carried out? Who is responsible for controls? • If required, does the company have evidence that the customer was informed and did agree on the outsourced process(es)?
4.4.7	A written agreement shall be in place, covering the outsourced processes and describing any arrangements made in connection with it, including in-process controls, sampling and analyses.	• Is a written agreement in place for the outsourced process(es)? In relation to the written agreement: • Are the requirements for product safety, quality, legality and authenticity included? • Is the liability defined? • Are the mechanisms and time frame for informing of any issue related to the product compliance defined? • Are in-process controls, sampling and analysis, traceability and documents for the delivery included?

No.	IFS PACsecure Requirements	Guidance
4.4.8	The company shall approve the supplier of the outsourced processes through: • certification to IFS PACsecure or other GFSI recognised production of food packaging certification standard, or • documented supplier audit, performed by an experienced and competent person, and shall cover at least the requirements related to product safety, quality, legality and authenticity.	• Is the supplier of outsourced processes certified to IFS PACsecure or another equivalent GFSI standard certification? • Does the company request the renewal of the supplier certificate on a regular basis? • What kind of control activities has the company implemented to be aware of the certificate validity? • What actions has the company defined in case the supplier loses its certification? If the supplier of outsourced processes has no IFS PACsecure Certification, nor another equivalent GFSI standard certification: • Has the company conducted audits to the supplier? • Does the audit include, at a minimum, requirements for product safety, quality, legality and authenticity, process controls, and good manufacturing practices? • How are the audits documented? • Is there an action plan from the supplier audits? How are the follow-up of corrective actions carried out? • What are the requirements of competencies and audit experience defined for auditors who perform supplier audits? Is there evidence that defined requirements are fulfilled by the auditors performing supplier audits?
4.5	**Product wrapping**	
4.5.1*	Based on hazard analysis, assessment of associated risks and intended use, the company shall define the key parameters for the wrapping materials in detailed specifications complying with the current relevant legislation and other relevant hazards or risks. The company shall check and verify the suitability of the wrapping material used on products by means of the relevant test / analysis, such as: • sensory tests • chemical analysis • functional test • storage and distribution tests • migration test results.	• What materials are used for product wrapping? • Does a risk assessment determine the key parameters for the wrapping materials? • Which are the key parameters identified? • How is it ensured that wrapping materials have no negative effects on the product? • Is there any legal requirement applicable to the wrapping used? If so, are the legal requirements included in the specifications? • Are specifications available for wrapping materials used? • How is the suitability of wrapping materials checked and verified?

No.	IFS PACsecure Requirements	Guidance
4.5.2	For all wrapping material which could have an impact on products, certificates of conformity shall exist which attest conformance with legal requirements. In the event that no specific legal requirements are applicable, evidence shall be available to demonstrate that wrapping materials are suitable for use. This applies for wrapping material which could have an influence on raw materials, semi-finished and finished products.	• When required by legislation, are certificates of conformity in place? • Does the company have evidence available to demonstrate the suitability of wrapping materials?
4.5.3	The company shall ensure that the wrapping and labelling in use corresponds to the product being wrapped and complies with agreed customer product specifications. When applicable, special consideration shall be given to these specific issues: • label reprints • label and / or wrapping rework activities • suitability of reused containers or wrapping materials • Information to be added on labels when special transport or storage conditions for products are used. This shall be regularly checked and documented.	• What kind of control activities are taken to avoid mixing and wrong information in label reprints, and rework activities? • How are the containers reused verified? • Are there special transport or storage conditions for products that shall be included on labels? If so, Are these included?
4.6	**Factory location**	
4.6.1*	The company shall investigate the extent to which the factory environment (e.g. ground, air) may have an adverse impact on product safety and product quality. Where it is established that product safety and / or product quality is at risk of being compromised, appropriate control activities shall be implemented. The effectiveness of the implemented control activities shall be periodically reviewed (examples: extremely dusty air, strong smells).	• Does a location investigation exist? • Can a location have a negative influence on product safety and product quality? • What kind of control activities have been established if potentially damaging materials / substances are nearby? • Is efficiency of control activities regularly reviewed? • Who reviews the efficiency of the established control activities? • How is efficiency of established control activities reviewed?

No.	IFS PACsecure Requirements	Guidance
4.7	**Factory exterior**	
4.7.1	All external areas of the factory shall be clean, tidy, and maintained in good condition. Where natural drainage is not effective, a suitable drainage system shall be installed.	• Are factory exteriors tidy? • Are factory exteriors reviewed through internal audits? • 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?
4.7.2	Outdoor storage shall be kept to a minimum. Where goods are stored outside, it shall be justified by risk assessment to ensure that there is no risk of contamination or adverse effects on product safety and quality.	• Are goods stored outdoors? • What is stored outdoors? • What rules exist for outdoor storage? • Is outdoor storage justified by risk assessment?
4.8	**Plant layout and process flows**	
4.8.1	A site map covering all buildings of the production site shall be available. Plans shall be in place that clearly describe the process flow of: • finished products • raw materials • wrapping materials • personnel • waste • water.	• Is the site map available? • Does the site map cover all production site buildings? • Are plans available that describe the listed process flows? • In regard to the described process flows, Is cross-contamination avoided?
4.8.2*	The process flow from receipt of goods to dispatch, shall be established, reviewed and where necessary, modified to ensure that microbiological, chemical and physical contamination risks of raw materials, wrapping, semi-finished and finished products are avoided. The risk of cross-contamination, mix-ups and mixing, shall be minimised through effective control activities.	• Has the risk of cross-contamination, mix-ups and mixing been identified within factory premises and process flows? • How is the risk avoided within factory premises and process flows? • What kind of actions and control activities has the company implemented to minimise the identified risks? • How is the effectiveness of control activities checked?

No.	IFS PACsecure Requirements	Guidance
4.8.3	In the case of areas sensitive to microbiological, chemical and physical risk(s) which is / are justified by risk assessment, they shall be designed, operated and monitored to ensure product safety is not compromised.	• Are there sensitive areas? • What sensitive areas were defined? What were the risks identified? • What kind of controls are implemented? **Note:** In case of no sensitive areas, this can be scored as "N / A"
4.8.4	Laboratory facilities and in-process controls shall not affect product safety.	• Is there a laboratory on-site? • Does the lab have direct access to production premises? • Can lab waste (e.g. lab waste water) contaminate the production premises?
4.9	**Production and storage premises**	
4.9.1	**Constructional requirements**	
4.9.1.1*	Premises, where products are prepared, treated, processed and / or converted, wrapped and stored, shall be designed and constructed to ensure product safety.	• Are the premises designed and constructed to ensure product safety? • Are the premises in good condition?
4.9.2	**Walls**	
4.9.2.1	Walls shall be designed and constructed to prevent the accumulation of dirt, to reduce condensation and mould growth, and to facilitate cleaning. Walls shall be impervious, wear-resistant, and their surfaces shall be clean and in good condition, to minimise product contamination risks.	• Are walls mouldy? • How often are walls cleaned?
4.9.2.2	The junctions between walls, floors, and ceilings shall be clean, in good condition, and shall not pose contamination risks.	• Are junctions and corners clean and in good condition?
4.9.3	**Floors**	
4.9.3.1	Floor coverings shall be designed to meet production requirements, and to facilitate cleaning. Floors shall be impervious, wear-resistant, and their surfaces shall be clean and in good condition, to minimise product contamination risks.	• Are floors cleanable? • How often are floors cleaned?

No.	IFS PACsecure Requirements	Guidance
4.9.3.2	The hygienic disposal of water and other liquids shall be ensured. Drainage systems shall be easy to clean and designed to minimise the product contamination risks (e.g. entry of pests, transmission of odours, among others).	• How is water and other liquids disposal ensured? • How often are gullies cleaned?
4.9.3.3	Water or other liquids shall reach drainage without difficulties to minimise product contamination risks. Puddles shall be avoided.	• Are there water or other liquid puddles on the floors of production areas?
4.9.3.4	In product handling areas, machinery and piping shall be arranged to allow waste water, if possible, to flow directly into a drain.	• Where is machinery which produces a large amount of waste water located?
4.9.4	**Ceilings / Overheads**	
4.9.4.1	Ceilings (or, where no ceilings exist, the inside of roofs) and overhead fixtures (including piping, cableway, lamps, etc.) shall be constructed to minimise the accumulation of dirt and condensation, and shall not pose any physical and / or microbiological contamination risks.	• How often are ceilings cleaned?
4.9.4.2	Where false ceilings are used, access to the vacant area shall be provided to facilitate cleaning, maintenance and inspections for pest control.	• How often are false ceilings cleaned?
4.9.5	**Windows and other openings**	
4.9.5.1	Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in a clean and good condition.	• Can dirt accumulate on window sills?
4.9.5.2	Where there are contamination risks, windows and roof glazing shall remain closed and fixed during production.	• Are windows kept open?

No.	IFS PACsecure Requirements	Guidance
4.9.5.3	Where windows and roof glazing are designed to be opened for ventilation purposes, they shall be fitted with protective barriers to minimise the product contamination risk. If pest screens are utilised, they shall be maintained in good condition and clean.	• Are windows sealed with insect gratings? • Is the integrity of gratings regularly reviewed?
4.9.5.4	In areas where exposed products are handled (e.g. not covered or protected by wrapping), windows shall be protected against breakage.	• How are windows protected against breakage?
4.9.6	**Doors and gates**	
4.9.6.1	Doors and gates shall be maintained in a clean and good condition. They shall be constructed with materials which avoid: • splintering parts • flaking paint • corrosion.	• Are doors damaged?
4.9.6.2	External doors and gates shall be constructed to prevent the access of pests; if possible, they shall be self-closing.	• Do external doors prevent pest entrance into production areas?
4.9.6.3	Plastic strip curtains separating the internal areas shall be clean and in good condition.	• Are plastic strip curtains damaged?
4.9.7	**Lighting**	
4.9.7.1	All production / conversion, storage, receipt and dispatch areas shall have the levels of light according to the activities carried out.	• Is there a legal requirement applicable regarding lighting? • Which are the criteria defined by the company to determine light conditions? • How is this checked? • What is the assurance that all working areas have adequate levels of light according to the activities carried out?
4.9.8	**Air conditioning / Ventilation**	
4.9.8.1	Natural and / or artificial ventilation covering process / product needs shall be in place in all areas.	• If required due to product and / or process requirements, Is the air adequate in terms of volume, condition and / or quality? • How is ventilation reviewed?

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4.9.8.2	If ventilation equipment is installed, filters and other components shall be easily accessible and checked, cleaned or replaced as necessary.	• How are air filters maintained and cleaned?
4.9.8.3	Air conditioning equipment and artificially generated airflow shall not compromise product safety and quality.	• Is the use of air during production based on hazard analysis? • Are there production areas with under- or over-pressurization?
4.9.8.4	Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated.	• Are there areas where large amounts of dust are formed? • Do dust extraction devices exist in these areas?
4.9.9	**Water**	
4.9.9.1*	Water which is used as an ingredient in the production / conversion process or for cleaning shall be of potable quality at the point of use and supplied in sufficient quantity; this also applies to steam and ice used within the production / conversion area.	• Where does the water supply come from? (City supply, well water, tanker)? • Is water demand always covered?
4.9.9.2	Recycled water, which is used in the process, shall not pose contamination risk.	• For what purpose is water used in the company (staff facilities, cleaning procedures, product ingredient)? • 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?
4.9.9.3	The quality of water (including recycled water), steam or ice shall be monitored following a sampling plan based on hazard analysis and assessment of associated risks.	• Is the water, steam or ice used monitored? • What kind of piping system exists (e.g. ring-pipes, water-tanks)? • What is piping made from? • Is the analysis and sampling plan based on hazard analysis?
4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall neither be connected to the drinking water system nor allow the possibility of reflux to avoid contamination of potable water sources or the factory environment.	• Is drinking water system completely separated from non-potable water piping? • What other systems are there (e.g. used water, cooling water, water used for firefighting)? • Are water systems properly marked and where are they located? • Is reflux avoidance equipment installed wherever necessary?

No.	IFS PACsecure Requirements	Guidance
4.9.10	**Compressed air and gases**	
4.9.10.1*	The quality of air (including compressed air) that comes in direct contact with products or surfaces in direct contact with products, shall be monitored based on hazard analysis and assessment of associated risks. If gases are used, their safety and quality shall be demonstrated through a declaration of compliance and shall be suitable for the intended use.	• Is compressed air used in direct contact with products or surfaces in direct contact with products? • What kind of oil is used in the compressor? • What kind of filter is in use? • How often are filters changed? If compressed air is used: • What kind of hazard / risks has the company identified and assessed? • In regard to the identified and assessed hazard / risks, what kind of controls has the company implemented? If gases are used: • In which products / processes is the gas used? What for? • What are the characteristics relevant for product safety and quality? How is this monitored? • Is there a declaration of compliance for gases?
4.9.10.2	Compressed air shall not pose a risk of contamination.	
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 • dosage of cleaning and disinfection chemicals • the areas to be cleaned and / or disinfected • cleaning and disinfection frequency • documentation requirements • hazard symbols (if necessary).	• Who is in charge of cleaning and disinfection? • What kind of cleaning products and disinfectants are used? • Are the instructions for use in place? • What shall be observed when using different cleaning products and disinfectants? • Is the dosage of cleaning and disinfection chemicals defined and controlled? • What areas are cleaned and disinfected? • How often are areas cleaned and disinfected? • Where are cleaning and disinfection procedures documented? • Do hazard symbols exist? • Does a contract exist for external service providers? ***Additional explanation*** *Cleaning schedules can include SSOP's.*
4.10.2	Defined cleaning and disinfection methods shall be implemented, documented, monitored, and shall result in effectively cleaned premises, facilities and equipment.	• Where are the cleaning and disinfection methods documented? • How is their adequate implementation monitored? • How are the cleaning and disinfection methods validated?

No.	IFS PACsecure Requirements	Guidance
4.10.3	Monitoring records for cleaning and disinfection shall be available.	• How is cleaning and disinfection monitoring performed? • Who performs such monitoring? • How often is cleaning and disinfection monitoring performed? • Where are cleaning and disinfection monitoring records documented?
4.10.4	Only qualified personnel shall be allowed to undertake cleaning and disinfection. The personnel shall be trained and retrained to carry out the cleaning and disinfection schedules.	• Are cleaning personnel qualified? • How often are they trained? • Who trains them? • Are these training documented?
4.10.5	The effectiveness and safety of the cleaning and disinfection activities shall be verified and justified by risk assessment. The verification shall be based on an appropriate sampling schedule and shall consider: • visual inspection • rapid testing • analytical testing methods Resultant corrective actions shall be documented.	• How is the effectiveness and safety of the cleaning and disinfection activities verified? • Who performs these verifications? • How often are these verifications performed? • Where are these verifications documented? • When are corrective actions executed? • Who executes corrective actions? • Who reviews effectiveness of corrective actions? • Where are corrective actions documented?
4.10.6	Cleaning and disinfection schedules shall be reviewed and modified in the event of a change to products, processes, cleaning and disinfection activities and / or equipment, if necessary.	• When are cleaning and disinfection procedures validated? • Who adapts cleaning and disinfection procedures? • How often are cleaning and disinfection schedules changed?
4.10.7	The intended use of cleaning and disinfection utensils shall be clearly identified. Cleaning and disinfection utensils shall be used in a way that avoids contamination.	• How can the intended use of utensils be identified? • What kinds of control activities are in place to avoid the contamination of utensils? • Where are utensils stored?
4.10.8*	Safety Data Sheets and instructions for use shall be available for chemicals and cleaning and disinfection agents. Personnel responsible for cleaning and disinfection shall be able to demonstrate their knowledge of such instructions, which shall be always available on-site.	• Are current safety data sheets available for all chemicals and cleaning and disinfection agents? • How are instructions transmitted to personnel in charge of cleaning procedures? • Where and when can the instructions be inspected?

No.	IFS PACsecure Requirements	Guidance
4.10.9*	Cleaning and disinfection chemicals shall be clearly labelled, used and stored appropriately, to avoid contamination. The access to cleaning and disinfection chemicals shall be limited to authorised personnel.	• Are the chemicals labelled? • What kinds of control activities are in place to ensure chemicals are used according to instructions and intended use, to avoid contamination? • Where are chemical stored?
4.10.10	Cleaning and disinfection activities shall be carried out in periods of non-production. If this is not possible, these operations shall be controlled in order not to affect the products.	• When is the cleaning and disinfection activities carried out? • When cleaning and disinfection activities are carried out in periods of production; what kinds of controls are taken to ensure cleaning and disinfection activities do not affect the products?
4.10.11*	Where a company hires a third-party service provider for cleaning and disinfection activities, all requirements specified within section 4.10 shall be clearly defined in the service contract.	• Are cleaning and / or disinfection activities executed by external service providers? **Note:** If no third-party service provider has been hired, the requirement can be scored as N / A. **If a third-party service provider for cleaning and disinfection activities is hired:** • Where has the company defined the requirements for the third-party service provider?; are the relevant requirements included? • Does the contract include requirements about personal hygiene, declaration of health issues or infectious diseases, or any other control activities (e.g. access restrictions, training, etc.), in order to prevent any negative impact on products? • If absences of external personnel occur, what kind of actions are taken by the third-party service provider and the company? • Are requirements about personal hygiene, declaration of health issue or infectious disease, or any other control activities (e.g. access restrictions, training, etc.), included in the contract to prevent any negative impact on products? • How does the company monitor the execution of the hired activities? • How does the company verify the effectiveness of the hired activities? • Who is responsible for the monitoring and verification activities?; what are the competencies defined for the responsible person?

No.	IFS PACsecure Requirements	Guidance
4.11	**Waste management**	
4.11.1*	A waste management procedure shall be in place to avoid cross contamination.	• Has the company implemented a waste management procedure? • What kind of waste has the company defined? • What are the controls defined to manage the waste and avoid cross-contamination? • How is the waste collected and storage?
4.11.2	All local legal requirements for waste disposal shall be met.	• How is it ensured that current legal waste disposal requirements are met? • How is waste material disposed of?
4.11.3	Product waste and other waste shall be removed as quickly as possible from areas where the product is handled. The accumulation of waste shall be avoided.	• How often are product waste and other wastes removed from packaging material handling areas? • Who is responsible for waste removal?
4.11.4	Waste collection containers shall be clearly marked, suitably designed, in a good state of repair, easy to clean, and where necessary disinfected.	• What kind of waste exists? • What wastes are collected in separate containers? • When appropriate, are hands free openings utilised? • How are waste containers marked? • Can waste containers be easily cleaned? • How often are waste containers cleaned? • Are waste containers in a good state of repair? • If applicable, how are waste containers disinfected and how often?
4.11.5	Waste collection rooms and containers (including compactors) shall be maintained tidy, clean and in good condition to minimise pest attraction.	• Are the waste collection rooms and containers kept clean and tidy? • Are waste collection rooms protected from pests?
4.11.6	Waste shall be collected in separate containers in accordance with the intended means of disposal. Such waste shall be disposed of by authorised third parties only. Records of waste disposal shall be kept by the company.	• Is waste collected in separate containers regarding the intended means of disposal? • Who is responsible for waste disposal? • Is the waste disposed of by an authorised third party? • What kinds of waste disposal records exist? • Are records of waste disposal available?

No.	IFS PACsecure Requirements	Guidance
4.11.7*	A procedure to manage and control the disposal and / or destruction of trademark materials / products shall be in place. The procedure shall comply with legal requirements and customer agreements, when applicable. The disposal and / or destruction of trademark materials / products shall be recorded, and shall be included in the traceability system of the company	• 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? • Who is responsible for waste disposal and / or destruction of trademark materials? • How is traceability ensured?
4.12	**Foreign material risk mitigation**	
4.12.1	The products being processed shall be protected against physical contamination, which includes but is not limited to: • environmental contaminants • oils or dripping liquids from machinery • dust spills. Special consideration shall be given to product contamination caused by: • equipment and utensils, • pipes, • walkways, • platforms, • ladders. In the event that this is not possible due to technological characteristics and / or requirements, appropriate controls shall be defined and applied.	
4.12.2* KO No. 6	**Based on hazard analysis and assessment of associated risks, procedures shall be in place to avoid contamination with foreign materials. Contaminated products shall be treated as non-conforming products.**	• What kinds of foreign material may be found? • Where are sources of foreign material identified through hazard analysis? • Are staples used? • How are contaminated products handled?

No.	IFS PACsecure Requirements	Guidance
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.	• Where are the foreign material detectors installed? • How are the metal parts found in the product? • What effects do the shape, position and type of metal have on the detection? • Has the position of the test sample been correctly chosen? • Is the text sample size and material appropriate for the product? • Has the functioning of the metal detector been validated regarding products, processes and processes condition?
4.12.4	The accuracy of all equipment and methods designed to detect and / or eliminate foreign materials shall be specified. Functionality checks of such equipment and methods shall be carried out regularly. In case of malfunction or failure, corrective actions shall be defined, implemented and documented.	• How often are detector accuracies checked? • Who checks functionality and accuracy of equipments? • What corrective actions exist when a detector is defective? • Are corrective actions verified? • Are operational defects documented?
4.12.5	Potentially contaminated products shall be isolated. Access and actions for the further handling or checking of these isolated products shall only be carried out by authorised personnel according to defined procedures. After this check, contaminated products shall be treated as non-conforming products.	• Are contaminated products automatically isolated? • Who may handle / has access to isolated products? • How are isolated products handled?
4.12.6	In areas where raw materials, wrapping materials, semi-finished and finished products are handled, the use of glass and / or brittle materials shall be excluded; however where the presence of glass and / or brittle materials cannot be avoided, the risks shall be controlled and the glass and / or brittle materials shall be clean and pose no risks to product safety.	• Does a hazard analysis exist concerning contamination through glass? • Where is glass used in the plant? • How is glass protected from breakage?

No.	IFS PACsecure Requirements	Guidance
4.12.7	Based on hazard analysis and assessment of associated risks, preventive measures shall be in place for the handling of all kinds of containers used in production / conversion processes (including wrapping materials) which are made of glass or brittle material. After this process step there shall be no further contamination risks.	• Has a hazard analysis been performed? • What preventive measures are in place?
4.12.8	Procedures shall be in place describing the measures to be taken in case of glass breakage and / or brittle material. Such measures shall include identifying the scope of goods to be isolated, specifying authorised personnel, cleaning the production environment and releasing the production line for continued production.	• What is done in case of glass breakage? • What should be taken into account? • Who cleans the production environment? • Who permits production continual?
4.12.9	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.	• Is every glass breakage documented? • Where is glass breakage documented? • Are there exceptions to documentation? • Are exceptions justified?
4.12.10	In areas where raw materials, wrapping materials, semi-finished and finished products are handled, the use of wood shall be excluded; however where the presence of wood cannot be avoided, the risks shall be controlled and the wood shall be clean and pose no risk to product safety.	• Under what circumstances is the use of wood allowed? • Is the wooden tool in use in a good and clean condition? • Where is the use of wood allowed and what kinds of conditions were defined for this? • Are the wooden surfaces / tools in use in good conditions (clean, free from splinters or other sources of physical contamination)? • Who inspects and how often is the condition of the wooden tool inspected? • Are pallets checked to verify that they are clean, sound, dry, free from damage and contamination?
4.12.11*	Where visual inspection is used to detect foreign materials, the employees shall be trained and operative changes shall be performed at an appropriate frequency to maximise the effectiveness of the process.	• Where are visual inspections carried out? • What different kinds of visual inspections exist? • Which influences shall it take into account? • At what frequency are the operative changes carried out? • How has the effectiveness of the process been checked?

No.	IFS PACsecure Requirements	Guidance
4.13	**Pest monitoring and control**	
4.13.1	Site infrastructure and operations shall be designed and built to prevent pest infestation.	
4.13.2*	Based on hazard analysis and assessment of associated risks, the company shall have adequate pest control activities in place which shall be in compliance with local legal requirements and shall take into account, at a minimum: • factory environment (potential pests) • type of raw material / finished products • site plan with area for application (bait map) • constructional designs susceptible for pest activity, such as ceilings, cellars, pipes, corners • identification of the baits on-site • responsibilities, in-house / external • agents used and their instructions for use and safety • frequency of inspections • rented storage if applicable.	• How is pest control organised? • Which pests are controlled? • Which kinds of baits are used? • Is product contamination through baits prevented? • Who is responsible for pest control? • What is the inspection schedule?

No.	IFS PACsecure Requirements	Guidance
4.13.3	Where a company hires a third-party service provider for pest control, all requirements specified above shall be clearly defined in the service contract, to prevent any negative impact on products. A person at the company shall be appointed and trained to monitor the pest control activities. Even if the pest control service is outsourced, responsibilities of the necessary actions (including ongoing supervision of pest control activities) shall remain within the company.	• Is pest control executed by own staff members? • Who is responsible for pest control? • What kind of training does the responsible person have? • Is pest control executed by an external service provider? • Where has the company defined the requirements for the third-party service provider?; are the relevant requirements included? • What kind of training does the external service provider have? • Does the contract include requirements about personal hygiene, declaration of health issue or infectious disease, or any others measures (e.g. access restrictions, training, etc.), in order to prevent any negative impact on products? • If absences of external personnel occur, what kind of actions are taken by the third-party service provider and the company? • Are control activities to manage the incidents and / or potential emergency situations which could have an impact on the product requirements and / or the provision of services included in the contract? • How does the company monitor the execution of the hired activities? • How does the company verify the effectiveness of the hired activities? • Who is responsible for the monitoring and verification activities?; what are the competencies defined for the responsible person?
4.13.4	Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded. Any infestation shall be documented and control activities taken promptly.	• Where are inspections and resulting corrective actions documented? • Are documents signed and dated by both parties? • Which corrective actions were executed lately? • Are control activities defined in case an infestation occurs? What kind of control activities are defined? In the case of an intervention threshold, how is it notified and controlled? • Are the personnel aware of the need to report any evidence of plague to responsible person?
4.13.5	Baits, traps and insect exterminators shall be fully functioning, sufficient in number, designed for purpose, placed in appropriate positions and used in a way that avoids any contamination risks.	• Where are electrical fly killers installed? • Are all fly killers working correctly and connected?

No.	IFS PACsecure Requirements	Guidance
4.13.6	Incoming deliveries shall be inspected on arrival for the presence of pests. Any findings shall be recorded and control activities taken.	• Are incoming goods inspected for pest contamination? • Where is this documented? • Is pest presence documented? • What control activities are taken when pests are found? • Where are these control activities documented?
4.13.7	The effectiveness of the pest control activities shall be monitored, including trend analysis, to take actions as soon as possible. Records of this monitoring shall be available.	
4.14	**Receipt and storage of goods**	
4.14.1*	All incoming goods, including wrapping materials, shall be checked for conformity against specifications and to a determined inspection plan. The inspection plan shall be justified by risk assessment. Records of those inspections shall be available.	• What goods (including semi-processed products) are inspected when received? • What is checked when received? • Is receipt documented? • Who checks?
4.14.2	The storage areas of raw materials, wrapping materials, semi-finished and finished products, including loading / unloading areas to store and dispatch bulk goods, shall: • be clearly identified, • allow cleaning and inspection, • be clean and in good conditions to minimise the contamination risks or other negative impact (e.g. cross-contamination, mixing issues).	• Where are raw materials, semi finished products and wrapping materials stored? • How is contamination avoided? • Where and how are products and equipments stored? • How is contamination through products avoided? • How is the return of products to the storeroom regulated? • What kind of storage regulations exist? • Are pests taken into account during storage? • Are there baits laid out in storage rooms? • Are there sensitive products stored? • What kinds of control activities are in place for these goods?
4.14.3	Appropriate storage facilities shall be available for the management and storage of working materials, equipments, tools, process aids, and additives. The personnel responsible for the management of storage facilities shall be trained.	• How are chemicals stored? • Who uses chemicals and takes them out of storage? • How is equipment and its tools stored? • Is the equipment and its tools in a good condition of cleanliness? • Are the chemicals users trained? • Is training documented?

No.	IFS PACsecure Requirements	Guidance
4.14.4*	A system shall be implemented and maintained to manage the storage of raw materials, semi-finished, finished products and wrapping materials. It shall consider, at a minimum: • clear identification of all products • control activities to ensure the storage conditions correspond to product specification and shall not have any negative impact on other products • Usage of products in accordance with the principles of First In / First Out and / or First Expired / First Out. • how to proceed when converting time established or expiry date of products is exceeded • how to manage incoming goods, including wrapping materials, which have no converting time established or expiry date.	• What kind of control activities are carried out to ensure the storage conditions correspond to product specification? • How does the company proceed when the recommended converting time or expiry date is exceeded? • How does the company manage incoming goods, including wrapping materials, which have no converting time established or expiry date?

No.	IFS PACsecure Requirements	Guidance
4.14.5	Where a company hires a third-party storage service provider, the service provider shall be certified to IFS Logistics or any other GFSI recognised product safety certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own storage practices shall be fulfilled and this shall be clearly defined in the respective contract, to prevent any negative impact on products.	• Is storage leased to storage service provider? **Note:** if no third-party service provider has been hired, the requirement can be scored as N / A. **If a third-party storage service provider is hired:** • Does the third-party storage service provider have an IFS Logistics Certification or another equivalent GFSI standard certification? If the third-party storage service provider has no IFS Logistics Certification, nor another equivalent GFSI standard certification: • Where has the company defined the requirements for the third-party service provider?; are the relevant requirements included? • Are requirements about personal hygiene, declaration of health issue or infectious disease, or any other control activities (e.g. access restrictions, training, etc.), to prevent any negative impact on products included in the contract? • Are actions to manage the incidents and / or potential emergency situations which could have an impact on the product requirements and / or the provision of services included in the contract? • How does the company monitor the execution of hired activities? • How does the company verify the effectiveness of hired activities? • Who is responsible for the monitoring and verification activities?; what are the competencies defined for the responsible person?

No.	IFS PACsecure Requirements	Guidance
4.15	**Transport**	
4.15.1*	The transport vehicles used to transport goods shall be in good condition and shall protect the products from adverse weather conditions and external influences. The conditions of transport vehicles, such as: • cleanliness, • pests, • foreign materials (e.g. wood splinters, stones, organic contaminants, etc.), • strange odours, • surfaces, shall be checked before loading, and these checks shall be documented to ensure compliance with the specified conditions. When applicable, actions shall be taken to avoid any negative impact on products and to ensure compliance with the specified conditions.	• What is checked before loading? • Where is inspection documented? • What corrective actions are taken?
4.15.2	Procedures to prevent contamination during transport, including loading and unloading, shall be in place. This shall consider different categories of goods (e.g. products, wrapping materials, etc.).	• May goods be transported alongside non packaging material products? • How is contamination prevented?
4.15.3	Where goods shall be transported at certain conditions, these shall be checked and documented inside the vehicle before loading. The maintenance of these conditions during transport shall be ensured and documented.	• Are products which require certain conditions (e.g. humidity during paper transportation) being loaded? • Are vehicle conditions checked and documented before loading? • What procedures are to be followed when vehicle condition is not according to specifications or other legally required documentation? • How does the company ensure the compliance of conditions during transport? • How is it ensured that products reach destination in good conditions?
4.15.4	Hygienic requirements for all transport vehicles and equipment used for loading / unloading (e.g. hoses of silo installations) covering product and process needs shall exist. There shall be records of the control activities and actions taken.	• Are transport vehicles cleaned? • Where are cleaning procedures documented?

No.	IFS PACsecure Requirements	Guidance
4.15.5	The loading / unloading area shall be appropriate for its intended use. They shall be constructed in a way that: • the risks of pest ingress are mitigated • products are protected from adverse weather conditions and external influences • accumulation of waste is avoided • condensation and growth of mould are prevented • cleaning can be easily undertaken.	• How is the reception of goods organised? • How is loading organised? ***Additional explanation*** *Some examples of external influence are pollen, climate, etc.*
4.15.6	Where a company hires a third-party transport service provider, the service provider shall be certified to IFS Logistics or any other GFSI recognised product safety certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own transportation practices shall be fulfilled and this shall be clearly defined in the respective contract, to prevent any negative impact on products.	• Is transport leased to a transport service provider? **Note:** if no third-party service provider has been hired, the requirement can be scored as N / A. **If a third-party transport service provider is hired:** • Does the third-party transport service provider have an IFS Logistics Certification or another equivalent GFSI standard certification? If the third-party transport service provider has no IFS Logistics Certification, nor another equivalent GFSI standard certification: • Where has the company defined the requirements for the third-party service provider?; are the relevant requirements included? • Are requirements about personal hygiene, declaration of health issue or infectious disease, or any other control activities (e.g. access restrictions, training, etc.), to prevent any negative impact on products included in the contract? • Are actions to manage the incidents and / or potential emergency situations which could have an impact on the product requirements and / or the provision of services included in the contract? • How does the company monitor the execution of hired activities? • How does the company verify the effectiveness of hired activities? • Who is responsible for the monitoring and verification activities?; what are the competencies defined for the responsible person?

No.	IFS PACsecure Requirements	Guidance
4.16	**Maintenance and repair**	
4.16.1*	An adequate maintenance plan shall be in place, maintained and documented, that covers all critical equipment (including transport) for compliance with product requirements. This applies both to internal maintenance activities and service providers. The plan shall include responsibilities, priorities and due dates.	• How is maintenance organised? • Where are maintenance procedures documented? • Which equipments are subject to external maintenance?
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.	• How is it ensured that maintenance and repair works do not affect product safety? • How are lighting fixtures repaired? • Where are repair works documented? • What rules are in place for re-activating equipment when maintenance is completed?
4.16.3	All materials used for maintenance and repair shall be fit for the intended use and shall not pose contamination risks.	• How is it ensured that materials used in maintenance or repair work are fit for intended use? • What kinds of greases are used? • Are the lubrication points identified and have application methods been implemented to prevent product contamination with lubricants while these are used / applied during production process and maintenance? • Are application methods validated regarding prevention of product contamination?
4.16.4	Failures and malfunctions of plant and equipment (including transport) essential for product safety and quality shall be notified, documented and reviewed to carry out prompt actions and to improve the maintenance plan.	• What happens when a failure occurs? • Are key management personnel notified of equipment failures and malfunctions? • Are processing interruptions documented? • Are processing interruptions considered in maintenance planning?
4.16.5	Temporary repairs shall be carried out so that product requirements are not affected. Such work shall be identified, documented and a short-term deadline set for eliminating the fault.	• Are temporary repairs allowed? • Where are these documented? • How quickly shall temporary repairs be definitely mended? • Who verifies this?

No.	IFS PACsecure Requirements	Guidance
4.16.6	Where a company hires a third-party maintenance and repair service provider, all the company specified requirements regarding material, equipment and operational rules shall be clearly defined, documented and maintained in the service contract or agreement, to prevent any negative impact on products.	• Is maintenance and / or repair activities leased to a third-party maintenance provider? **Note:** if no third-party service provider has been hired, the requirement can be scored as N / A. **If a third-party maintenance and repair service provider is hired:** • Where has the company defined the requirements for the third-party service provider?; are the relevant requirements included? • Are requirements about personal hygiene, declaration of health issue or infectious disease, or any other control activities (e.g. access restrictions, training, etc.), to prevent any negative impact on products included in the contract / agreement? • Are actions to manage the incidents and / or potential emergency situations which could have an impact on the product requirements and / or the provision of services included in the contract / agreement? • How does the company monitor the execution of the hired activities? • How does the company verify the effectiveness of the hired activities? • Who is responsible for the monitoring and verification activities?; what are the competencies defined for the responsible person?
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.	• Are equipments suitably designed and were they checked before start up?
4.17.2	For all equipment and tools in direct contact with products, a certificate of conformity shall be in place, which confirms compliance with legal requirements. In case no specific legal requirements are in place, evidence shall be available, such as: • certificate of conformity • technical specifications • manufacturer's self-declaration to demonstrate that they are suitable for the intended use.	• Are conformity certificates or other certificates available for all equipment and tools which come into direct contact with products?

No.	IFS PACsecure Requirements	Guidance
4.17.3	All equipment shall be located to allow effective cleaning, disinfection and maintenance operations. The company shall ensure that all product equipment and its related tools are identified, controlled, maintained in good condition without any negative influence on products, stored and transported in a way that does not compromise product safety and product quality (e.g. damage, mixing, printing errors).	• Is equipment suitably designed and is it checked before start up? • What rules exist for the start up of new equipments? • Is new equipment immediately considered in maintenance plan? • Does an equipment installation plan exist? • Are product equipment and related tools identified and controlled? • Are product equipment and related tools in good condition?
4.17.4	The company shall ensure that in the event of changes to processing methods and equipment, process characteristics are reviewed in order to assure that product requirements, as agreed with customers, are complied with.	• What happens in case of equipment failures?
4.18	**Traceability**	
4.18.1* KO No. 7	**A traceability system shall be in place which enables the identification of product batches and their relation to batches of raw materials and wrapping materials. The traceability system shall incorporate all relevant records of:** • **receipt** • **production / conversion processes** • **use of rework** • **distribution** **Traceability shall be ensured and documented until delivery to the customer.**	• How is the finished product batch identified? • Is the traceability system defined by the company including the relation between finished product batches, raw materials, production / conversion processes and controls involved? • How is traceability ensured? • What products come from which supplier? • Is there a list available with all current suppliers?

No.	IFS PACsecure Requirements	Guidance
4.18.2*	The traceability system shall be tested on a periodic basis, at least annually and each time the traceability system changes. The test samples shall represent the complexity of the company´s product range. The test records shall verify upstream and downstream traceability (from delivered products to raw materials, and vice versa). The traceability of the finished products shall be performed within four (4) hours maximum.	• When was the last test for verifying the traceability system carried out? • The samples was selected according to which criteria? • Did the test include verification of upstream and downstream traceability? • Are complete records for the test available? • What percentage of the total amount was traced? • How big is a batch? • How much time did the company take to trace the final products?
4.18.3	Test results, including the timeframe for obtaining the information, shall be recorded and where necessary appropriate actions shall be taken. Timeframe objectives shall be defined and be in compliance with customer requirements.	• Are there customer requirements for the timeframe? • Have timeframes been respected during own traceability exercises?
4.18.4	Traceability shall be in place to identify the relationship between batches of final products and their labels.	
4.18.5	Traceability shall be ensured at all stages, including work in progress, post treatment and rework.	• Can rework be completely traced? • How is rework documented?
4.18.6	Labelling of semi-finished or finished product batches shall be made at the time when they are directly wrapped to ensure their clear traceability. Where they are labelled at a later time, the temporarily stored of semi-finished or finished products shall have a specific batch labelling.	• When is batch labelling done? • What is the batch labelling code? • When are labels applied to product units? ***Additional explanation*** *Where semi-finished or finished products are labelled at a later time, the converting time of the finished products shall be calculated from the original production batch.*
4.18.7	If required by the customer, identified samples representative for the manufacturing batch number shall be stored appropriately and kept until expiration of the recommended converting time of the finished product and if necessary for a determined period beyond this date.	• Does the customer request retained samples? • What is the purpose of the retained sample system? • Was the representative sampling of retained samples agreed with the manufacturer? If yes, where are the retained samples kept?; under which conditions? • Is a sample bank implemented? • How are these samples managed?

No.	IFS PACsecure Requirements	Guidance
4.19	**Allergen risk mitigation**	
4.19.1*	The company shall identify and maintain a continuously up to date listing of all raw materials containing or potentially containing allergens (e.g. traces, due to the adventitious or technically unavoidable presence) used at its premises. The formulas / configurations, semi-finished products and finished products, in which such raw materials are utilised shall be also identified.	• Does the company have a list with all raw materials containing allergens? • Are the allergens identified in formulas / configurations, semi-finished products and finished products? • Are allergens identified in specifications? • Does a list exist that covers allergens in use? ***Additional explanation*** *Some examples of allergens present in raw materials are soy-based grease, nut-based oils, starch-based glues, among others.*
4.19.2*	Based on hazard analysis and assessment of associated risks, a documented allergen management plan shall be developed and implemented to ensure that: • all allergens entry are identified • potential cross-contamination of products by allergens is minimised. The potential cross-contamination risks related to the environment, transport, storage, raw materials, equipment, personnel (including contractors and visitors), cleaning and disinfection activities, process flow (from receipt of goods to dispatch) and rework shall be considered. • the declaration of allergens are in accordance with legal and customer requirement, if existing. The preventive and control measures, methods of control and monitoring shall be defined, implemented, and controls shall be verified.	• Is a documented allergen management plan implemented? • Are legal and customer requirements related to the declaration of allergens in final products? • Are preventive and control measures in place to minimise potential cross-contamination risks? • How are preventive and control measures verified?

No.	IFS PACsecure Requirements	Guidance
4.19.3	The allergen management plan shall be regularly reviewed, at least annually, and / or in the event of increased risks, or in case of changes in legal and / or customer requirements. If necessary, the allergen management plan and the related preventive and control measures shall be revised / updated accordingly.	• How often is the allergen management plan reviewed? • Are control and monitoring requirements changed, and if so, why? • What are the criteria defined for the allergen management plan to be reviewed in addition to the annual review, i.e. when changes to risk could occur? • Is the effectiveness of the allergen management plan reviewed? If so, how is this undertaken?
4.20	**Product fraud**	
4.20.1	The responsibilities for a product fraud vulnerability assessment and mitigation plan shall be clearly defined. The responsible person(s) shall have the appropriate specific knowledge and full commitment from the senior management.	• Who is responsible for product fraud mitigation activities? • How is it ensured that the responsible person has the appropriate knowledge? • How is the support of senior management ensured? ***Additional explanation*** *The IFS product fraud mitigation guideline has been designed to assist users of IFS Standards to understand the concept of risk management in relation to product fraud threats and how vulnerability assessments are an integral part of the risk management process.*
4.20.2*	A documented product fraud vulnerability assessment shall be undertaken on all raw materials, wrapping materials and processes (including outsourced), to determine the risks of fraudulent activity in relation to substitution, mislabelling, adulteration or counterfeiting. Criteria considered within the vulnerability assessment shall be defined.	• What is the defined vulnerability assessment methodology? • Are all raw materials, processes and labelling subject to a vulnerability assessment? • Are vulnerability assessments undertaken on new raw materials, suppliers, processes and products? • Did the company cluster specific products into groups? If so, Is it reasonably justified? • Are vulnerability scores, ranking or grading available for review? • Which risk factors are defined for raw materials, suppliers, processes and products?

No.	IFS PACsecure Requirements	Guidance
4.20.3*	A documented product fraud mitigation plan shall be developed, with reference to the vulnerability assessment, and implemented to control any identified risk. The methods of control and monitoring shall be defined and implemented.	• What are the control activities applied to mitigate the risk of potential product fraud activity identified within the vulnerability assessment? • How is the product fraud mitigation plan defined? • Are control activities regularly reviewed for suitability and effectiveness? • Who monitors, and where necessary takes action when issues are identified by the control activities? • Are control activities appropriately and consistently applied in accordance with identified risks?
4.20.4*	The product fraud vulnerability assessment shall be regularly reviewed, at least annually, and / or in the event of increased risks. If necessary, the product fraud mitigation plan shall be revised / updated accordingly.	• How often is a vulnerability assessment undertaken? • Are control and monitoring requirements changed, and if so, why? • What are the criteria defined for the product fraud vulnerability assessment to be reviewed in addition to the annual review, i.e. when changes to risk could occur? • Is the effectiveness of the product fraud mitigation plan reviewed? If so, how is this undertaken?

No.	IFS PACsecure Requirements	Guidance
5	**Measurements, analyses, improvements**	
5.1	**Internal audits**	
5.1.1* KO No. 8	**The company shall have an effective internal audit program in place which shall cover, at least, all the requirements of the IFS PACsecure Standard. Scope and frequency of internal audits shall be determined and justified by risk assessment. The internal audit program shall also apply to off-site storage locations owned or rented by the company.**	• How is the audit program organised? • Is there an audit plan? • Is the audit plan determined by risk assessment?

No.	IFS PACsecure Requirements	Guidance
5.1.2*	Internal audits of activities which are critical to product safety and quality shall be carried out at least once a year.	• Which are the critical activities to product safety and quality identified? • How often are internal audits performed? ***Additional explanation*** *The following issues can be taken into consideration for internal audits:* • *all production steps (packaging area, labelling, GMP's, CP's / CCP's)* • *traceability* • *control plan (e.g. analyses, calibration, etc.)* • *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.	• Who are the auditors? • How are auditors qualified for this job? • Do the auditors have any connection with the audited area / department? ***Additional explanation*** *Some examples of alternatives to fulfil the independent criteria might comprise:* • *Allow the internal auditors to only audit those processes and departments in which they are not directly involved or for which they are not responsible.* • *Exchange internal auditors from other company sites to execute the internal audits.* • *Hire an IFS Consultant or an external professional with the relevant competencies to execute the internal audits.*
5.1.4	Internal audit results shall be communicated to the senior management and to persons responsible for the concerned activities. Necessary corrections, corrective actions and a schedule for implementation shall be determined, documented and communicated to the relevant persons. All corrections and corrective actions resulting from the internal audits shall be verified.	• How are audit results communicated to the persons in charge of the process(es) where deviation(s) and / or non-conformity(ies) were identified? • Is the communication immediate and in sufficient time for actions to be taken? • Are corrective actions documented? • Is a time schedule in place for corrective actions? • From which audits were corrective actions derived? • How are audit results communicated to the senior management? • How are corrections and corrective actions verified? • Who verifies and when?

No.	IFS PACsecure Requirements	Guidance
5.2	**Site and factory inspections**	
5.2.1*	Site and factory inspections shall be planned and carried out for topics, such as: • constructional status of production and storage premises • external areas • product control during processing • hygiene during processing and within the infrastructure • foreign material hazards • personal hygiene • product defence The frequency of inspections shall be justified by risk assessment and be based on the history of previous experience. Any deviation and the associated actions shall be documented.	• How often and who performs site inspections? • How was the frequency defined? • What is reviewed during site inspections? • For which areas do site inspections exist? • Are actions documented in case of deviations?
5.3	**Validation and control of the process and working environment**	
5.3.1*	The criteria for the validation and control of the process and working environment shall be clearly defined. The validation of the process and working environment parameters shall be performed using the collected data that is relevant for product safety and quality. If substantial modifications occur, a revalidation shall be carried out.	• Which are the criteria defined for validation? • Which are the criteria defined for the control of the process? • Which are the criteria defined for the control of the working environment? • Does the company have a procedure / protocol regarding process validation? • When was the last process validation conducted (process, date, result)? • What kind of validation, verification and monitoring activities are considered by the company? • How are the monitoring and verification activities defined? • At what frequency are the monitoring and verification activities carried out? ***Additional explanation*** *The working environment parameters refers to the conditions that shall be controlled for ensuring the production of conforming products.* *Depending on the impact on product compliance, some examples of parameters to be controlled are biological contaminants (e.g. pathogens, moulds or yeast that could cause spoilage), chemicals contaminants in surfaces, temperature, humidity, among others.*

No.	IFS PACsecure Requirements	Guidance
5.3.2	Where the control of process and working environment parameters are essential to ensure the capability of consistently producing conforming products, such controls and parameters shall be validated, monitored and recorded continuously and / or at appropriate intervals. Procedures shall be in place for prompt notification, recording and monitoring of the deviations on the process and / or parameters. Where necessary appropriate actions shall be taken and these shall be recorded.	• What kind of controls and working environment parameters has the company defined as essential to ensure the production of conforming products? • Have these controls and working environment parameters been validated? • At what frequency are these controls and working environment parameters monitored? • How are the deviations notified? • Has the company identified the issues that can lead a final non-conforming product? • In which stages can these issues occur? • Have measures been implemented to prevent, identify and handle the identified issues?

No.	IFS PACsecure Requirements	Guidance

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

5.3.4*	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.	• How is it assured that reworks comply to specifications or other legally required documentations? • Where is rework documented? • Who reviews rework results? • Who decides on the release of rework?

No.	IFS PACsecure Requirements	Guidance
5.4	**Calibration, adjustment and checking of measuring, monitoring devices and inspection equipment**	
5.4.1*	The company shall identify and record the measuring and monitoring devices required to ensure compliance with product requirements. Their calibration status shall be recorded, and when possible, visible on the device (e.g. labelled). Measuring and monitoring devices shall be agreed with the customer, or conform to accepted industry standards (e.g. spectrophotometers, lighting in print inspection cabinets, pantone patterns), and legally approved, if required by legislation.	• What kinds of monitoring devices exist? • What is demanded of monitoring devices? • What monitoring device is relevant for which kind of measurement? • How are monitoring devices identified? • Do calibrated devices exist? • How is the calibration status of a measuring device identified?
5.4.2*	All measuring devices shall be checked, adjusted and calibrated at specified intervals under a monitoring system in accordance with defined, recognised national or international standard / methods and within relevant limits of the process parameter values. The results of the checks, adjustments and calibrations shall be documented. When inspection equipments are used to control parameters relevant for the compliance with product requirement, the company shall specify the method and accuracy to control the parameter values and its limits. The continuous operation and efficiency of the inspection equipments to control the parameters under the values and limits defined shall be monitored on a regular basis.	• How are measuring device checks organised? • Are measuring devices regularly calibrated? • Who is responsible for calibration? • How is calibration carried out? Where is it documented? • What corrective actions are taken when a tolerance deviation is found? • Is calibration up to date? When the company has inspection equipments: • What kind of equipment is used? • Which are the inspection parameters? • How is the equipment functioning monitored? • How is the equipment effectiveness verified? ***Additional explanation*** *Some examples of inspection equipments are:* • *In-line vision inspection systems (e.g. to detect mix-ups; check cap inserts; inspect cracks or flaws in glass bottles, inspect coating thickness on beverage cans; check printed materials, among others).* • *X-ray inspection systems (e.g. to detect packaging deformations, foreign bodies, among others).*

No.	IFS PACsecure Requirements	Guidance
5.4.3	All measuring, monitoring devices and inspection equipment shall be used exclusively for their defined purpose. Where the results of measurements or the status of the device / equipment indicate a malfunction or failure, the device in question shall be immediately repaired or replaced. Where necessary, corrections and corrective actions on processes and products shall be carried out.	• What actions are taken when measurement results are uncertain? • How are device / equipment with malfunction / failure identified?
5.5	**Quantity control monitoring**	
5.5.1*	The company shall define compliance criteria to control batch quantity. A frequent and methodological approach for quantity control shall be in place to meet legal requirements of the production and destination countries, and customer specifications.	• What are the defined compliance criteria? • If they exist, are legal requirements and customer specifications considered? • How is quantity control carried out? • How is it ensured that legal and customer requirements for quantity control are met?
5.5.2	Checks shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing batch. Results of these checks shall be compliant with defined criteria for all products ready to be delivered.	• Is a sampling plan implemented? • How was the size of sampling and the frequency of checks determined?
5.6	**Product and process analyses**	
5.6.1*	Testing plans for internal and external analyses shall be justified by risk assessment to ensure that product safety, quality, legal and specific customer requirements are met. The plans shall cover topics, such as: • raw materials • semi-finished products • finished products • wrapping materials • contact surfaces of processing equipment • relevant parameters for the control of the process and environmental monitoring. All test results shall be recorded.	• Does an inspection plan exist? • Who organises the inspection plan? • Which products are encompassed in the inspection plan? (raw materials, semi-finished and finished products, wrapping materials, environmental tests?) • Is the inspection plan based on hazard analysis? • Where are test results documented? • Which chemical, physical or microbiological analyses are made or subcontracted? • Which analyses are performed by own laboratory and which by external?, and how frequently?

No.	IFS PACsecure Requirements	Guidance
5.6.2*	Analyses, which are relevant for product safety, shall preferably be performed by laboratories with appropriate accredited programs / methods (ISO/IEC 17025). If the analyses are performed internally by the factory or a laboratory without appropriate accredited programs / methods, the results shall be verified on a regular basis by laboratories accredited to these programs / methods (ISO/IEC 17025).	• Is there an analytical laboratory on-site? Is it accredited under ISO/IEC 17025? • Are internal lab results verified by an accredited lab? • Which external laboratories are used? Are these accredited under ISO/IEC 17025?
5.6.3	Procedures shall exist which ensure the reliability of the internal analyses results, based on officially recognised analysis methods. This shall be demonstrated by ring tests or other proficiency tests.	• How is it ensured that internal analytical methods are appropriate? • Are ring tests performed?
5.6.4	Results of analyses shall be evaluated promptly by competent personnel. Appropriate corrective actions shall be undertaken for any unsatisfactory results. The analytical results shall be reviewed regularly to identify trends and, where necessary, corrective actions shall be taken.	• Who reviews analytical results? • How are analytical results verified? • Are trends investigated? • Are corrective actions introduced when results are unsatisfactory?
5.6.5	Where internal analyses or controls are undertaken, these shall be carried out in accordance with defined procedures, by trained and approved personnel, in defined areas or laboratories using appropriate equipment.	• Which tests are performed internally? • What qualifications do lab technicians have? • Is an internal lab available? • How is product contamination by an internal lab prevented?
5.6.6	When it is relevant for the verification of products requirements and / or is specified by the customer, internal sensory tests shall be carried out regularly. These tests shall be in accordance with specifications and related to the impact on respective parameters of product characteristics. The results of these tests shall be documented.	• When and how are sensorial tests performed?

No.	IFS PACsecure Requirements	Guidance
5.6.7	The testing plan shall be regularly reviewed and updated, based on results, changes to legislation or issues that may have an impact on product safety, quality or legality.	• What was the last review of the testing plan? • How was the review executed? • How does the company update the plan in case of legislation changes? • Are product fraud topics included for the plan review?
5.7	**Product release**	
5.7.1*	A procedure for quarantine (blocking / hold) and release shall be in place that is justified by risk assessment. The procedure shall ensure that only raw materials, semi-finished, finished products and wrapping materials conforming to product requirements, are processed / converted and dispatched.	• Does the company have a quarantine and release procedure? • What are the criteria defined to block / hold products? • Which measures are in place to promptly block goods? • What are the criteria defined to release products that are on hold / blocked? • Who quarantines or releases products? • How are quarantined products identified?
5.8	**Management of complaints**	
5.8.1*	A procedure shall be in place for the management of complaints. The procedure shall consider, at a minimum: • Product complaints by customers, and when applicable, by consumers • Any written notification from the competent authorities – within the framework of official controls –, any ordering action or measure to be taken when non-compliance in products is identified. • Raw materials complaints by the company to its suppliers	• How does the company handle complaints? • Is a prompt reaction to every complaint ensured? • Which complaints occurred recently? • How is a uniform procedure for complaint handling ensured? • What is the range or indicator of complaints raised by customers, consumers (if applicable), and authorities separately?
5.8.2*	All complaints shall be registered, readily available and assessed by competent staff. Where it is justified, appropriate actions shall be taken immediately.	• How are complaints received, and by whom? • Who evaluates complaint significance? • Who defines the actions to be taken? • Within what time frame shall actions be taken?

No.	IFS PACsecure Requirements	Guidance
5.8.3	Complaints shall be analysed with a view to implementing appropriate actions to avoid the recurrence of the non-conformity.	• How are complaints analysed?, how often are they analysed? • Who manages complaint statistics? • Is there a breakdown for the different complaint reasons? • Does the company investigate the causes for complaints? • Are there examples of corrective actions resulting from complaints? • Were these corrective actions effective? • What actions are taken to avoid recurrence? • Who is responsible for the process?
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?

No.	IFS PACsecure Requirements	Guidance
5.9	**Management of incidents, product withdrawal, product recall**	
5.9.1*	A procedure shall be implemented and maintained for the management of incidents and of potential emergency situations with an impact on product safety, legality and quality. It shall include, at a minimum: • the decision-making process • the nomination of a person, authorised by the company and permanently available, to initiate the incident management process promptly • the nomination and training of an incident management team • an up to date alert contact list including customer information, sources of legal advice, contacts availability • a communication plan including authorities.	• Has the company defined an incident management team? If so, who belongs to the team?; are the team members trained in topics relating to risk and incident management?; is there a set infrastructure to enable regular meetings between members of the crisis team? • Has the company considered external resources (e.g. lawyer)? • Who is the person responsible for initiating the incident management process?; is this person permanently available?; how are potential absences covered (vacations, sick leave, etc.)? • How can the incidents and emergency situations be detected by the company? • What are the sources of information to be aware / alert of new potential emergencies / incidents?; is there an information system to keep the crisis team up-to-date as a basis for decisions? • What are the incidents and emergencies currently identified by the company?; what are the identified critical processes and resources to support them?; what is the level of risk of those incidents and emergencies defined regarding product and process compliance and in regard to operational and financial aspects? • What are the plan and actions defined to recover, resume and restore the activities in case the emergency / incidents described by the company occurs?; are the responsibilities clearly defined within the defined actions?; are potential external business corporations considered to ensure customer supply continuity? • Does the company have an internal / external communication plan (in case of incidents, product withdrawal, product recall, considering who, what, how, restrictions, timelines, etc.)? • Is an up to date alert contact list available? ***Additional explanation*** *In regard to the management of incidents, the company should consider the impact for consumers, customers, and the impact on the relationship with other stakeholders, such as reputation, confidence gained, corporate image, and business continuity.*

No.	IFS PACsecure Requirements	Guidance
5.9.2* KO No. 9	**An effective procedure for the withdrawal and / or the recall of all products shall be in place. This procedure shall include a clear assignment of responsibilities and a comprehensive information policy for customers, including consumers and competent authorities when applicable.**	• To what extent is distribution involved with incident management? • Has the company implemented a recall and withdrawal procedure? • Which are the actions defined in case of recall / withdrawal? • Are the responsibilities clearly defined within the defined actions? • How does the company evaluate that the procedure is implemented? • Has a comprehensive information policy for customers been established? • When and who informs the customer?
5.9.3	The procedures for the management of incidents and withdrawal / recall shall be regularly tested for effectiveness, at least annually. The tests shall be carried out to ensure the effective implementation and operation of both procedures and shall include the verification of the updated contact data.	• How does the company evaluate that the procedures (management of incidents and potential emergency; withdrawal / recall) are effective? • How often is effectiveness of the procedures tested? • Is the update of contact data verified? • Are corrective actions taken in case the procedures are not effective?
5.10	**Management of non-conformities and non conforming products**	
5.10.1*	A procedure shall be in place for the management of all non-conforming raw materials, semi-finished products, finished products, converting / processing equipment and wrapping materials. This shall include, at a minimum: • defined responsibilities • isolation / quarantine procedures • risk assessment • identification including labelling • decision about the further use (e.g. release, rework, blocking, quarantine, rejection / disposal).	• What procedures exist for non-conforming product management? • How are non-conforming products identified? • What rules exist for product isolation / quarantine procedures? • Does the company have an identifiable isolation / quarantine area(s) for non-conforming products? • How is the isolation / quarantine area(s) identified on-site? • Are only non-conforming products stored in isolation / quarantine area(s)? • What kind of actions and control activities has the company implemented to prevent the cross-contamination with the isolation / quarantine area(s)? (e.g. between products with / without allergens compounds; between contaminated product destinated to disposal and the one intended for rework, etc.)

No.	IFS PACsecure Requirements	Guidance
5.10.2	The procedure for the management of non-conforming products shall be understood and applied by all relevant employees.	• Who is responsible for putting non-conforming products into quarantine? • Who may release quarantined products? • How is it ensured that only authorised persons release quarantined products?
5.10.3	Where non-conformities are identified, immediate actions shall be taken to ensure that product requirements are complied with.	• What procedures are implemented with non-conforming products? • Who decides about non-conforming products?
5.10.4	Finished products (including wrapping) that are out of specification shall not be placed on the market, unless written approval from the customer is available. The out of specification products shall be destroyed appropriately and records of this shall be maintained.	• How are out of specification products destroyed? Are records of this available? • If the customer allowed the release of products out of specification, is there written evidence of this approval?
5.11	**Corrective actions**	
5.11.1*	A procedure shall be in place for the recording and analysis of non-conformities and non-conforming products, by preventive actions, corrections and / or corrective actions. The root cause analysis for corrective actions related to product safety shall be documented; in any other case, the need to document the root cause analysis shall be defined and justified by risk assessment.	
5.11.2* KO No. 10	**Corrective actions shall be clearly formulated, documented and undertaken as soon as possible. The actions defined shall be focused on avoiding the recurrences of non-conformities. The responsibilities and the timescales for corrective actions shall be clearly defined.**	• Which corrective actions were implemented? • Where are corrective actions documented? • Who is responsible for corrective actions? • How long may it take to implement corrective actions?
5.11.3	The effectiveness of the implemented corrective actions shall be assessed and the results of the assessment documented.	• Where are corrective actions documented? • How are corrective actions verified?

No.	IFS PACsecure Requirements	Guidance
6	**Product defence plan**	
6.1	The responsibilities for the product defence plan shall be clearly defined. Those responsible shall have the appropriate specific knowledge and training, and have full commitment from the senior management.	• Who has the accountability for the product defence program? • What are the competences and qualifications demonstrated for the person(s) responsible for the product defence program? • What is the position of the person(s) responsible for the product defence program with respect to the management team? • How do management teams support the person(s) responsible for the product defence program? • Where are the responsibilities clearly defined? • Was this communicated to the members of the company? How?
6.2	A documented product defence assessment shall be undertaken to determine the risks of malicious and ideologically motivated threats. This shall include, at a minimum: • legal requirements • customer requirements • site security conditions • identification of critical or high risk areas of the site • practices and policy of access by employees, visitors and contractors • any other appropriate control activities The criteria considered within the vulnerability assessment shall be defined.	• Are legal / customer product defence 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?; how can the company demonstrate compliance with such requirements? • What is the process / procedure used to perform the vulnerability assessment? • Is the vulnerability assessment 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? • What areas have been identified as critical? • What are the implications if a major breach is identified?

No.	IFS PACsecure Requirements	Guidance
6.3	A documented product defence plan shall be developed, with reference to the product defence assessment, and implemented in place to effectively mitigate the identified risks. The methods of control and monitoring shall be defined and implemented.	• What kind of policies and control activities are in place in order to control the entrance of employees, visitors and contractors to critical or high risk areas? • How is the company alerted of any product defence breach? • Are there means to verify if products have been tampered with? • 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? • Has product defence breach been detected? • What kind of control activities have been defined? • How does the company evaluate the effectiveness of the product defence program? • Has product defence breach been detected? • What kind of control activities have been implemented? • Are there tests to verify that measures against tampering are properly applied and working properly? • How does the company evaluate the effectiveness of the product defence plan? • How often is effectiveness of the product defence plan tested? • Are corrective actions taken in case the product defence plan is not effective?
6.4*	The product defence plan shall be reviewed at least annually, and updated when appropriate. The test on the effectiveness of the product defence plan and the related control activities shall be included in the internal audit and the inspection plan	• What are the sources of information to be aware / alert of increasing and / or new threats? • What criteria does the company consider in order to determine the frequency to review the vulnerability assessment, if it is not done annually? • Was the product defence plan updated due to the product defence assessment review?

No.	IFS PACsecure Requirements	Guidance
6.5	A documented procedure shall exist for managing external inspections and regulatory visits. Relevant personnel shall be trained to execute the procedure.	• Is there a documented procedure that defines the criteria to follow in case an external organisation requires access to the company's premises? • Are there clearly defined levels of authority to provide access to external organisations 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 the activities carried out and details of the visit? **Note:** If no product defence legislation exists in the country where the assessment takes place which requires external product defence inspections and / or regulatory product defence visits, or if the company doesn't export to countries where product defence inspection is required, the requirement can be scored as N / A.

PART 3
Requirements for accreditation bodies, certification bodies and auditors

0 Introduction

IFS Certification is a product and process certification. All bodies involved shall comply with the international rules and IFS specific requirements described in this document. This part of the IFS Standard mainly deals with requirements applicable to 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 IAF (International Accreditation Forum).

In order to ensure interactive communication, accreditation bodies shall appoint an IFS contact person within their organisation. This contact shall be made known to the IFS.

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

In general, relevant accreditation body personnel engaged in concerned IFS Accreditation activities shall have sufficient knowledge of the IFS PACsecure Standard, the related normative documents and the packaging industry.

Accreditation decisions can only be made following the recommendation of a competent person or an accreditation committee.

The person in charge or at least one member of the accreditation committee shall have taken part in the "Assessments under the IFS PACsecure Standard" course (organised by IFS) or shall be able to demonstrate an equivalent level of knowledge. In the case of a committee, the trained person shall provide the other members of the accreditation committee with the necessary information. This information is based on the main points of the "Assessments under the IFS PACsecure Standard" course with the main emphasis on Part 1 (IFS PACsecure Certification protocol), Part 3 (requirements for accreditation bodies, certification bodies and auditors), Part 4 (assessment report, certificate) of the IFS PACsecure Standard, the IFS PACsecure Doctrine and the IFS Auditors' examinations process.

1.3 Competencies of the assessor(s) of the accreditation body

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

- Accompanying IFS PACsecure Auditors during registered IFS PACsecure Assessments (accreditation witness assessment).
- Assessing the head office of the certification body (head office assessment), according to ISO / IEC 17065:2012 norm and IFS specific requirements.

In general, the assessor(s) shall have working knowledge of the ISO / IEC 17065:2012 norm and the IFS normative documents (IFS PACsecure Standard and Doctrine). The person at the accreditation body responsible for IFS Standards can participate in IFS official training / certification body conferences / accreditation body meetings to train assessors internally.

Witness assessors shall, at a minimum:

- Be able to demonstrate a working knowledge of IFS (e.g. by taking part in the yearly IFS certification body conference, IFS Calibration Training, "Assessments under the IFS PACsecure Standard" course, or by being trained internally by an accreditation body leader who has taken part in the IFS training(s) / certification body conference)
- Taken part in a hazard analysis and risk assessment training course.
- Have a minimum of two (2) years' experience in the packaging industry sector.

Head office assessors shall, at a minimum:

- Have detailed knowledge of the current versions of IFS normative documents.

To maintain assessors up-to-date, IFS will provide any new information on the IFS PACsecure Standard and the IFS PACsecure Doctrine to the accreditation body.

1.4 Frequency of the assessments of certification bodies

A head office assessment (with review of at least one full IFS PACsecure Certification process) and at least one accreditation witness assessment shall be performed during an initial assessment.

The certification body is allowed to perform a maximum of ten (10) IFS PACsecure Assessments and to operate for a maximum of one year before achieving the accreditation for IFS PACsecure. In this case, at least one of the IFS Assessments shall be assessed by the accreditation body (accreditation witness assessment) and all IFS Assessments (including at least one full certification process) shall be reviewed by the accreditation body during the initial head office assessment.

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

During the surveillance of the accreditation cycle, the following number of assessments shall be performed:

- A minimum of one head office assessment per year
- A minimum of one accreditation witness assessment every two (2) years. Different product scopes shall be considered within the accreditation witness assessments (see ANNEX 3).

Note: A flexibility of maximum three (3) months can be permitted 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, at a minimum:

- For certification bodies with up to 200 certificates: at least three (3) IFS PACsecure Certification site files
- For certification bodies with up to 400 certificates: at least five (5) IFS PACsecure Certification site files

For each additional up to 200 certificates at least one additional IFS PACsecure Certification site file.

- For certification bodies with up to 10 auditors: at least three (3) auditor files
- For certification bodies with up 20 auditors: at least five (5) auditor files.

For each additional up to 20 auditors at least one additional auditor file.

The use of non-exclusive auditors shall be adequately addressed in the sample of auditor files. For consecutive accreditation witness assessments, the accreditation body shall, wherever possible, select two (2) different IFS PACsecure Auditors of the certification body in order to cover different scopes.

1.5 Accreditation of an internationally active certification body

The head office assessments and the accreditation 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 ISO / IEC 17065:2012 norm. The IAF MD 12:2016 Accreditation assessment of conformity assessment bodies with activities in multiple countries shall apply.

1.6 Conditions for recovering accreditation after withdrawal or suspension

If the accreditation body decides to withdraw or suspend accreditation, the certification body shall stop performing IFS Assessments and issuing IFS Certificates. The accreditation body shall inform IFS about the suspension of a certification body active in IFS.

To recover accreditation after a withdrawal or suspension, the same conditions as for initial assessment apply. In case of accreditation suspension, IFS reserves the right to conduct further own activities connected to a lift of accreditation suspension for a certification body.

2 Requirements for the certification bodies

Certification bodies intending to perform IFS PACsecure Assessments shall comply with the following rules.

2.1 Contract with the IFS Management GmbH

The certification body shall have signed the IFS Framework Agreement before it is authorised to perform any IFS Assessment (including the first assessment(s) during the accreditation process). The certification body shall demonstrate that they are actively applying for accreditation to the ISO / IEC 17065:2012 norm for IFS PACsecure.

As part of the IFS Framework Agreement, the certification body is obliged to send at least one participant to the annual IFS certification body conference. This person shall either be the IFS Standard manager, the approved IFS Trainer, or one of their officially assigned deputies, and shall be fluent in English.

2.2 ISO / IEC 17065:2012 norm accreditation process for IFS PACsecure

The certification body shall be accredited to the ISO / IEC 17065:2012 norm for IFS PACsecure by an IAF recognised accreditation body.

Certification bodies in the process of accreditation may organise a maximum of ten (10) Assessments including the accreditation witness assessment before having achieved accreditation status. All Assessments (including at least one full certification process) shall be reviewed by the accreditation body during the initial head office assessment.

Note: In case of withdrawal or suspension of accreditation against ISO / IEC 17065:2012 norm for IFS, the whole certification process shall be stopped, and the certification body is no longer allowed to issue any IFS Certificate. The certification body cannot issue IFS Certificates from the date of withdrawal or suspension, even for Assessments which have been already performed but which are still in the certification process (report review, certification decision, etc.).

2.3 Complaints and appeals procedure

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

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

For the handling of complaints received by the IFS Offices, the basis for complaint management is described in the IFS Framework Agreement with certification bodies:

- If the complaint relates to the quality of IFS Assessments or the content of IFS Assessment Reports, the IFS Offices require the certification body to provide a statement on the cause and the measures identified to rectify the problem within two (2) weeks.
- If the complaint relates to administrative errors, e.g. in IFS Assessment Reports, IFS Certificates or in the IFS Database, the IFS Offices ask the certification body to provide a statement and rectify the problem within one week. The statement shall be issued in writing, by e-mail or post.

2.4 Certification decision

The decision concerning certification can only be made following the recommendation of a competent person or a certification committee (chart 7). Furthermore, the decision can only be made by a different person than the one who performed the assessment.

Chart 7: Functions and requirements related to certification decision process

Function	Profile / requirements	Further requirements
Technical report review and the recommendation for a certification decision	by one nominated person from the certification body who is approved as: • IFS PACsecure Auditor, or • IFS PACsecure Pure Reviewer	This shall not be the person who performed the assessment. The review shall be documented.
Certification decision	by the certification body, either a nominated person or a committee.	The certification body shall retain authority for its decisions relating to certification. The certification decision is made following recommendation by a competent person. The decision shall be made by the certification body, either a nominated person or a committee. There will be no involvement of the person who performed the assessment.

2.5 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 Certificates, in order to decide if further actions (e.g. withdrawal of recent certificates or additional recertification assessments) will be necessary.

2.6 Certification body responsibilities for IFS PACsecure Auditors, IFS PACsecure Reviewers, IFS PACsecure Trainers and IFS PACsecure Witness Auditors

The certification body shall ensure compliance with ISO / IEC 17065:2012 norm and the IFS Framework Agreement.

It is the responsibility of the certification body to ensure that processes are in place to monitor and maintain the competencies of all IFS PACsecure auditors, IFS PACsecure Reviewers, IFS PACsecure Trainers and IFS PACsecure Witness Auditors, as is required by the IFS Standard. Therefore, certification bodies have the following responsibilities:

- To manage witness audits (by accreditation bodies, Integrity Program, and certification body through the monitoring program and sign-off audits).
- To ensure that auditors or assessment teams are qualified for the full scope of the assessment and are able to apply relevant laws, regulations, IFS requirements and the certification body's own rules.
- To maintain auditor competencies (by continuous supervision by the certification body) and monitor assessment performance of every auditor by an on-site witness audit at least once every two (2) years (see more details in chapter 3, Part 3).
- To witness auditors who are already IFS PACsecure Auditors but new to the certification body when starting to perform IFS PACsecure Assessment for them (this witness audit can count as the regular monitoring assessment so that the next regular monitoring assessment will be performed in the second year).
- To ensure that auditors act impartially (e.g. not acting against IFS rules, not having acted as a consultant or having had involvement with or acted on behalf of the companies being assessed during the previous two (2) years).
- To ensure that no auditor shall perform more than three (3) consecutive IFS PACsecure Assessments at the same production site (this only applies for full Assessments, irrespective of the time between them; this does not apply for follow-up assessments, extension assessments, and assessments that have been observed as a trainee, including auditor in progress (AIP) assessments 1 to 5)
- To ensure that all auditors have a valid contract with them.
- To obtain a signed agreement from the auditors for each assessment, which includes the statement:
  - **of compliance with all rules defined by the certification body, including confidentiality and independence from commercial and other interests**
  - **of absence of conflict of interest, including a declaration in case of any association to the company being assessed, currently or within the last two (2) years.**
- To ensure that at least one member of the certification body staff is responsible for certification body in-house IFS training. This approved IFS Trainer shall have taken part in the "Assessments under the IFS PACsecure Standard" course organised by IFS.
- To organise eight (8) hours of in-house training for IFS PACsecure Auditors and IFS PACsecure Reviewers per year, for the purpose of sharing experience, calibration and updating knowledge of relevant legal requirements, among other relevant aspects related to the standard and IFS Assessments. The IFS Trainer is responsible for the content of the training and shall lead at least part of the training. The content of the IFS yearly in-house training shall include, at a minimum, the following contents:
  - packaging-related legislation,
  - hazard trends in packaging materials,

- relevant elements of the IFS PACsecure Standard and IFS PACsecure Doctrine,
- assessment practices according to the IFS Good Assessment Practices guideline,
- failures in reports and findings,
- exercises to calibrate criteria regarding the IFS Scoring System.

Topics such as legislation, assessment practices, product safety updates can be the same as for other GFSI recognised certification standards in the related scope.

- The IFS yearly In-house training shall be solely dedicated to IFS and can either take place via face-to-face meeting or via online session(s). The signature list and the agenda of the training shall be available upon request.
- To be fully cognisant of the examination regulations provided by IFS and available on the IFS Website.
- To ensure the assessment report and associated documentation including auditor's notes are stored safely and surely for a period of five (5) years and shall be available on request.

The certification body is responsible for appointing an auditor or an assessment team with the corresponding product scope(s), language, competency / ies, etc., for each IFS Assessment.

Every certification body shall have a minimum of:

- One contracted IFS PACsecure Auditor
- One contracted IFS PACsecure Reviewer
- One approved IFS PACsecure Trainer
- An IFS responsible person (contact person for IFS).

In case of any changes related to IFS Trainers and IFS responsible persons, the certification body shall inform the IFS Certification Body Management.

3 Requirements for IFS PACsecure Auditors, IFS PACsecure Reviewers, IFS PACsecure Trainers and IFS PACsecure Witness Auditors

Certification bodies shall ensure the specific roles and functions of certification body staff complies with the following rules.

3.1 Requirements for IFS PACsecure Auditors

IFS PACsecure Auditors can work on an exclusive basis with only one certification body or on a non-exclusive basis for one or more certification bodies.

An exclusive auditor shall have submitted all relevant information about her / his competencies to the certification body and the certification body shall have assessed and confirmed her / his competencies before they register her / his as a new exclusive auditor in the IFS Database.

A non-exclusive auditor is fully responsible for her / his own application as IFS PACsecure Auditor and shall register her- / himself as a new non-exclusive auditor in the IFS Database. The competencies of a new non-exclusive auditor are assessed directly by IFS Auditor Management via their online CV.

The role of an IFS PACsecure Auditor is to perform IFS PACsecure Assessments according to the IFS PACsecure Standard and the IFS PACsecure Doctrine.

The following sections detail the requirements for being approved as an IFS PACsecure Auditor.

3.1.1 Auditor approval process

In general, the auditor shall meet the requirements of chapters 7.2.2 and 7.2.3 of ISO / IEC 19011.

For an exclusive auditor, the contract, which includes the requirements described under section 2.6, shall be signed with the certification body (see ISO / IEC 17065:2012 norm) before applying for IFS PACsecure Examination.

For a non-exclusive auditor, the contract with one (or more) certification bodies can be signed after the IFS PACsecure Examination.

All auditors shall have signed the "General terms and licensing conditions of IFS Management GmbH for IFS Auditors" and the "Integrity Program rules for Auditors.

3.1.2 General requirements for auditors when applying for IFS PACsecure Examination

Candidates applying to qualify as IFS PACsecure Auditors shall meet the following minimum requirements and provide evidence with the application documents. The CV has to be submitted via the IFS Database.

a) Education

One of the following options shall be met:

Option 1: A packaging technology or material engineering-related degree (minimum a bachelor's degree or equivalent) or at least a successfully completed packaging-related professional higher education AND a food hygiene and HACCP training course based on CODEX, with a duration of at least two (2) days / 16 hours.

Option 2: A food-related or bioscience degree (minimum a bachelor's degree or equivalent) or at least a successfully completed food-related professional higher education.

b) Working experience

A minimum of two (2) years full-time professional experience related to the packaging industry sector, achieved by one, or a combination of, the following functions:

- Experience related to packaging manufacturing activities (quality assurance, product safety, production, R&D …)
- Packaging safety auditing
- Packaging safety inspection or enforcement.

c) Qualification

The candidate shall have:

- Taken part in a recognised lead auditor course (e.g. IRCA) with a duration of at least 40 hours.
- Taken part in a risk assessment techniques training course (based on internationally recognised standards/norms), with a duration of at least two (2) days/16 hours.

d) General audit experience

A minimum of three (3) full packaging safety audits shall have been performed by the auditor in the packaging industry during the previous three (3) years. Audits shall have been carried out at different production sites.

Following types of audits are accepted as valid general audit experience:

- GFSI recognised certification audits in the related scope
- IFS Progress PACsecure Assessments at Intermediate Level
- Recognised second party audits according to the "Recognisable audit experience procedure for IFS PACsecure" which is available in the certification body log in area of the IFS Database

In addition, the candidate shall have participated in two (2) full IFS PACsecure Certification Assessments as a trainee during the last two (2) years.

The audits shall have been carried out at different production sites.

e) Specific and practical knowledge per product scope

For each applied product scope, one of the following options shall be met:

Option 1: two (2) years full-time professional experience related to the packaging industry sector, in functions related to the packaging manufacture activities (quality assurance, product safety, production, R&D…). Experience from consultancy in relation to the packaging manufacture activities may be recognised as a maximum of one (1) year towards the work experience, if it can be proven by customer contracts, invoices, orders or confirmations.

Option 2: At least five (5) full packaging safety audits performed in the relevant product scope by the auditor in the packaging industry, carried out at different production sites, belonging to the following categories:

- GFSI recognised certification audits in the related scope
- IFS Progress PACsecure Assessments at Intermediate Level
- Recognised second party audits according to the "Recognisable audit experience procedure for IFS PACsecure" which is available in the certification body log in area of the IFS Database

If professional work experience (option 1) or audit experience (option 2) do not individually fulfil the requirements to apply for a product scope, a combination of both can be accepted (e.g. one year of work experience plus three (3) audits or equivalent combinations).

In case of scope 1, 2 and 7, following combinations are possible:

Chart 8: Possible combinations to obtain product scope(s) 1, 2, and / or 7:

To obtain	Option 1	Option 2
Scope 1 **Flexible plastic**	At minimum of three (3) audits on scope 1 AND Two (2) audits on scope 1 and / or 2	At minimum of one year of work experience in scope 1 AND Three (3) audits on scope 1 and / or 2
Scope 2 **Rigid plastic**	At minimum of three (3) audits on scope 2 AND Two (2) audits on scope 2 and / or 1	At minimum of one year of work experience in scope 2 AND Three (3) audits on scope 1 and / or 2
Scope 7 **Other packaging components**	At minimum of three (3) audits on scope 7 AND Two (2) audits in any other product scope where these materials are included in the production / conversion of the final product and are part of it.	At minimum of one year of work experience in scope 7 AND Three (3) audits on scope 7 and / or in any other product scope where these materials are included in the production / conversion of the final product and are part of it.

The candidate shall have participated in all steps of the audits (on-site audit, assessment and auditor's on-site decision-making processes). Audits shall have been preferably carried out at different production sites, with a maximum of three (3) audits at the same production site.

Note: The product scopes defined for IFS PACsecure are listed in ANNEX 3.

f) Language

If the auditor wishes to perform assessments in language(s) different to her / his mother tongue, she / he shall be able to provide evidence of fluency in this / these other language(s). For further information about the acceptance of other languages, see the IFS PACsecure Doctrine.

g) "Assessments under the IFS PACsecure Standard" course

The candidate shall have taken part in the "Assessments under the IFS PACsecure Standard" course organised by IFS. The "Assessments under the IFS PACsecure Standard" course shall not have taken place more than one year prior to the date of initial application for the IFS Examination. The intention of this course is to prepare the candidates for the IFS Examination.

h) Online modular course provided by IFS ("IFS Training on product / process approach")

The candidate shall have taken part in the IFS Training on product / process approach.

Relevant considerations related to the initial application:

- For exclusive auditors, the auditor's CV shall be confirmed by a person from the certification body.
- Non-exclusive auditors have to confirm the correctness and completeness of the data provided in their CV by themselves.
- IFS Offices have the possibility to withdraw an IFS PACsecure Auditor approval or not to accept them for the examination if the information provided in the CV is false.

3.1.3 IFS PACsecure Examination process

Auditors who comply with the requirements mentioned in chapter 3.1.2, Part 3, can then take part in the written IFS PACsecure Examination which is executed online.

The written IFS PACsecure Examination is divided into two main sections:

- General exam (independent of product scopes the auditor is confirmed for).
- Product scope exam(s) (dependent on the product scopes the auditor is confirmed for).

Detailed rules for the online written IFS PACsecure Examination are provided at the IFS Website.

3.1.4 Sign-off audit

Upon successful completion of the written IFS Examination, the auditor shall be signed off during her / his first IFS PACsecure Assessment in the scope they will be approved for.

The sign-off audit is the first witness audit of an auditor after having passed the IFS Examination for the purpose of confirmation of competencies for final approval as an IFS PACsecure Auditor. The sign-off audit shall be performed during a full IFS PACsecure Certification Assessment.

Once the evidence of the performed sign-off audit has been approved by IFS, the auditor will be activated as an IFS PACsecure Auditor in the IFS Database and a personal IFS PACsecure Auditor Certificate will be issued for the activated Auditor. The IFS PACsecure Auditor Certificate mentions the duration of validity and the product scope(s) the auditor is approved for. Starting from the day of activation, the auditor is allowed to perform IFS PACsecure Assessments for the product scope(s) she / he has been approved for by IFS Offices.

The certificate validity starts from the date of the passed written IFS PACsecure Examination and stops at the end of the second calendar year, irrespective of the date of activation as an IFS PACsecure Auditor.

Example: If an auditor passes the written IFS PACsecure Examination on 20.10.2020, the auditor certificate will be valid until 31.12.2022.

3.1.5 Specific training program for "auditors in progress" ("AIP")

If a candidate has no auditing experience yet but fulfils all other requirements of 3.1.2 except "d) General audit experience", she / he can take part in the IFS training program for "auditors in progress". All other rules for auditors in the standard are not affected and shall be fulfilled.

In the framework of the AIP program, the candidate shall pass the written IFS PACsecure Examination before participating in an adjusted program for gaining audit experience. This program is only possible for exclusive auditors. However, an auditor can initially apply as a non-exclusive auditor, but after having passed the written IFS PACsecure Examination, she / he has to switch to the exclusive status to be able to gain audit experience and complete the AIP program under the responsibility of one certification body.

The steps for "Auditors in Progress (AIP)" are the following:

I. **Submit the CV via the IFS Database:** A full CV shall be filled in online via the IFS Database. Information regarding all requirements of 3.1.2 shall be provided, except for "d) General audit experience".

II. **Pass the written IFS PACsecure Examination.** Once the written IFS PACsecure Examination is passed, the candidate becomes an IFS "Auditor In Progress" (AIP).

III. **Gain the missing audit experience.** The AIP shall participate in a "witnessing program" consisting of five (5) audits / assessments which shall be performed in a specific order, with specific tasks assigned, as described in the following chart:

Chart 9: Auditor in progress auditing / assessing experience 1–5

N° of audit / assessment	Tasks	Possible audit / assessment types
1	Trainee Without participation in the audit	• GFSI recognised certification audits in the related scope • IFS Progress PACsecure Assessments at Intermediate Level.
2 – 3	Trainee Active participation in the audits / assessments under supervision and responsibility of an experienced lead auditor	• GFSI recognised certification audits in the related scope • IFS Progress PACsecure Assessments at Intermediate Level
4 – 5	Trainee Active participation in the IFS Assessments under the supervision and responsibility of an IFS approved auditor	IFS PACsecure Assessment
Additional information: • The assessment team shall never separate during the audits / assessments. • Audits / assessments 1 – 5 are accepted for scope extensions and can be performed in any product scope. Only one "auditor in progress" shall take part in these training audits / assessments.		

IV. **Sign-off witness audit.** After the 5th The AIP shall perform the 6th assessment under their own responsibility as a sign-off audit. This sign-off audit, which is performed during an IFS PACsecure assessment, shall be:

- performed in a company where the assessment scope matches the product scope(s) the "auditor in progress" is applying for
- witnessed by an IFS Witness Auditor who is approved for product scope(s) of the assessment.

The report of the sign-off audit shall be documented in the template provided by IFS.
The auditing / assessing experience, including the sign-off audit, shall be completed within a period of two (2) years after passing the IFS Examination.

V. **Release of the "auditor in progress".** If the sign-off audit has been performed successfully, the certification body will officially release the auditor and inform IFS. The "auditor in progress" performance reports for the audits / assessments 2 to 6 and the report for the sign-off audit shall be provided to IFS. If all requirements are fulfilled, the auditor will be activated as an IFS PACsecure Auditor in the IFS Database.

3.1.6 Maintenance of auditor's approval

The auditor's approval shall be reassessed before the end of validity of her / his auditor's certificate.

To maintain her / his approval, the exclusive auditor shall fulfil the following requirements:

- Every year: to have taken part in a one (1) day / eight (8) hours yearly in-house training by the certification body (see specifications on this training in 2.6).
- Every year: to have performed a minimum of five (5) IFS PACsecure Assessments as a lead or co-auditor. This is applicable from the first full year following the approval as an IFS PACsecure Auditor. This is applicable from the first full year following approval as an IFS PACsecure Auditor.
- Every two (2) years: to be assessed by the certification body during a full IFS PACsecure Assessment (on-site witness audit), in order to evaluate her / his competencies. This assessment can be performed at any time during the second calendar year following the year when the last witness audit took place. This can be replaced every second time (every four (4) years), by a full on-site witness audit performed during another GFSI recognised certification standards audit in the related scope and accredited to ISO / IEC 17065:2012 norm. The witness auditor shall not be part of the assessment (as a team member). For the on-site witness audit performed during an IFS PACsecure Assessment, the witness auditor shall be an approved IFS PACsecure Auditor and shall fulfil the requirements to act as an IFS Witness Auditor, as defined in chapter 3.4. The certification body shall specify the name of the witness auditor in the IFS Assessment Report. The witness audits should over time reflect the scopes an auditor is approved for.

A non-exclusive auditor is responsible for maintaining her / his own IFS approval.
To maintain her / his approval, the non-exclusive auditor shall fulfil almost the same requirements as for exclusive auditors, with the following variants (in bold):

- Every year: to have taken part in a one (1) day / eight (8) hours yearly in-house training with **each certification body** the non-exclusive auditor is linked to in the IFS Database.
- Every year: to have performed a minimum of five (5) IFS PACsecure Assessments as a lead or co-auditor. This is applicable from the first full year following approval as an IFS PACsecure Auditor. This is applicable from the first full year following approval as an IFS PACsecure Auditor.
- Every two (2) years: to be assessed by **each certification body** during a full IFS PACsecure Assessment (on-site witness audit).

Note 1: If the witness audit is performed during another GFSI recognised certification standards audit in the related scope, the witness auditor shall witness the auditor during the full calculated audit duration.

Note 2: Successfully completed witness assessments from accreditation bodies or witness audits from the IFS Integrity Program during IFS PACsecure Assessments can replace the witness audits from the certification body.

Note 3: For an assessment team, the lead auditor can only be witnessed if the assessment team did not split during the assessment.

For exclusive and non-exclusive auditors

- Every two (2) calendar years: to have attended and successfully completed a two (2) day IFS PACsecure Calibration Training, organised by IFS. Subsequent to passing the initial IFS Examination, the first mandatory IFS Calibration Training shall be completed in the second calendar year following the date when the written IFS Examination was passed.

Evidence of the above-mentioned requirements shall be uploaded in the IFS Database, where required by IFS, before the end of the validity of the auditor's certificate.

IFS manages auditor re-approval every two (2) years:

- If all requirements are fulfilled, IFS reissues a new auditor certificate which is valid for two (2) more years.
- If not all of them are fulfilled, the auditor shall participate in the IFS initial examination again.

Example of situation where all requirements are fulfilled:

- Date of passed written IFS Examination: 25th May 2019
- Date of end of validity for IFS PACsecure Auditor Certificate (initial approval): 31st December 2021
- The auditor shall participate in an IFS Calibration Training between 1st January and 31st December 2021.
- The auditor is authorised to perform IFS Assessments from the day of activation in the IFS Database until 31st December 2021.
- In 2021, if the auditor has:
  - performed five (5) IFS PACsecure Assessments per year and
  - taken part in the IFS Calibration Training (e.g. on 8th and 9th September 2021) and
  - fulfilled all other rules mentioned in 3.1.6
- The new end of validity date for IFS PACsecure Auditor Certificate (re-approval) is: 31st December 2023.

3.1.7 Specific situation of temporarily inactive auditor

If an auditor needs to take a timeout (i.e., a break from her / his activity as an IFS PACsecure Auditor for at least six (6) months and no longer than three (3) years), due to e.g. maternity / paternity leave or illness, the auditor's certification body shall inform IFS Auditor Management of both the start and end date of the timeout period as soon as possible. Non-exclusive auditors shall provide IFS Auditor Management with the above requested information.

If, due to the timeout, the requirements mentioned in to maintain auditor approval in 3.1.6 are not fulfilled (in-house training every year, witness audit every second year and IFS Calibration Training every second year), the auditor shall fulfil them within a one-year period following the

timeout and before she/he can resume her/his activity as an IFS PACsecure Auditor. If not, the auditor will lose her/his IFS PACsecure approval and shall participate in the IFS initial examinations again

3.1.8 Scope extension for approved IFS PACsecure Auditors

Auditors may, during the validity of their IFS PACsecure Auditor Certificate, extend their approval for product scope(s), based on new or extended experience gained after their initial application as an IFS PACsecure Auditor.

For extension of product scope(s), the auditor shall provide the same evidence as for the initial approval process (see 3.1.2 e), based on new experience different to that provided for initial application. The auditor shall additionally pass the corresponding written product scope exam, organised by IFS Offices.

Note 1: IFS PACsecure Assessments which were performed under the supervision of a witness auditor, can count for the witness auditor to apply for a product or technology scope extension.

Note 2: In the case of an assessment team, the auditors shall stay together during the whole IFS Assessment to use the performed IFS PACsecure Assessment as evidence for an auditor scope extension.

3.1.9 Further rules and explanations concerning the non-exclusive approach

Each auditor can switch her/his status between exclusive/non-exclusive (and vice versa). The concerned certification bodies will be notified automatically by IFS for every switch between the approaches.

A non-exclusive auditor shall not take over any position of responsibility regarding IFS in a certification body (e.g. she/he cannot be an IFS Trainer, an IFS responsible nor a contact person for IFS).

For further rules applicable for non-exclusive auditors, see the IFS PACsecure Doctrine.

3.1.10 General rules about assessment teams

All members of the assessment team shall be approved IFS PACsecure Auditors.

In case of assessing in teams, the following requirements apply:

- An IFS Assessment Team consists of IFS PACsecure Auditors whose combined profile (product scope(s)) complies with the scope of the assessed production site.
- A lead auditor shall always be appointed.
- Lead and co-auditor(s) shall always be approved for the product scope of the assessment scope.
- A minimum of two (2) hours shall be added to the calculated assessment duration. This additional time shall be allocated to the team for common tasks (e.g. opening and closing meetings, discussion about assessment findings, etc.) and not to an individual auditor.

- The remaining time can be split, as long as the auditor competencies for product scope are always covered during the assessment.

The assessment time schedule shall clearly indicate which auditor performed which part of the assessment.

3.2 Requirements for IFS PACsecure Reviewers

An IFS PACsecure Reviewer shall either be an IFS PACsecure Auditor or an IFS PACsecure Pure Reviewer (if not an IFS PACsecure Auditor).

The role of an IFS PACsecure Reviewer is to review the IFS PACsecure Assessment Reports according to the IFS PACsecure Standard and the IFS PACsecure Doctrine. This comprises, as a minimum, the following tasks:

- To check the overall consistency of the IFS Assessment Reports.
- To check if the IFS Assessment Reports are properly completed (e.g. compulsory fields, etc.).
- To check if the findings are well described and if the justifications are relevant.
- To check if the correction and corrective actions as well as the deadlines for implementation proposed by the assessed company have been validated by the auditor (or by a representative of the certification body) and are relevant.

Note: The review shall be documented.

The IFS PACsecure Auditor cannot review assessment reports where she / he has been involved in the execution of the assessment (e.g. as IFS Witness Auditor, trainee)

The following section details the requirements for being approved as IFS PACsecure Pure Reviewer.

3.2.1 General requirements for IFS PACsecure Pure Reviewers

Candidates applying to qualify as an IFS PACsecure Pure Reviewer shall meet the following minimum requirements and provide evidence with the application documents.

a) Education
Same professional education as requested for IFS PACsecure Auditors.

b) Working experience
Same working experience as requested for IFS PACsecure Auditors.

c) Qualification
The candidate shall have taken part in a risk assessment techniques training course (based on internationally recognised standards/norms), with a duration of at least two (2) days/16 hours:

d) General audit experience

The candidate shall have attended to:

- Two (2) IFS PACsecure Assessments as trainee, AND
- Three (3) packaging safety audits as trainee or auditor, belonging to the following categories:
  - GFSI recognised certification audits in the related scope
  - IFS Progress PACsecure Assessments at Intermediate Level
  - Recognised second party audits according to the "Recognisable audit experience procedure for IFS PACsecure" which is available in the certification body log in area of the IFS Database

The audits / assessments listed above shall be executed during the previous five (5) years and shall have been carried out at different production sites.

e) Language

If the candidate wishes to review assessments in language(s) different to her / his mother tongue, she / he shall be able to provide evidence of fluency in this / these other language(s). The decision if a reviewer's language skills are sufficient to carry out a technical review in a proper way, in the respective language, is the responsibility of the certification body.

f) "Assessments under the IFS PACsecure Standard" course

The candidate shall have taken part in the "Assessments under the IFS PACsecure Standard" course organised by IFS.

g) Online modular course provided by IFS ("IFS Training on product / process approach")

The candidate shall have taken part in the IFS Training on product / process approach.

h) In-house training related to the IFS PACsecure Reviewer task

One (1) day of in-house training, organised by the certification body, dedicated to specific tasks related to the reviewer role.

Relevant considerations related to the application:

- Once the reviewer has fulfilled the above-mentioned requirements and this has been approved by IFS, she / he will be activated as an IFS PACsecure Pure Reviewer in the IFS Database and a personal IFS PACsecure Reviewer Certificate will be issued.
- Starting from the day of activation, the IFS PACsecure Reviewer is allowed to perform technical reviews of IFS PACsecure Assessment Reports.
- The certificate validity period starts from the date of activation in the IFS Database and stops at the end of the second calendar year, irrespective of the actual activation date.

3.2.2 Maintenance of IFS PACsecure Pure Reviewer's qualification

The pure Reviewer's approval shall be reassessed before the end of validity of her / his reviewer's certificate.

To maintain her / his approval, the IFS PACsecure Reviewer shall fulfil the following requirements:

- Every year: to have taken part in a one (1) day / eight (8) hours yearly in-house training by the certification body (see specifications on this training in 2.6).

- Every two (2) years: to have taken part (as trainee) at one IFS PACsecure Assessment.
- Every two (2) calendar years: to have attended and successfully completed a two (2) day IFS PACsecure Calibration Training, organised by IFS. The IFS Calibration Training shall be completed in the second calendar year following the date of the initial approval.

3.3 Requirements for IFS PACsecure Trainers

The role of an IFS PACsecure Trainer comprises following tasks:

- Train auditors and Reviewers
- Generate the content for the yearly in-house training for IFS PACsecure Auditors and IFS PACsecure Reviewers
- Organise the training program for all IFS PACsecure Auditors and IFS PACsecure Reviewers of the certification body
- When a new IFS Doctrine is published, to train all approved IFS PACsecure Auditors and IFS PACsecure Reviewers before they perform any new assessment or technical review (this training can be done face-to-face, online or by webinar).

The following section details the requirements for being approved as an IFS PACsecure Trainer.

3.3.1 General requirements for IFS PACsecure Trainers

Candidates applying to qualify as an IFS PACsecure Trainer shall meet the following minimum requirements and provide evidence with the application documents.

a) Education
Same professional education as requested for IFS PACsecure Auditors.

b) Working experience
Same working experience as requested for IFS PACsecure Auditors.

c) Qualification
The candidate shall have taken part in a risk assessment techniques training course (based on internationally recognised standards/norms), with a duration of at least two (2) days/16 hours.

d) General audit experience
Same general audit experience as requested for IFS PACsecure Auditors.

e) Language
The IFS PACsecure Trainers shall be fluent in English and in the language(s) used when conducting the training.
If the candidate wishes to execute training in language(s) different to English and her/his mother tongue, she/he shall be able to provide evidence of fluency in this/these other language(s).
The decision if a trainer language skill is sufficient to carry out a training in a proper way, in the respective language, is the responsibility of the certification body.

f) "Assessments under the IFS PACsecure Standard" course
The candidate shall have taken part in the "Assessments under the IFS PACsecure Standard" course organised by IFS.

g) Online modular course provided by IFS ("IFS Training on product / process approach")
The candidate shall have taken part in the IFS Training on product / process approach.

3.3.2 Maintenance of IFS PACsecure Trainer's qualification

To maintain her / his approval, the IFS PACsecure Trainer shall fulfil the following requirements:

- Every year: to carry out or have taken part in a one (1) day / eight (8) hours yearly in-house training by the certification body (see specifications on this training in 2.6).
- Continuously: to stay informed about any new information on IFS PACsecure Standard and IFS PACsecure Doctrine (provided by IFS to their certification body)

3.4 Requirements for IFS PACsecure Witness Auditors

The role of an IFS Witness Auditor comprises following tasks:

- Supervise the audit / assessment activity of the AIP
- Monitor the assessment performance of IFS PACsecure auditors by an on-site witness audit for the maintenance of auditor's approval
- Witness the sign-off witness audit
- Provide comprehensive witness audit reports, in the template provided by IFS.

Candidates applying to qualify as an IFS PACsecure Witness Auditors shall meet the following minimum requirements:

a) Qualification and experience
The candidate shall be:

- An experienced IFS PACsecure Auditor [to have already performed at least ten (10) full IFS Assessments as lead auditor], OR
- An experienced IFS Auditor (Food or HPC) [to have already performed at least ten (10) full IFS Assessments as lead auditor] who has taken part in the course "Assessments under the IFS PACsecure Standard", OR
- An IFS PACsecure Trainer who is also an IFS PACsecure Pure Reviewer

b) Language
The candidate shall be approved for the language(s) in which the assessment is performed.

c) IFS Witness Auditor online course
The candidate shall have taken part in the IFS Witness Auditor online course (provided by IFS)

d) Registration as IFS Witness Auditor
Once the previous requirements are fulfilled, the candidate shall be appointed as a witness auditor in the IFS Database
It is the responsibility of the certification body to ensure that the witness auditor has the required skills, both on interpersonal and professional levels, to be able to witness other auditors in a constructive manner.

3.5 Requirements for approved IFS PACsecure Auditors, IFS PACsecure Reviewers, IFS PACsecure Trainers and IFS PACsecure Witness Auditors when a new IFS PACsecure version is released

When a new version of the IFS PACsecure Standard is published, all the IFS PACsecure Auditors, IFS PACsecure Reviewers, IFS PACsecure Trainers and IFS PACsecure Witness Auditors shall have taken part in the new version of the "Assessments under the IFS PACsecure Standard" course organised by IFS before they perform Assessments and technical reviews based on the new version. This training shall be performed in addition to the annual in-house training.

3.6 Overview about requirements for initial and maintenance of approval and the tasks of each IFS role in a certification body

The following chart (chart 10) gives an overview about requirements for initial and maintenance of approval, as well as for the tasks of the specific IFS roles in a certification body.

Chart 10: Overview about requirements for initial and maintenance of approval and the tasks of each IFS role in a certification body

Function / role in certification body	Profile / requirements for initial approval	Requirements for maintenance of approval	Task
IFS PACsecure Auditor (see chapter 3.1)	• Professional Education • Work experience • Qualifications • General audit experience • Specific knowledge in product scope • "Assessments under the IFS PACsecure Standard" course • Online modular course provided by IFS ("IFS Training on product / process approach") • Passed IFS PACsecure Examinations (written) • Sign-off audit	• Every year: One (1) day (8 hours) in-house training by the certification body • Every year: five (5) IFS PACsecure Assessments. • Every two (2) years: one IFS PACsecure witness audit (every second time, i.e., every four (4) years, it can be replaced by an on-site witness audit during another GFSI certification standards audit in the related scope and accredited to ISO / IEC 17065:2012 norm) • Every two (2) years: IFS PACsecure Calibration Training, organised by IFS	• Perform IFS PACsecure Assessments. • Option to be IFS PACsecure Reviewers (if not performed the assessment her- / himself)

Function / role in certification body	Profile / requirements for initial approval	Requirements for maintenance of approval	Task
IFS PACsecure Pure Reviewers (see chapter 3.2)	• Professional Education • Work experience • Qualifications • General audit experience (as trainee or performed her- / himself) • "Assessments under the IFS PACsecure Standard" course • Online modular course provided by IFS ("IFS Training on product / process approach")	• Every year: One (1) day (8 hours) in-house training by the certification body • Every two (2) years: One (1) IFS PACsecure Assessment as trainee • Every two (2) years: IFS PACsecure Calibration Training, organised by IFS	• Review IFS PACsecure Assessment Reports
IFS PACsecure Trainers (see chapter 3.3)	• Professional Education • Work experience • Qualifications • General audit experience • Fluency in English language • "Assessments under the IFS PACsecure Standard" course • Online modular course provided by IFS ("IFS Training on product / process approach")	• Every year: to carry out or have taken part in one (1) day (8 hours) in-house training by the certification body • Continuously: check and communicate the IFS updated information provided by IFS.	• Train auditors and Reviewers • Generate the content for the yearly in-house training for IFS PACsecure Auditors and • Reviewers • Organise the training program for all IFS PACsecure Auditors and Reviewers • When a new IFS Doctrine is published, to train all approved IFS PACsecure Auditors and Reviewers

Function / role in certification body	Profile / requirements for initial approval	Requirements for maintenance of approval	Task
IFS PACsecure Witness Auditors (see chapter 3.4)	• Experienced IFS PACsecure Auditor [at least ten (10) full IFS Assessments as a lead auditor], OR experienced IFS Auditor (Food / HPC) [at least ten (10) full IFS Assessments as a lead auditor] who has taken part in the course "Assessments under the IFS PACsecure Standard", OR IFS PACsecure Trainer who is also an IFS PACsecure Pure Reviewer • Witness auditor course provided by IFS • Approved for the language(s) in which the assessment is performed.	• Linked to the maintenance of approval as IFS Auditor / IFS PACsecure Pure Reviewer and IFS PACsecure Trainer	• Supervise the audit / assessment activity of the AIP • Witness auditors (sign-off, maintenance of auditor's qualification)

PART 4
Reporting, auditXpressX™ software and IFS Database

0 Introduction

After performance of an IFS PACsecure Assessment, a detailed and well-structured assessment report shall be completed. In general, the language of the report shall be the working language of the company. In special cases defined by the certification bodies and agreed with the retailer(s) and different involved parties, the version of the report can be in English.

Note: For any combined assessment (IFS PACsecure / IFS Broker or IFS PACsecure / IFS Logistics), two (2) separate reports shall be written, and two (2) separate certificates shall be issued and uploaded in the IFS Database.

The IFS PACsecure Assessment Report shall be prepared according to the following format:

- the assessment overview (chapter 1.1)
- the main content (chapter 1.2).

1 Reporting

1.1 IFS Assessment Report: assessment overview (ANNEX 9)

Cover page

The cover page of the IFS Assessment Report shall include:

- certification body logo
- IFS PACsecure Logo
- name of the assessed site
- dates(s) of the assessment (in case of a follow-up and /or extension assessment, the date(s) shall additionally be specified)
- legal authorisation number and packaging code, if applicable
- name and address of the certification body
- certification body's accreditation details
- "Unannounced assessment" phrase if the assessment was unannounced.

Assessment overview

The assessment overview shall include the following mandatory information:

- **Assessment Option**
  - if the assessment was unannounced, "Unannounced assessment" shall be mentioned on the assessment overview of the report.

- **Assessment details**
  - name of the lead auditor, reviewer (person in charge of the technical report review), co-auditor, trainee and witness auditor, if applicable
  - Assessment date(s) (in case of a follow-up assessment, the date of the follow-up assessment shall additionally be specified)
  - duration of the assessment (start and end time for each assessment day)
  - previous assessment dates (start and end time for each assessment day)
  - name of the certification body and the auditor who performed the previous assessment
  - name and address of the assessed site
  - name and address of the company (or head office / central management)
  - COID (IFS identification code number) as defined in the IFS Database
  - details of the contact person in case of emergency (e.g. recall): name, e-mail and phone number at a minimum
  - version of the standard.
- **Scope of the assessment**
  - detailed description of processes and products, including the information about the intended use of products (primary and / or secondary packaging materials).
  - codes / numbers of product scopes.
- **Additional information**
  - description if products are food contact materials and / or non-food contact materials, according to intended use.
  - description of exclusions, if applicable
  - description of partly outsourced processes (explanations, number of subcontractors, description including name, address and certification status, COID(s)), if applicable
  - description of decentralised structure(s), if applicable, and off-site warehouse(s) (name the location):
    - if certified for IFS Logistics, provide the COID
    - if not, mention if it has been covered during the IFS PACsecure Assessment
    - if not, describe the company's control measures.
  - description of multi-location production sites, if applicable. If this applies, it shall include the following compulsory information:
    - all COIDs of the production sites linked to the head office / central management
    - the assessment date of the head office / central management assessment
    - the description of the centrally managed processes and the outcome of the assessment from the head office / central management)
- **Final result of the assessment**
  - final assessment result with level and percentage
  - time window in which the recertification assessment shall be performed or if it will be unannounced.
  - in case of a follow-up assessment, specify that a follow-up assessment has taken place and the outcome ("the Major non-conformity has been solved" or "the Major non-conformity still valid")

- **Observations regarding non-conformities (D evaluation of KO requirement(s) and Majors)**
- **Description of follow-up on corrections and corrective actions from previous assessment**
  - Description of corrections and corrective actions from the previous assessment (see part 1, chapter 2.3.2).
- **Company profile**
  - The company profile requires compulsory information on the company's structure and activities and is divided into two (2) standardised sections: company data and assessment data. This allows readers to have a clear understanding of the company's structure, organisation, production, processes, etc. In addition to the required compulsory information, further information can be added by the auditor for each section.

Note: In case of a follow-up assessment, additional explanations shall be provided in assessment overview (see part 1, chapter 4.2.1.1).

1.2 IFS Assessment Report: main content (ANNEX 10)

The main content of the IFS Assessment Report is structured as follows:

- General summary in a tabular format for all chapters, listing the number of assessed requirements per scoring for each chapter and the result (in percentage) per chapter.
- Overall summary: table of compulsory fields for specific IFS PACsecure Assessment requirements. For those specific requirements, the auditor shall provide additional justifications and / or further background information, even in case of an A scoring. This leads to a more significant and descriptive report, even if the assessed site almost fulfils all IFS PACsecure requirements and adds value for every user / reader.
- List of all identified deviations and non-conformities for each requirement per chapter.
- Summary of points of attention (requirements scored with a B).
- List (including explanations) of all requirements evaluated as N / A (not applicable).
- Detailed assessment report (checklist).
- Annex of the assessment report, including:
  - Assessment participants' list: list of key personnel present during the assessment. The assessment participants' list is also included in case of extension and/or follow-up assessments.
  - Reminder of IFS rules: tables on product scopes, IFS Scoring System and conditions for issuing of certificate.

1.3 Action plan (ANNEX 7)

For each assessment requirement, the IFS Auditor shall describe and explain all identified deviations and non-conformities (D evaluation of KO requirement(s), Majors) in the action plan, which has a specified format. For additional information, see also chapter 4, Part 1.

1.4 Minimum requirements for the IFS Certificate (ANNEX 11)

After successful completion of the IFS PACsecure Assessment process, the certification body shall issue a certificate. For the purpose of international recognition and overall consistency, IFS PACsecure Certificates issued by the certification body shall include, at a minimum:

- if the assessment was unannounced, "Unannounced assessment" shall be mentioned
- name and address of the certification body, including its logo
- accreditation body logo (used in conformity with accreditation body's rules) or its name and registration number
- name and address of the assessed site
- COID (IFS identification number) as defined in the IFS Database
- packaging code and legal authorisation number, if applicable
- in case of multi-location production sites: name of the site's head office / central management, if applicable
- description of the assessment scope, which shall always be translated in English
- description of processes / products
- name and number of product scope(s)
- in case of partly outsourced processes, addition of the following sentence: "Besides own production, the company has partly outsourced processes"
- description of product exclusions, if applicable
- in case of additional broker activities: Certification status by writing the sentence: "The company has own broker activities which are / are not IFS Broker certified". (for further information, see chapter 2.2.1, Part 1 and ANNEX 1)
- level achieved
- assessment score in percentage
- last unannounced assessment date (last day of the assessment). If an unannounced IFS PACsecure Assessment has not yet been conducted for the respective COID, the certificate shall indicate the following: "Last assessment conducted unannounced: N / A".
- assessment date(s)
- follow-up assessment date, if relevant
- next assessment time period (recertification assessment), specify if unannounced
- certificate issue date
- expiry date of the certificate (certificate validity shall remain the same each year, as described in Part 1)
- name and signature of the responsible person at the certification body
- place and date of signature
- current IFS PACsecure Logo
- QR-code with the information about COID, standard and issue date of certificate (QR-code will be automatically generated when the new IFS PACsecure report is uploaded.).

Note: The auditXpressX™ software includes a certificate format with the minimum required content, but each ISO / IEC 17065:2012 norm-accredited certification body for IFS may use its own layout, providing that it includes this mandatory information.

1.4.1 QR-code on the IFS Certificate

QR-code on the certificate via auditXpressX™
The QR-code is 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.
Scanning the QR-code allows the certification status of the COID to be checked.
The colour of the QR-code is, by default, the colour of the respective standard if the contrast is sufficient for the QR-code to be recognised when scanned. Users may change the colour and position of the QR-code by using the template.

QR-code for creating a certificate for non auditXpressX™ users
For certification bodies that generate certificates and do not use auditXpressX™, there is an area in the IFS Database ("My customers") where a QR-code for the respective COID can be downloaded.

The QR-code can be created via the "My Clients" function, by providing the following information:

- COID
- name of IFS Standard (e.g. IFS PACsecure)
- issue date of the certificate (important for the correlation in the IFS Database)
- colour: the colour of the IFS PACsecure Standard is shown as a suggestion; the contrast shall be sufficient to make the QR code scan recognisable. The QR-code can alternatively be uploaded in black and white.

Position on the IFS PACsecure Certificate
The QR-code shall either be in the top right corner or on the bottom of the IFS PACsecure Certificate and shall be of a suitable size to be scanned.

Verification of the certificate through the QR-code
A security mechanism has been added to the QR-code verification, so that a limited number of QR-codes can be verified in a certain lapse of time from the same IP-address.

QR-code data
The QR-code displays the following data:

- certificate in the IFS Database: yes / no
- COID
- company name
- certification body name
- IFS Standard
- issue date of the certificate
- end of validity date of the certificate
- certificate validity (valid or locked).

1.5 Further rules about reporting

1.5.1 Information to be translated into English

If the report is written in a different language to English, the following information of the report shall be translated into English:

- Assessment scope
- Company profile (company data and assesment data)
- Exclusions
- Partly outsourced processes
- Overall summary of compulsory information
- Deviations and non-conformities
- Corrections and corrective action(s) in the action plan

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 assessment data through a user-friendly interface
- creation of quick and error-free IFS Assessment Reports
- automatic evaluation of the assessment results by dynamic computation of all relevant items
- automatic generation of a standardised assessment report
- temporary storage of interim assessment data for later completion
- secure export of completed assessment reports in the IFS Database
- exchange of assessment files between auditors and their certification body
- an updated option provides constant access to the most recent version of the IFS Standard.
- accessible offline, i.e., no continuous Internet connection is required

Additional information can be found by the certification body in the login area of the IFS Database.

3 The IFS Database (www.ifs-certification.com)

Every IFS Assessment shall be uploaded in the IFS Database by the certification body (uploading of the report, action plan and certificate).

There are six (6) IFS Database user groups who can have access to the IFS Database:

- Auditors
- Certification bodies
- Certified companies / suppliers
- Retailers
- Verified authorities
- Consultants (special access).

The different groups' access rights are as follows:

Auditors

- Manage their own data
- Download their own auditor profile, which includes all information about their approval: standards and scopes
- Oversee performed Assessments
- Register for the courses
- Receive account notifications and IFS Newsletters.

Note: Non-exclusive auditors can also administer the certification body / ies they are working with.

Certification bodies

- Manage their certified companies (generate login data, upload IFS Assessment Reports, action plans and certificates, update contact information, create head office / central management account)
- Suspend / unlock certificates in specific situations
- Manage all IFS Assessment dates via the diary function, enabling retailers and companies to have an overview of the scheduled assessments. All assessment dates for announced assessments shall be inserted in the diary function of the IFS Database: for an initial assessment or before the date of a recertification assessment, the date shall be inserted at latest two (2) weeks before the assessment date. For unannounced assessments, they shall be registered at least four (4) weeks before the start of the assessment time window.
- Manage their sub-accounts
- Manage their auditors via the IFS Database
- Download the IFS Logo(s)
- Receive important notifications and IFS Newsletters.

Certified companies / suppliers

- Access to their own data
- Compare two (2) consecutive assessment reports and action plans, for improvement purposes

- Download the IFS Logo(s)
- Manage their certification body
- Manage company personnel access (create sub-accounts) to the assessment data
- Search for other certified companies
- Manage suppliers using a "favourites" option via "Supplier management"
- Manage all their certified sites through a single access point via head office / central management (access created by the certification body).
- Receive important notifications (possibility to define notification preferences) and IFS Newsletters.

Retailers

- Search for certified companies
- Manage their certified companies using a "favourites" option via "Supplier management"
- See the upcoming assessment date of a supplier
- Compare two (2) consecutive assessment reports and action plans (if access was authorised)
- Download a list of all suppliers with suspended certificates
- Receive important notifications and relevant lists that can be set individually
- Receive IFS exclusive Newsletters translated in different languages.

Verified authorities

- Search for certified companies
- Manage their certified companies using a "favourites" option via "Supplier management"
- Receive a list of assessments where further information is unlocked by the suppliers
- See the upcoming assessment date of a supplier
- Compare two (2) consecutive assessment reports and action plans (if access was authorised)
- Download a list of all suppliers with suspended certificates
- Receive important notifications and IFS Newsletters.

Special access for IFS Consultants

- Manage own data about standards, scopes, languages
- Get access to special consultant training
- Visible on the public IFS Website – including reviews from customers
- Download own individualised IFS Logo
- Receive important notifications and IFS Newsletters.

Security of the IFS Database

The security system used for the IFS Database is based on an internationally recognised and commonly used security system.

Data protection

Data protection is an important issue for IFS Management GmbH. IFS fulfils all data protection regulations that are applicable to the company. The data policy of IFS Management GmbH is available on the IFS Website www.ifs-certification.com.

The access to IFS Database provides general information about all certified companies. If no further authorisation is granted by the certified companies, the user groups are able to see the following information only:

- the company's name, address and GPS data
- the certification body's name and address
- the auditor's name
- the scope of the assessment
- the date and duration of the assessment
- the level and percentage achieved at the assessment
- the IFS Certificate's date of issue, its validity duration and the time frame for the realisation of the recertification assessment
- the IFS Certificate itself

By accessing their secure login, the certified companies can themselves authorise access to the following detailed information:

- Assessment report and action plan.

The IFS Database user groups automatically receive access to the unlocked data by the certified company after the data has been unlocked. Communication to retailers and other IFS Database user groups is made 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. For further information, see the IFS Website.

Tool "Supplier management"
The tool "Supplier management" enables retailers, authorities and suppliers to select their favourites from all certified companies that are listed in the IFS Database and to store them in a separate list.

For each certified site listed as a favourite under "Supplier management" the user can pre-set the following e-mail notifications:

- Reminder three (3) months before the expiration date of the certificate.
- The certificate is expired, and no valid certificate exists.
- A surveillance assessment is recorded.
- The certificate is withdrawn by the certification body before the expiry date.
- A certificate has been issued.
- A new assessment has not been entered yet. The current certificate expired three (3) months ago.
- Monthly e-mail of all new registered assessments in the current month.
- A certificate or letter of confirmation has been registered
- A certificate has been prematurely withdrawn or temporarily suspended
- A certificate or the related assessment documents have been edited
- A certificate or assessment letter expires in three (3) months and no new date has been registered
- A certificate expires and no new certificate for this standard has been issued

Note: Please check directly with your favourites if no assessments have been performed or if the assessment has not been passed.

- There has been no valid certificate for an IFS Standard for at least three (3) months and no new date for this standard has been entered.
- A new assessment date has been created or an unannounced assessment has been made.
- An existing assessment date or registration has been removed or changed.
- A change of certification body has been made

IFS PACsecure

ANNEXES

ANNEX 1: Scope of application of the different IFS Standards and IFS Program

IFS Food

Standard for assessing food product processors / manufacturers.

IFS Food shall be used when a product is processed or where there is a risk of product contamination coming from primary packaging.

IFS Broker

Standard for assessing brokers, agents, and importers who may or may not own the products but who typically do not take physical possession of the products (e.g. who do not have warehouses, packaging stations or truck fleets, but are legal entities with mailboxes, offices, etc.).

The Standard applies to food, household and personal care products as well as to packaging materials.

IFS HPC

Standard for assessing companies that manufacture household and personal care products, or companies that pack loose household and personal care products. IFS HPC can only be used when a product is "processed" or when there is a hazard for product contamination during the primary packing.

IFS Logistics

Standard for companies whose activities are logistics services for food and non-food products, such as transport, storage, loading / unloading, etc. It applies to all types of transport: delivery by road, rail, ship, plane, etc., and to all types of products: frozen, refrigerated, ambient stable, etc.

The product IFS Standards under the specific subchapter about transport and / or storage already cover a production company's own logistics activities. Therefore, it is not necessary to perform a combined assessment for IFS Food, IFS HPC or IFS PACsecure in combination with IFS Logistics.

IFS PACsecure

Standard for assessing food and non-food packaging material manufacturers concerning the production, processing and / or conversion of packaging components and / or packaging materials.

IFS Wholesale / Cash & Carry

Standard for assessing companies who have wholesaling activities of food, household and personal care products and / or packaging materials. Furthermore, certain treatment and / or processing activities are covered by this standard. This standard also covers packing companies for fruit, vegetables and / or eggs.

IFS Progress

The IFS Progress Programs are assessment programs that enable suppliers to establish and develop appropriate processes to manage product safety and quality. The programs are built on standardised requirements and structured in two levels. They help suppliers progress towards IFS Certification within a defined time frame. Together with their customers, these companies can determine their path towards certification, including the pace and milestones. IFS offers Progress Programs for suppliers of food products, logistics services, packaging materials and household and personal care (HPC) products.

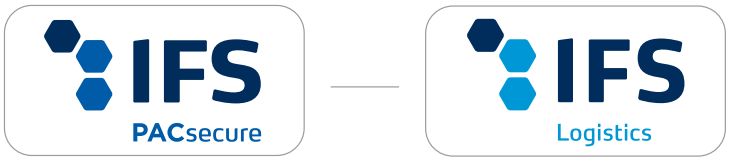
Scope determination between IFS PACsecure and other IFS Standards

IFS PACsecure AND IFS HPC

If a packaging manufacturer produces products which are intended to be used as daily use household products, then an IFS HPC Assessment applies (see IFS HPC Standard, Part 1, chapter 5.1.1).

IFS PACsecure AND IFS Broker

If a packaging manufacturer additionally carries out trading activities and would like to IFS certify these activities, a combined assessment IFS PACsecure / IFS Broker shall be performed. For a combined assessment, the company shall obtain two (2) reports and two (2) certificates.



IFS PACsecure AND IFS Logistic

If a packaging manufacturer and additionally carries out logistic activities and would like to IFS certify these activities, a combined assessment IFS PACsecure/IFS Logistic shall be performed. For a combined assessment, the company shall obtain two (2) reports and two (2) certificates.

Clarifications of scope application between IFS PACsecure and IFS Logistics:

When the packaging manufacturer conducts own logistics and / or transport activities (storage and distribution), these activities are included in the IFS PACsecure under the specific sub-chapter about transport or storage. However, if the company or the customer wishes to have this operation certified for IFS Logistics, an IFS Logistics Assessment is also possible. In this case, the following requirements shall be fulfilled:

a) If the logistics activities owned by the packaging manufacturer are situated at the same physical location as the company, then:

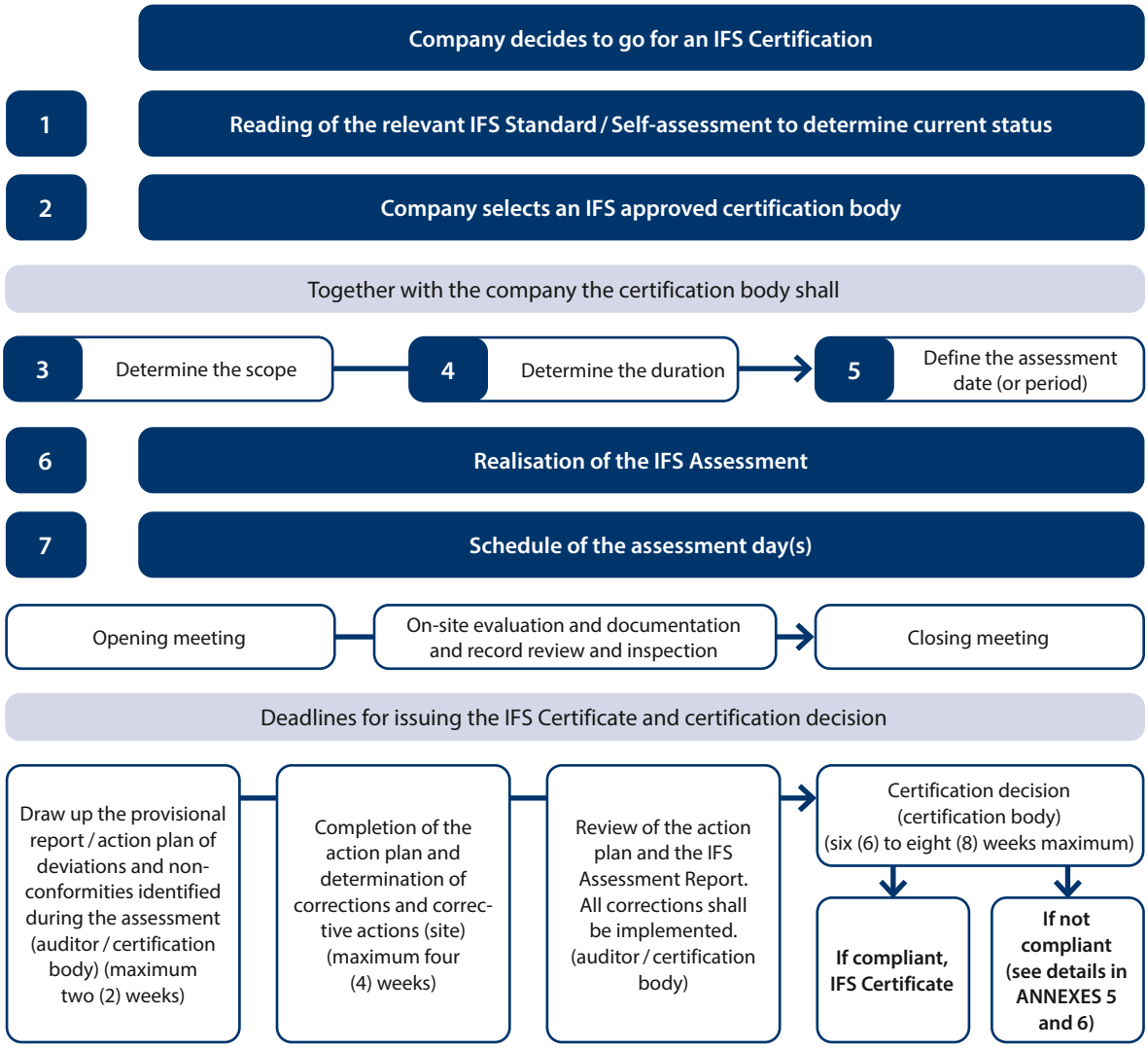
- the logistics activities are only carried out for pre-packed products,
- the respective scope of each assessment (IFS PACsecure and IFS Logistics) shall be clearly defined in the two (2) certificates, and also in the assessment report,
- considering the IFS Logistics is an additional certification, the requirements of IFS PACsecure concerning transport and storage shall be evaluated during the IFS PACsecure Assessment in any case.
- an IFS PACsecure Assessment of the packaging manufacturer shall be performed.

b) If the logistics activities owned by the packaging manufacturer are situated off-site, the company has the following three possibilities:

- include it as a decentralised structure;
- not assess it, but clearly state in the company profile that this site is not IFS Logistics certified;
- gain an IFS Logistics Certification.

For any kind of processing / converting activities, meaning that the characteristics of the products are modified (or primary packaging is carried out), IFS Logistics is not applicable.

ANNEX 2: Certification process



ANNEX 3: Product scopes

Product scopes	
1.	Flexible plastic
2.	Rigid plastic
3.	Paper and board
4.	Metals and alloys
5.	Glass and ceramic
6.	Other natural materials
7.	Other packaging components

Multi-component packaging materials shall be assigned based on the material which is the "main component of the material".

The main component of the material is the component present in the highest percentage by weight. In the case in which 2 or more components represent the highest weight, the main component will be the one with the higher density.

The main component shall be mentioned in the scope of the assessment on the report and the detailed list of all components in the company profile.

Examples of multi-component packaging materials are poly-coated board paper, aluminium composite film bags, capsules, multilayer films, valves, lids / caps, etc.

ANNEX 4: Exclusion tree

By definition, all processes and products that are managed at the same site **shall be included in the IFS PACsecure Assessment scope**.

All processing steps shall be assessed as the exclusion is related to the finished product(s). The key concept is the evaluation of the product risk analysis which may confirm whether an exceptional product exclusion is possible (with no impact on product safety and quality).

Only in those exceptional situations where the assessed company would like to exclude product(s) from the IFS PACsecure Assessment scope, the following rules shall be fulfilled:

a) Application

- The company shall inform the reasons for products exclusion and provide all relevant and documented evidence to support that the contamination risk between the included and excluded products is adequately controlled.
- If the certification body accepts the exclusion request, the certification body shall complete the **"IFS PACsecure questionnaire for certification bodies, to define, under exceptional circumstances, product exclusions in the assessment scope".** The answers provided in the questionnaire shall be justified and documented.
- If, as a result of the questionnaire, product(s) exclusion is (are) not possible, then the certification body shall inform the company and verify with them the final scope of the IFS Assessment to be included into the assessment report and certificate.
- If, as a result of the questionnaire, product(s) exclusion is (are) possible, then the certification body shall inform the company the exclusion has been accepted, but that it will be approved only when the auditor will verify on-site the relevance of the exclusion.

b) On-site verification by the auditor

- The auditor shall always check on-site if defined exclusions are relevant and in line with the questionnaire, by assessing the risks which may arise from excluded products (e.g. contaminants, allergens).
- Any exclusion which has not been justified in advance and is noticed by the auditor during the IFS Assessment, shall be assessed either directly during the assessment (with a necessary review of the assessment scope and the assessment duration) or through an extension assessment.
- If exclusions are applicable, the auditor shall confirm the relevance of the exclusions to the certification body and shall explain the exclusions in the corresponding field of the IFS Assessment report.

c) Approval

- After the IFS Assessment and with the inputs provided by the auditor into the IFS Assessment Report, the certification body shall inform the company the exclusion has been approved.
- The exclusion shall always be explained in the company profile of the IFS Assessment Report and clearly specified in the assessment scope of the IFS Assessment Report and certificate.

d) Additional requirements for the companies and certification bodies

- Product exclusion shall always be re-considered and reviewed each year by the certification body to ensure that the product exclusion is still valid, and that the assessment scope is still up to date.
- In case the company processes new products/private labels during the IFS certification cycle, the company shall contact its certification body to ensure that defined exclusions are still valid and that no further actions are necessary.

IFS PACsecure questionnaire for certification bodies, to define, under exceptional circumstances, product exclusions in the assessment scope

If, under exceptional circumstances, the company decides to exclude specific product(s) from the scope of the IFS PACsecure Assessment, the following questionnaire has to be filled in by the certification body to check if any exclusions are allowed. The filled in questionnaire shall be part of the assessment time schedule.

Company name: _____ COID: _____

Planned assessment scope
(product scope and description): _____ Planned assessment date: _____

Date of questionnaire validation: _____

Product(s) excluded: _____

Name of the certification body
employee who filled in the questionnaire: _____

Name of the company
employee who requested the exclusion: _____

Name of the certification body
employee who approved the requested exclusion: _____

1) Is the product to be excluded a private label (retail / wholesale branded) product?

☐ No ☐ Yes → **Exclusion is NOT possible**

2) Has the product any information printed on it, which is critical for the customer and / or final consumers? *Examples of critical information are ingredient list(s), allergens, identification code, customer logo, etc.*

☐ No ☐ Yes → **Exclusion is NOT possible**

3) Is the product seasonal / sporadic?

☐ No ☐ Yes → Are the products and hazard analysis and risk assessment system identical for seasonal / sporadic products and regular products?

☐ No ☐ Yes → **Exclusion is possible OR product can be included with a documentary on-site evaluation**

4) Is the product clearly differentiable from the product(s) which is / are included in the assessment scope?

☐ Yes ☐ No → **Exclusion is NOT possible**

5) Is / are the initial production / conversion processes of the product to be excluded common with the one of the included product(s)?

☐ Yes ☐ No → **Exclusion is possible (e.g. where area / processing line is fully independent since the beginning, without any contamination risk)**

6) Does the product to be excluded go to a different area than the one related to the product included in the assessment scope?

☐ Yes ☐ No → **Exclusion is NOT possible**

7) Is the contamination risk controlled between included and excluded products?

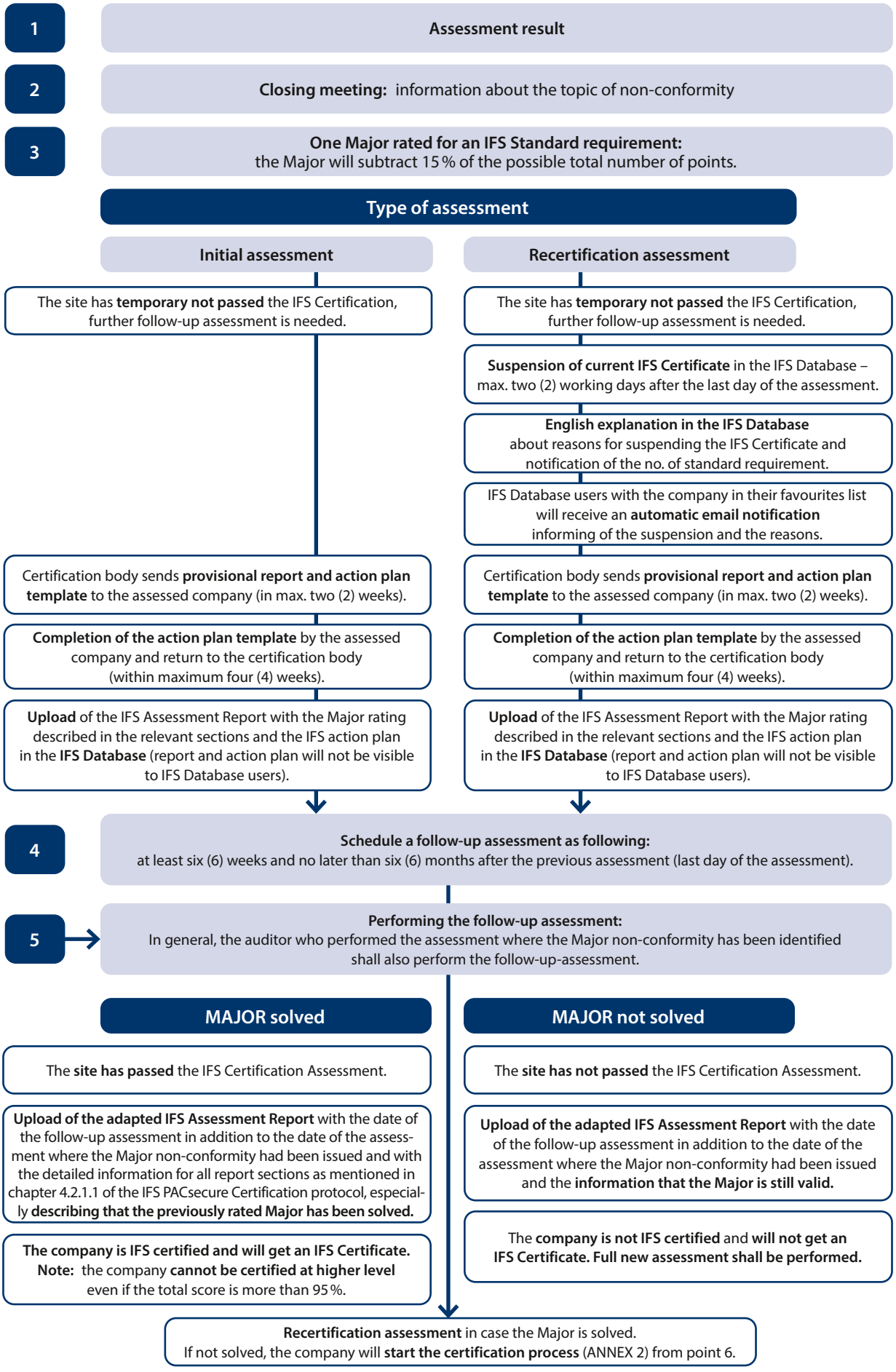
The manufacturer shall demonstrate the control of contamination risks between excluded and included products (allergens, chemical, physical, microbiological hazards, also at the level of storage and warehouse). Process flow chart related to the product to be excluded shall be sent to the certification body.

☐ No ☐ Yes → **Exclusion is possible**

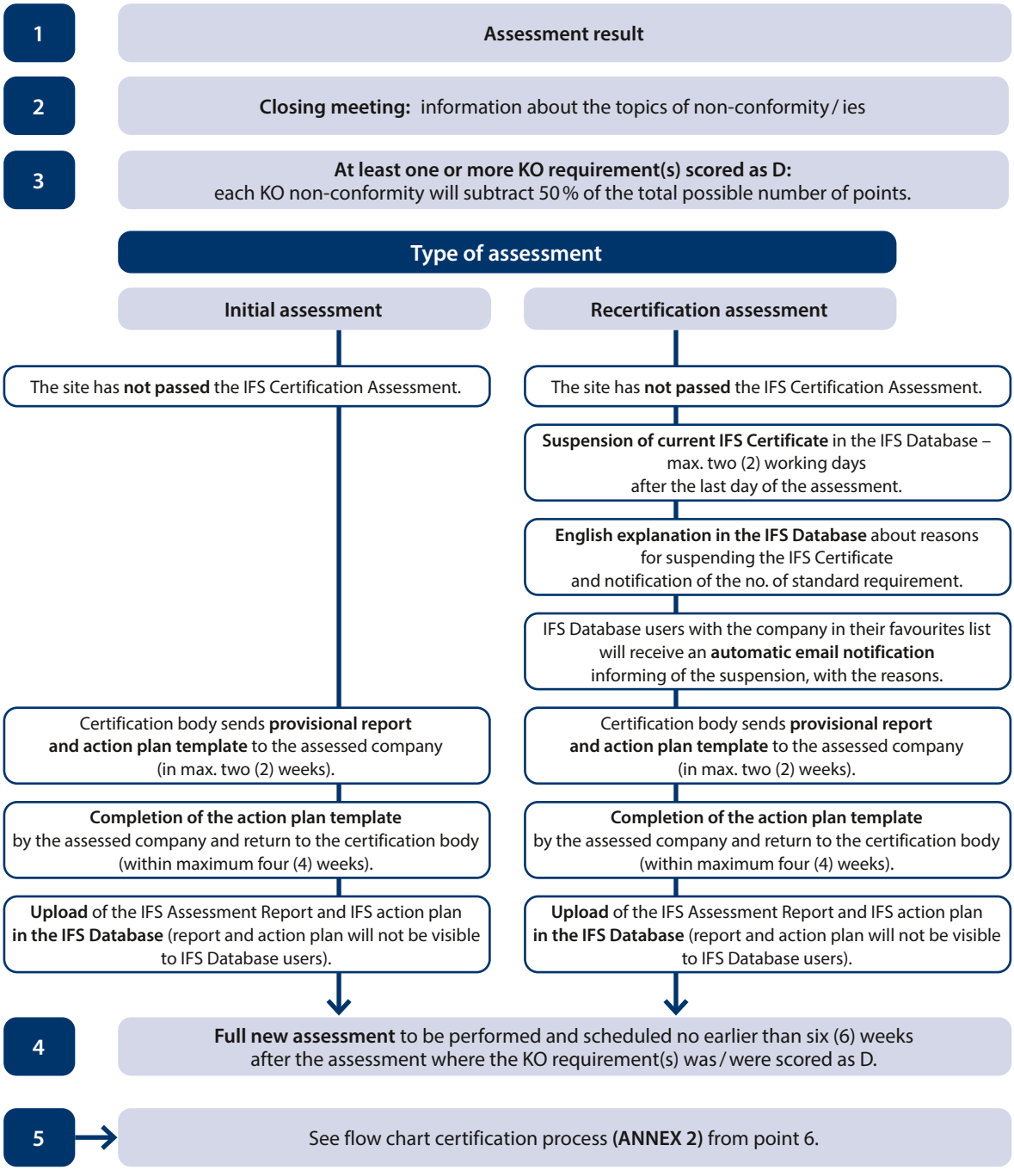
Exclusion is NOT possible

The auditor shall always check on-site if defined exclusions are relevant and in line with the questionnaire, by assessing the risks which may arise from excluded products (e.g. contaminants, allergens).

ANNEX 5: Flow chart for management of one Major non-conformity and total score ≥ 75%



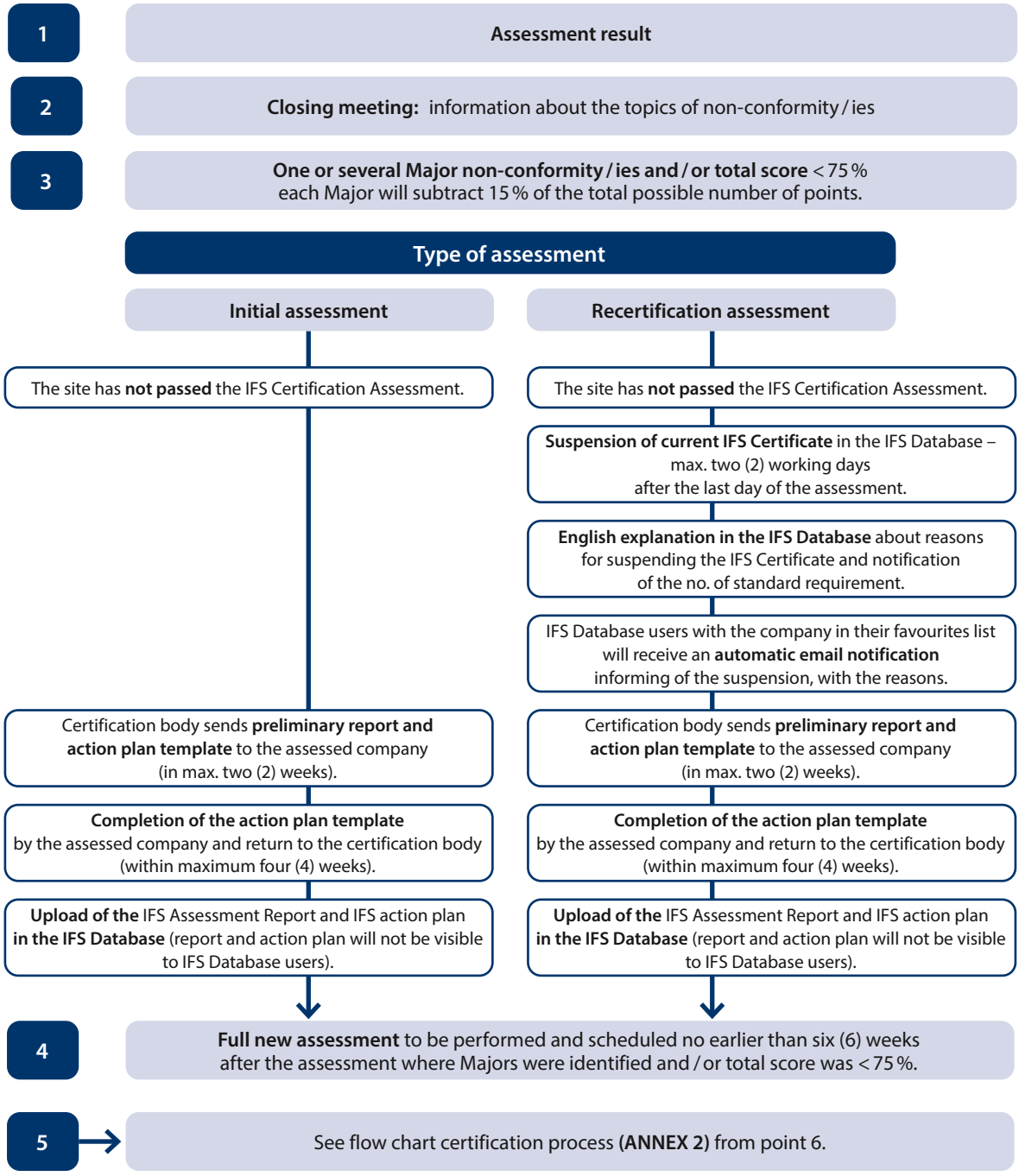
ANNEX 6: Flow chart for management of KO requirement scored with "D"



ANNEX 7: Action plan

N° of the requirement	IFS requirement	Evaluation	Explanation (by the auditor)	Correction (by the company)	Responsibility Date and status of implementation (by the company)	Type of evidence(s) and name of the document(s)	Corrective action (by the company)	Responsibility Date and status of implementation (by the company)	Release and date of release (by the auditor)
1.2.2	**KO N°1: The senior management shall ensure that…**	KO / C							
1.2.3	**The senior management shall provide…**	Major							
1.2.4	**The senior management shall ensure that all processes…**	C							

ANNEX 8: Flow chart for management of one or several Major non-conformity / ies and / or total score < 75 %



ANNEX 9: IFS Assessment Report: assessment overview

Cover page

Unannounced assessment (if applicable)

Logo of the certification body

IFS PACsecure Version 2
JULY 2021

Final IFS Assessment Report

Assessed company: "Paper and Plastic Ltd"
[GS1 GLN(s) and where applicable legal authorisation number]

Date of Assessment: 02.03./03.03.2021

Name and address of certification body

Accreditation number of the certification body

(Unannounced, if applicable) Assessment Overview
IFS PACsecure Version 2, JULY 2021

Assessment details

Lead auditor: Max Mustermann date / time: ***Co-auditor:*** date / time: ***Trainee:*** ***Witness auditor:*** ***Reviewer:*** ***Interpreter:*** ***Technical expert:***	***Date / time of current assessment:*** 02. 03. 2021 (09:00–18:00) 03. 03. 2021 (08:30–17:30)	***Date / time of previous assessment:*** 09. 03. 2020 (09:00–18:00) 10. 03. 2020 (08:30–12:30) ***Certification body and auditor of previous assessment:*** TEST GmbH / Frank Test

Name and address of the company (or head office): Perfect Packaging Example street 12345 Witzenhausen Germany		***Name and address of the assessed site:*** Paperboard solutions Ltd Musterstraße 12346 Berlin Germany	
		COID:	
		Contact person in case of emergency (e.g. recall): [Name, e-mail and phone number at a minimum]:	
Phone: 0 12 34 56	Fax: 01 23 45 67 89	Phone: 0 12 34 57	Fax: 01 23 45 67 88
Website: www.perfectpackaging.com	E-mail: info@perfectpackaging.com	Website: www.perfectpackaging.com	E-mail: info@paperboardsolutions.de

Scope of the assessment

Sheeting, printing, laminating, die-cutting, windowing and glueing of laminated / coated paperboard packaging intended to be used as primary packaging for food and cosmetic industry.

Product scope(s): 3 Paper and board

Additional information

Food contact materials: [yes/no] and [description]
Exclusions: [yes/no] and [description]
Partly outsourced processes: [yes/no] and [description]
Multi-location production sites: [yes/no] and [description]
Decentralised structure(s): [yes/no] and [description]

Final result of the assessment

As a result of the assessment performed on 02. 03. and 03. 03. 2021, "xyz" found that the processing activities of **Paper and Plastic Ltd** for the above-mentioned scope of assessment comply with the requirements set out in the IFS PACsecure Standard, Version 2, at **Foundation level**, with a score of XX %.	Recertification assessment between XX. XX and XX. XX in case of announced assessment and between XX.XX and XX.XX in case of unannounced assessment.

Observations regarding non-conformities (D evaluation of KO requirements and Majors):

Description of follow-up on corrections and corrective actions from previous assessment

Company profile
Company data
Year of construction of the assessed site(s):
If the site was fully reconstructed, enter the year:
Area of the production site:
Number and description of buildings, floors and production lines (including decentralised structure(s), if applicable):
Maximum number of employees at peak season within a calendar year and explanation:
Detailed description of product groups and products per scope produced in the company. Full view of the company's on-site processes: from raw materials receipt to finished products.
Does the assessed site have seasonal production? If "yes", provide description.
If there are seasonal breaks in the production process for more than one week, specify the timeframe and provide explanation.
Does the assessed site have fully outsourced products in addition to the main processes / products? If "yes": specify these products, if the site is certified for IFS Broker and / or describe the certification status and COID if applicable or describe the certification status of the subcontractors and COID, if applicable.
Does the assessed site have traded products in addition to main processes / products? If "yes": specify these products, if the site is certified for IFS Broker and / or describe the certification status and COID if applicable or describe the certification status of the subcontractors and COID, if applicable.
Description about key investments made by the company related to the production and product safety and quality in the last 12 months (construction changes, machinery, etc.)
Does the company fulfil the requirements about the use of the IFS (PACsecure) Logo, as defined in the IFS PACsecure Certification protocol (Part 1)? [yes/no] If "no": [explanation]
Working language of the site and language in which the product safety and quality management system is written:
If the site is certified for other standards, specify the name(s) of the standard(s): [description]
Additional information:
Assessment data
Language in which the IFS PACsecure Assessment was conducted:
Assessment duration:
In case of reduction / extension of assessment duration, justify:
Which products were produced, and which processes have been running during the on-site evaluation?
Additional information:

ANNEX 10: IFS Assessment Report: main content

IFS PACsecure
Version 2, JULY 2021

IFS Assessment Report

Summary table of all chapters and result (in percentage) per chapter

	Chapter 1	Chapter 2	Chapter 3	Chapter 4	Chapter 5	Chapter 6
	Governance & commitment	Product safety and quality management system	Resource management	Operational processes	Measurements, analyses, improvements	Product defence plan
KO Non-conformities	0	0	0	0	0	0
Major non-conformities	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
Result per chapter (%)						

Overall summary: Table of compulsory fields for specific defined IFS PACsecure Assessment requirements and key elements

Part of the IFS Assessment Report	N° of IFS PACsecure v2 require-ment	Compulsory information to be added
Policy	1.1.1*	• Date of the corporate policy approval and date(s) of the specific objectives.
Corporate structure	1.2.1*	• Version and date of last issue of the organisational chart (or any other similar document showing the structure of company, hierarchy and relations)
	1.2.2* KO No. 1	• Description
	1.2.5*	• Description of how the company ensures that all relevant information is made available for all responsible staff.
	1.2.6*	• Name of the authorities. • Date and time of last visit (if existing, even when more than 12 months ago) and name of the authorities.
Management review	1.4.1*	• Date of the last review of the product safety and quality management system
Document Management	2.1.1.2*	• Date and version of the procedure.
Records and documented information	2.1.2.2*	• Date and version of the documented information (procedure).
Hazard analysis and risk assessment	2.2.3.7.1*	• List CCP type(s), if existing.
	2.2.3.8.1* KO No. 2	• Description of the monitoring procedure for each CCP which includes at a minimum: process step, control method, critical limit, control frequency. • Description of the sample(s) checked during the IFS Assessment. • In case of N / A evaluation, provide explanations.
	2.2.3.10.1*	• Date of last hazard analysis and risk assessment system verification.
Personal hygiene	3.2.1*	• Date and version of the document(s) related to personal hygiene.
	3.2.2* KO No. 3	• Description of the requirements for personal hygiene that are in place and applied.
	3.2.5*	• Description of the protective clothing.
Training and instruction	3.3.1*	• Date and version of the training and/or the instruction program.
	3.3.2*	• Number of training and monitoring records checked during the IFS Assessment.

Part of the IFS Assessment Report	N° of IFS PACsecure v2 require-ment	Compulsory information to be added
Staff facilities	3.4.1*	• Comment on the suitability of staff facilities in line with the type of production.
	3.4.5*	• Description of hand hygiene facilities.
Specifications	4.2.1.2* KO No. 4	• Description of raw material specifications which have been checked during the IFS Assessment. • Description of how the company ensures that the specifications are up to date. • Indicate if any raw material used comes from a recycled source.
	4.2.1.3*	• Description of finished product specifications which were checked during the assessment. • Indicate if the finished product specifications have been agreed upon with the customers
	4.2.1.5*	If applicable: • Date and version of the procedure. • Description of claims • Description of methods of treatment or production that are excluded. • Are recycled material, plant based material, or functional additives used? If yes, describe.
Formula / configuration	4.2.2.1* KO No. 5	If applicable: • Description of customer agreements which were checked during the IFS Assessment, specifying the topics of the customer agreement which were checked in detail.
Product development, product modification, and / or modification of production / conversion processes	4.3.2*	• Description of the sample(s) checked during the IFS Assessment.
	4.3.3*	• Description of the sample(s) checked during the IFS Assessment.
	4.3.5*	• Date and version of the procedure. • Description of the sample(s) checked during the IFS Assessment.
Purchasing	4.4.1*	• Mention the process documentation checked during the IFS Assessment.
	4.4.2*	• Date and version of the procedure for purchasing (including exceptional situations).
	4.4.3*	• Date of last supplier's assessment. • Description of the sample(s) of the purchased service checked during the IFS Assessment.
Product wrapping	4.5.1*	• Description of the kind of wrapping materials used for finished products.
Factory location	4.6.1*	• Description of the location of the site and the conditions of the external areas

Part of the IFS Assessment Report	N° of IFS PACsecure v2 require-ment	Compulsory information to be added
Plant layout and process flows	4.8.2*	• Comment on the suitability of the layout and the process flows to minimise product safety risks.
Constructional requirements	4.9.1.1*	• Comment on the suitability of the site's premises.
Water	4.9.9.1*	• Description of the type of source(s) of the potable water / used water. • Description of how the potable water / used water is checked, stating particularly whether the water is checked by the company's own laboratory or via an external laboratory. • Which analyses are performed? (with parameters)
Compressed air and gases	4.9.10.1*	• Date and version of the hazard analysis and assessment of associated risks. • If gases are used, provide the name of declaration of compliance checked during the IFS Assessment.
Cleaning and disinfection	4.10.1*	• Description of the applied cleaning and disinfection procedures (e.g. CIP, manual cleaning of rooms and equipment, cleaning by own personnel or third-party service provider, etc.). • Date and version of the cleaning and disinfection schedule checked during the IFS Assessment.
	4.10.8*	• Name and date of the Safety Data Sheet checked during the IFS Assessment.
	4.10.9*	• Description of the site's storing conditions.
	4.10.11*	If applicable: • Name of areas cleaned and disinfected by a third-party.
Waste management	4.11.1*	• Date and version of the procedure.
	4.11.7*	• Date and version of the procedure.
Foreign material risk mitigation	4.12.2* KO No. 6	• Description of the equipment and methods used to detect foreign materials (e.g. filters, sieves, X-ray, metal detection) and where they are placed in the process. • If foreign material detectors are not defined as CCP, description of the test pieces and sizes. • If no foreign material detection equipment is available, descriptions of the used preventive measures (e.g. visual detection methods).
	4.12.11*	If applicable: • Description of visual detection method, changing frequency for personnel and last training for personnel.

Part of the IFS Assessment Report	N° of IFS PACsecure v2 require-ment	Compulsory information to be added
Pest monitoring and control	4.13.2*	• Are the pest control services managed by in-house staff or by an external provider used? • Frequency and kind of checks. • In case of identification of pest activity, what were the corrective actions?
Receipt and storage of goods	4.14.1*	• Date and version of the inspection plan.
	4.14.4*	• Description of the system. • Description of the sample(s) checked during the IFS Assessment.
Transport	4.15.1*	• Description of the sample(s) checked during the IFS Assessment.
Maintenance and repair	4.16.1*	• Date and version of the maintenance plan.
Equipment	4.17.1*	• Description of the sample(s) checked during the IFS Assessment.
Traceability	4.18.1* KO No. 7	• Description of the traceability system and documentation for traceability in the company. • Description of product/s was / were used for the traceability test during the IFS Assessment including details concerning used raw materials, rework, wrapping for the final product / mass balance / results of the traceability tests backwards and forward. **Note:** The traceability test(s) shall always be based on samples chosen by the auditor.
	4.18.2*	• Date and product(s) of last traceability test.
Allergen risk mitigation	4.19.1*	• Indicate if any allergen has been identified
	4.19.2*	• Are allergens present? • What kind of preventive measures and control measures are in place to ensure that cross contamination is minimised? • Date of the risk assessment and last verification.
Product fraud	4.20.2*	Was a vulnerability assessment performed? If yes: • Which raw material groups / product groups were identified in the vulnerability assessment? • Description why the identified raw material is vulnerable to product fraud. • Explain which criteria were selected in the vulnerability assessment. • Provide details of the vulnerability assessment (dates, responsibilities, points of discussion, etc.).
	4.20.3*	• Date of the mitigation plan and date of the last review.
	4.20.4*	• Date of the last product fraud vulnerability assessment review.

Part of the IFS Assessment Report	N° of IFS PACsecure v2 require-ment	Compulsory information to be added
Internal audits	5.1.1* KO No. 8	• Description of the sample(s) checked during the IFS Assessment.
	5.1.2*	• Which activities has the company identified as critical for product safety and quality?
Site and factory inspections	5.2.1*	• Description of the sample(s) of the site and factory inspection checked during the IFS Assessment. • Mention the frequency of inspections.
Validation and control of the process and working environment	5.3.1*	• Description of identified criteria for process and work environment validation. • Last process and work environment validation conducted (date, result). • Description of the environmental monitoring parameters defined by the company based on a risk assessment.
	5.3.4*	• Description of the sample(s) of use of rework checked during the IFS Assessment.
Calibration, adjustment and checking of measuring, monitoring devices and inspection equipment	5.4.1*	• Description of the sample(s) checked during the IFS Assessment.
	5.4.2*	• Description of the sample(s) checked during the IFS Assessment.
Quantity control monitoring	5.5.1*	• Description of the frequency and methodology of quantity checking.
Product and process analyses	5.6.1*	• Which analyses are performed by own laboratory and how frequently? • Which analyses are performed by an external laboratory and how frequently?
	5.6.2*	• Mention if the laboratories (internal / external) used are accredited under ISO 17025 (accreditation number of the laboratory).
Product release	5.7.1*	• Date and version of the procedure.
Management of complaints	5.8.1*	• Range or indicator of complaints raised by consumers, customers and authorities separately. • Range or indicator about complaints relating to foreign materials found in the finished products, specifying the kind of foreign materials.
	5.8.2*	• Description of the sample(s) checked during the IFS Assessment.

Part of the IFS Assessment Report	N° of IFS PACsecure v2 require-ment	Compulsory information to be added
Management of incidents, product with-drawal, product recall	5.9.1*	• Date and version of the procedure.
	5.9.2* KO No. 9	• Date and version of the procedure. • Specify how many withdrawals and recalls have been performed since the last assessment. • Specify the product(s) involved and the cause(s) of withdrawals and product recall. • Date of last test
Management of non-conformi-ties and non conforming products	5.10.1*	• Date and version of the procedure.
Corrective actions	5.11.1*	• Date and version of the procedure.
	5.11.2* KO No. 10	• Description of samples chosen during the assessment for the follow-up of the corrective actions originating from internal audits, customer audits, certification assessments, complaints, lab analysis, etc., and or any other source except the previous IFS Assessment.
Product defence plan	6.4*	• Version and date of the product defence assessment • Version and date of the product defence plan • Date of the annual review and last test.
If applicable, additional information		
Note: additional information can also be given for requirements not listed as a compulsory field or any other auditor remark		

Summary of all deviations and non-conformities found for each chapter and requirement:

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

Summary of points of attention:

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

Detailed IFS Assessment Report:

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

ANNEX to the IFS Assessment Report

List of key participants:

Assessment participants					
Name	Position	Opening meeting	On-site evaluation	Documen-tation review	Closing meeting
Mr. Quality	Quality Manager	X	X	X	X
Mr. Manager	General Manager	X			X
Mr. Interpreter	Interpreter	X	X	X	X

Product scopes (based on ANNEX 3)

IFS Scoring System (based on chart 1, Part 1)

Scoring and issue of certificate (based on chart 4, Part 1)

ANNEX 11: IFS Certificate

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 IFS Management GmbH, confirms that the site's process(es) and product(s) of …

Name of the assessed company

Address

(GS1 GLN(s) and where applicable, sanitary legal authorisation number)
COID, (head office, if applicable)

for the Assessment scope:
(detailed descriptions of process(es) / product(s)),

additional information:

If there are partly outsourced processes, the following sentence shall be added:
"Besides own production, the company has partly outsourced processes",

description of product exclusions, if applicable,

if the company performs additional broker or logistics activities, provide the certification status by writing the sentence:
"The company has own broker / logistics activities which are / are not IFS Broker and / or IFS Logistics certified".

Number and name of the product scope(s)

meet the requirements set out in the

IFS PACsecure Version 2, JULY 2021

at Foundation level / Higher level
and other associated normative documents

with a score of XX %

Certificate-Register number:
Date of the last unannounced assessment (last day of the assessment):
If no unannounced IFS PACsecure Assessment has been conducted for the respective COID yet, the certificate shall indicate the following:
"Last Assessment conducted unannounced: N / A"

Assessment date (if relevant: plus date of the follow-up assessment):

Certificate issue date:

Date of expiration of the certificate (the certificate validity shall remain the same each year as described in the IFS PACsecure Certification protocol, Part 1):

Next assessment to be performed within the time period:
(Recertification assessment between XX.XX and XX.XX in case of announced assessment and between XX.XX and XX.XX in case of unannounced assessment)

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

ANNEX 12: Glossary

Terms	Related definitions
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 / UK)	Food causing an adverse reaction that is mediated by an immunological response. Defined allergens are: • 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 (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoiesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia) 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 SO_2. Regulation (EU) No 1169 / 2011 of the European Parliament and of the council.
Allergen (US)	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. (1) "Major food allergen" means: (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. (2) "Major food allergen" does not include: (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).

Terms	Related definitions
Assessment (IFS)	Determination process which includes evaluation methods such as auditing and inspection, to determine to what extent a production site and its related processing activities comply with the specified requirements (laid down in Part 2). The IFS Assessment is conducted by following an assessment trail, including an on-site evaluation and a documentation and record review / inspection in which auditing and inspection technics are applied alternately.
Assessment time window (unannounced assessment)	Period of time during which the unannounced assessment may be performed. The date of reference for this time window is the assessment due date (the date of first certification assessment). Within the IFS PACsecure Certification protocol (Part 1), the time window is [16 weeks; + 2 weeks] of the assessment due date.
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. **Note:** In IFS Standard, conformity assessment body is named certification body.
Audit	Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. In the IFS Assessment, auditing is limited to the examination of management processes which are leading to a compliant process / product.
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.
Auditor in progress (AIP)	Candidate who is in the process of gaining auditing / assessing experience and has to pass the IFS Examinations to become an IFS PACsecure Auditor. **Note:** For further information, see chapter 3.1.4, Part 3 of the standard.
Batch (or lot) number	A unique combination of numbers, letters, and / or symbols that identifies a batch (or lot) and from which the production and distribution history can be determined. **Note:** When a company uses the word "lot" and "batch" simultaneously; the company shall determine what is the definition and application of both words used.
Biological hazards	Parasites, bacteria, moulds, or viruses that have the ability to cause illness or death.
Blackout period	Period of time the company may notify to its certification body in which the unannounced assessment cannot take place. This includes a maximum of ten (10) operational days when the production site is not available for assessment (e.g. staff holidays, maintenance days, etc.) as well as non-operating periods. **Note:** The ten (10) operational days can be split into a maximum of three (3) periods. These, together with the non-operating periods, shall be notified to the certification body when registering for the unannounced assessment. Certification body will decide if the unannounced character of the assessment is fulfilled.

Terms	Related definitions
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.
Characteristics	A designated feature or property of product.
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.
Claim	Any message or representation, including pictorial, graphic or symbolic representation, in any form (product label, packaging, advertisement, specifications, product inserts), which states, suggests or implies that the product has particular characteristic(s) or effect(s) that is / are not inherent to the product and / or is not generally present in similar products. The following list of examples of the particular characteristic(s) and / or effects doesn't claim to be exhaustive: • nature or composition (e.g. organic, "natural", "free from", "source of", "reduced", etc.), • standards of identity for products (e.g. meat products, specific labels, etc.), • origin or provenance (e.g. "made in…", "product of…", PDO / PGI etc.), • methods of production / processing (e.g. fairtrade, religious claims, etc.), • specific properties, structure and / or function related to a risk reduction for customers and / or consumers (e.g. related to prevent or reduce the risk of health diseases, prevent the contamination by spoilage or pathogen micro-organisms, etc.), • specific properties, benefits and / or effects for customers and / or consumers due to the usage of the product (e.g. anti-aging effect in cosmetics, extend shelf life of food in packaging, improving or modifying a physiological function or biological activity associated with health in food, etc.). Claims linked to the product can be declared only if: • Evidential support is available to demonstrate their truthfulness, honesty, fairness and the legal compliance. • Are approved to be used by the relevant authority, when applicable. • Clear and understandable information is provided to the users (customer, consumer and / or end-user, as applicable) about the particular characteristic(s) and / or effect(s) declared in regard to the intended use of the product. **Note:** in case of IFS Assessments, claims shall not be used in the description of the assessment scope on the IFS Certificate, in order to avoid confusion on the scope of the IFS Assessment and certification.
Cleaning	The removal of soil, residue, dirt, grease or other objectionable matter.
Company	Any establishment in which any stage of production, conversion and / or distribution of products is carried out. The company can have one or several legal entities registered and / or approved by the relevant authority.

Terms	Related definitions
Composition	Quantified list of components / ingredients used to define the semi-finished or the finished product and how these are brought together. (e.g. batch formulation, recipe, configuration, etc.).
Consumer unit	It refers to the smallest unit of the product that can be sold to the final users and/or consumers, which is available on the market, at the point of purchase.
Contamination	Introduction or occurrence of a contaminant in product or product environment. A contaminant can be any biological, chemical agent, physical foreign material, or any other substances that may compromise product safety or suitability.
Contractor	A company or person who is contracted by the company to carry out work for the site.
Control measure (former CP)	A step within the production process identified by the hazard analysis and risk assessment at which control shall be applied and which is essential to prevent, eliminate or reduce to an acceptable level a hazard / risk in the product and / or the environment to an acceptable level. However, the loss of control at this point may not lead to an adverse health effect of the consumer (e.g. illness, injury, etc.). Acceptable levels may be derived from; legal and regulatory requirements; industry standards; scientific information; internal requirements; customer requirements; specifications, among others.
Converter	A manufacturer that takes raw materials and converts them into a usable package or package component (incl. printing process).
Converting time	The period in which a product may be processed / converted before being considered unsuitable for the purpose.
Correction	• Action to eliminate a detected deviation and / or non-conformity. • In the case of corrections for the action plan of the IFS Certification Assessment (part 1, 4.1.2), these shall be implemented, at latest, before a certificate is issued.
Corrective action	• Action to eliminate the cause of a detected deviation and / or nonconformity. • In the case of CA for the action plan of the IFS Certification Assessment (part 1, 4.1.2), these shall be implemented, at latest, before the recertification assessment.
Critical Control Point (CCP)	A step within the production process identified by the hazard analysis and risk assessment at which control can be applied and which is essential to prevent, eliminate or reduce to an acceptable level a product safety hazard. Loss of control at this step may increase the likelihood of an adverse health effect of the consumer (e.g. illness, injury, etc.).
Critical Limit	A maximum and / or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a product safety hazard.
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.

Terms	Related definitions
Customer agreement	A negotiated and usually legally enforceable understanding between a customer and the company.
Customer branded product	A product which is manufactured by the production site and sold under the brand name of its customer (e.g. private label).
Decentralised structure	Facility (for example a workshop or a warehouse) owned by the company where part(s) of the processes and operations of the production site take place.
Deviation	Non-compliance with a requirement, without any impact on product safety related to products and processes. In the IFS Standard, deviations are requirements scored with a C, D and KO requirements scored with a C.
End-Consumer	The ultimate consumer of a product who will not use the product as part of any packaging business operation or activity.
Equipment	Machines, instruments, apparatus, utensils or appliances used or intended to be used in or in connection with product handling and includes equipment used or intended to be used to clean and disinfect product premises or equipment.
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.).
Flow diagram	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular product item.
Formula	Exhaustive description of quantity and quality of raw materials to be used to process/convert the products, as required in customer specifications. Formula can also include technological parameters and specific "know-how" on the process.
Fully outsourced products	Products that are manufactured, wrapped and labelled under the own company brand or customer brand by a different company than the company being IFS PACsecure certified, either under its own brand or customer brand.
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	Genetically modified organism: 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 products during receiving, manufacturing, converting, storage and transportation, to ensure product safety. GMP regulation applicable in EU / US: • EU: Regulation (EC) No 2023 / 2006 of the European Parliament and of the council. • US: 21 CFR 174 - 21 CFR 190.
HACCP	Hazard analysis and critical control points: A system which identifies, evaluates and controls hazards which are significant for food safety.

Terms	Related definitions
Hazard	A biological, chemical or physical agent in the product, or in its condition, with the potential to cause an adverse health effect (e.g. illness, injury, etc.).
Hazard analysis	The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for product safety and therefore shall be addressed in the hazard analysis and risk assessment system.
Head office assessment (for accreditation bodies)	Assessment of the conformity assessment body head office. **Note:** In IFS Standard, conformity assessment body is named certification body.
Incident	A situation within the supply chain where there are possible and / or confirmed risks associated with product integrity; or any force majeure event (e.g. critical resources / services disruption, natural disasters, loss, emergency situations, crisis, etc.) with a direct impact on the delivering of trusted products.
Inert	Material without active chemical properties.
Inspection	Examination of a process / product, product design or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements. Inspection of a process includes inspection of product characteristics, customer requirements, persons, facilities, technology and methodology.
Instruction program	A defined program designed to provide clear and concise instructions to personnel to meet product safety and quality objectives.
Integrity Program	Program implemented by IFS in order to: • Monitor, as preventive actions, performance of auditors and certification bodies as well as assessed companies, • Manage, as corrective actions, any complaints addressed to IFS.
Intended use / purpose	The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer. Ref: GHTF / SG5 / N6:2012
Internal Audit	General process of audit, for all the activity of the company. Conducted by or on behalf of the company for internal purposes. An Internal auditing is an independent and objective assurance and consulting activity that is designed to add value and improve the operations of an organisation. 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.
Key roles	Personnel who have significant responsibilities and accountability for the development and maintenance of product integrity.
Legal autorisation number	Official authorisation number of the site.
Legal entity	A legal entity is the registered office of the packaging business where, according to agreement, the packaging business operator has its administrative center. It generally identifies the place where the administrative organization of the company is located.

Terms	Related definitions
Location	One physical address where the production site(s) is / are situated.
Monitoring	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether CCPs, other control measures, and control activities are under control.
Non-conformity	Non-fulfilment of a specified requirement. Non-conformity can be given in case of: • non-respect of legislation, • product safety issues, • internal dysfunctions, and • customer issues. In the IFS Standard, defined non-conformities are Majors and D evaluations of a KO requirement.
Non-operating periods	Periods when the production lines are not operating at all, e.g. planned maintenance work, bank holiday, planned company shutdown for holidays, etc.
On-site evaluation	Inspection and audit of the production area of the physical site, which includes: • Production processes • Receipt, storage and dispatch areas • Good Manufacturing Practices (GMP), including maintenance, hygiene, pest control and cleaning activities • Product development • On-site laboratory and / or maintenance facilities • Staff and sanitary facilities • External areas
Packaging material	Any material used to: • Contain the product, which depends on the product's physical form and nature • Protect and prevent the product from mechanical damage due to the hazards of distribution • Preserve the product, to prevent or inhibit chemical changes, biochemical changes and / or microbiological spoilage • Inform and communicate about the product (e.g. legal requirements, product ingredients, usage, brand communication, etc.) • Extend the shelf life or to maintain or improve the condition of the product (e.g. active food contact materials) • Monitor the condition of the packaged product or the environment surrounding the product (e.g. intelligent food contact materials) • Handling, delivery and presentation of products
Partly outsourced process	Production step(s) or part(s) of production / conversion process carried out off-site by a third-party on behalf of the IFS certified production site. In the IFS Standard, wrapping and labelling are also considered as production steps: if carried out outsourced, these shall be considered as partly outsourced processes.
Physical hazards	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.

Terms	Related definitions
Potable water	Water fit for human or animal consumption (e.g. drinking, cooking and food preparation) that in principle must be free from microorganisms and other contaminants that may endanger public health. Ref.: Regulation (EC) No 852 / 2004
Primary packaging material	Material that fulfils one or more of the following conditions: • It is in contact and / or intended to be in contact with goods (e.g. food, cosmetics, household chemical, etc.) • It can transfer their constituents to the goods, and if it is removed, the quality, safety and legality of its content is affected • It is part of the consumer unit **Note:** In the definition of primary packaging material, "consumer unit" refers to the smallest consumer unit of the product that includes legal information and a bar code, if applicable.
Procedure	Specified way to carry out an activity or process. Procedures shall be implemented and the elaboration of procedures shall be laid out in documents or process description (e.g. flowchart).
Product	Result of a process or activities transforming inputs into outputs. In the context of this standard a product is a packaging component and / or packaging material intended to be used as primary or secondary packaging under the scope of application of the IFS PACsecure Standard (see part 1, chapter 2.2)
Product autenthicity	The characteristic of a product in relation to its origin, and / or process of production / convertion and / or its inherent properties (e.g. sensory or chemical).
Product defence	Procedures implemented to assure the protection of products and their supply chain from malicious and ideologically motivated threats (e.g. contamination or adulteration by biological, chemical, physical, or radiological agents).
Product development	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.
Product fraud	The intentional substitution, mislabelling, adulteration or counterfeiting of product, raw materials, product formula / configuration or wrapping placed upon the market for economic gain. This definition also applies to outsourced processes.

Terms	Related definitions
Product fraud mitigation plan	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. The control measures required to be put into place may vary according to the nature of: • 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 wrapping.
Product fraud vulnerability assessment	A systematic documented form of risk assessment to identify the risk of possible product fraud activity within the supply chain (including all raw materials, formula / configuration, wrapping, product 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, at a minimum: • 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. • The development and implementation of the product fraud mitigation plan, using the results of the vulnerability assessment. • An annual review, or more often if there is increased risk identified by change to defined risk criteria. The criteria used to evaluate the level of risk should be as follows: • History of product fraud incidents • Economic factors • Ease of fraudulent activity • Supply chain complexity • Current control measures • Supplier confidence.
Product Integrity	The product safety, quality and other requirements or criteria that are defined by the company or customer.
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 authenticity, product legal and regulatory compliance, product functionality, process and specification

Terms	Related definitions
Product safety culture	Shared values, beliefs and norms that affect mindset and behavior toward product safety in, across and throughout an organization. Elements of product safety culture are those elements of the product safety and quality management which the senior management of a company may use to drive the product safety culture within the company These shall include as a minimum: • Communication about product safety policies and responsibilities, • Training, • Employee feedback on product safety related issues, • Performance measurement.
Product withdrawal	Any measure aimed at preventing the distribution, display and offer of an out-of-specification product and / or of a product that may be dangerous to the consumer.
Production area	Part of the production site which includes: • Production / conversion processes, • Receipt, storage and dispatch areas, • Good Manufacturing Practices (GMP), including maintenance, hygiene, pest control and cleaning activities, • Product development, • On-site laboratory and / or maintenance facilities, • Staff and sanitary facilities, • External areas.
Production site	An establishment in a specific physical location where the IFS PACsecure Assessment is conducted in which any stage of production, processing / conversion, and distribution of products defined in the IFS PACsecure Assessment scope can be carried out. It can also include facilities (for example workshop or warehouse) owned by the company where part(s) of the processes and operations take place.
Protective clothing	Clothing provided by the company (which includes footwear and gloves) which are worn by employees, contractors and visitors to protect the products from contamination.
Quarantine	The status of goods (incl. raw materials, semi-processed, finished products and wrapping materials) isolated physically or by other effective means pending a decision on their subsequent approval or rejection.
Raw material	A base material used for the manufacture of a product. Raw materials includes additives, inks, adhesives, solvents, wrapping materials, rework.
Reprocessing	Introducing a non-conforming semi-processed or finished products back into the process, to repeat one or more processing steps that are part of the established manufacturing process. Continuation of a process step after an in-process control test has shown that the step is incomplete is considered to be part of the normal process and is not reprocessing.
Resources	A stock or supply of money, materials, staff, and other assets that can be drawn on by the company in order to meet the product and process requirements, including the related to the product safety and quality management system.

Terms	Related definitions
Reviewer	Person of the certification body in charge of assessing the IFS Assessment Reports before a certification decision is made (see the role / tasks and requirements for IFS PACsecure Reviewer in chapter 3.2, Part 3).
Rework	Subjecting a non-conforming semi-processed or finished products to one or more processing steps, which are different from the established manufacturing process, to make it conform to the requirements.
Risk	A function of the probability of an adverse health effect and the severity of that effect consequential to (a) hazard(s) in products.
Risk assessment	Documented information of the process of risk identification, risk analysis, risk evaluation and acceptability of the risk, to determine control measures.
Root cause analysis	Process or procedure that helps understanding the initiating causes of a problem. The goal of this process is to determine the missing or inadequately applied controls that will prevent a recurrence.
Safety Data Sheets (SDS)	Safety data sheets (SDS) are safety instructions for handling dangerous substances, they are principally intended for use by professional users and must enable them to take the necessary measures in regards to 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.
Seasonal products	Products which are processed at a specific time in the year, or processes which are used at a specific time in the year, for getting new / different products than those processed all year long.
Secondary packaging material	Material used for grouping of a certain number of goods whether the latter is sold as such to the customer and/or consumer, or whether it serves only as a means to replenish product supply. It can be part of the consumer unit, but if it is removed, the quality, safety and legality of the goods are not affected.
Securely	To retain in a safe location, which is not open to unauthorised personnel or persons.
Senior management	Executive management.
Sensory tests	Methods to assess the changes in the organoleptic attributes of a product (e.g. odour, flavour) by the senses. **Note:** Some examples of standards about sensory test of packaging material are: DIN 10955, "Robinson test", ASTM standards (e.g. E619, E460–88, E462, E1870, E2609, etc.), UNE-EN 1230, ISO 13302, ISO 22308, among others.
Service	An organisation that provides a network, storage or processing service (e.g. transport, storage, order picking, pest control, cleaning and disinfection, among others).
Shifts	Work schedules in which employees change or rotate.
Sign-off audit	First witness audit of an auditor after having passed the IFS Examinations for the purpose of confirmation of competencies for final approval as IFS PACsecure Auditor. The sign-off audit shall be performed during a full IFS PACsecure Certification Assessment.

Terms	Related definitions
Staff facilities	Areas within a site, other than product handling areas, that are used by personnel, e.g. cloakrooms, toilets, canteens and rest rooms.
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 material	Material conceived to facilitate handling and transport of a number of grouped products, in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship, and air containers.
Traceability	Ability to trace and follow a material (e.g. raw material, packaging material, packaging compound, wrapping material) intended to be, or expected to be incorporated into a product, through all stages of production / conversion and distribution.
Traded products	Products manufactured, wrapped and labelled by and under a different company name than the company being IFS PACsecure certified and which are not customer branded products.
Validation	Obtaining evidence that a control measure or combination of control measures is capable of controlling the hazard to a specified outcome.
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.
Witness assessment (by accreditation bodies)	Assessment of the conformity assessment body when it is carrying out conformity assessment services within its scope of accreditation. **Note:** In IFS Standard, conformity assessment body is named certification body.

Terms	Related definitions
Witness audit, to be performed every two (2) years, for IFS PACsecure approved auditors	Every IFS PACsecure Auditor shall be assessed during a full IFS PACsecure on-site witness audit every two (2) years by the certification body, in order to evaluate her / his competencies. This audit can be performed at any time during the second calendar year after the year in which last witness audit has taken place. The witness auditor: • shall not be part of the assessment (as a team member). • shall be an approved IFS Witness Auditor (see the role / tasks and requirements for IFS Witness Auditor in chapter 3.4, Part 3). • may not be qualified for all product scope(s) of the assessment. The certification body shall specify the name of the witness auditor in the participants' list of the IFS Assessment Report and shall be able to provide, on request, a witness audit report of this witness audit. Every second time (every four (4) years) it can be replaced by a full on-site witness audit during another GFSI recognised certification standard audit accredited against ISO / IEC 17065:2012 norm in the related scope. **Note 1:** In case of an assessment team in which the team can split during the Assessment (as both auditors have company's product and technology scopes), it is not possible to perform a witness audit by a witness auditor, as the auditor who is witnessed doesn't perform a full IFS Assessment. But if the team does not split, it is possible to perform a witness audit by an observer for the lead auditor, as it will be possible to witness the auditor during a full IFS Assessment. **Note 2:** Accreditation witness assessments performed by accreditation bodies are accepted as a replacement of a witness audit performed by an observer from the certification body. **Note 3:** Witness audits performed by IFS Integrity Program during a full IFS PACsecure Assessments can also be accepted.
Wrapping	In the context of this standard, wrapping is the material used to package the final product of the assessed company. If they are removed, the quality, safety and/or legality of the final products are affected.

The IFS publishes information, opinions and bulletins to its best knowledge, but cannot take any responsibility for any mistakes, omissions or possibly misleading information in its publications, especially in this document.

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The English version is the original and reference document.

The IFS PACsecure Standard is available online via:
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