IFS PACsecure

IFS PACsecure

Standard for auditing product and process compliance in relation to packaging material safety and quality

VERSION 3

FEBRUARY 2024

ENGLISH

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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 audit of food suppliers. The audit 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 stakeholders the flexibility to implement the requirements into their business based on the specific risks in regard to the products and processes.

The IFS PACsecure Standard is built upon general aspects of a product safety and quality management system. However, the main emphasis is to create confidence in the products and processes, meaning that safety, quality, legality, authenticity and compliance with specified customer requirements are ensured via an on-site evaluation and documentation review and inspection.

The IFS PACsecure Standard version 3 has been revised by the following working groups: IFS PACsecure Technical Working Group, National Working Groups, International Technical Committee and the IFS Technical Team. Representatives of retailers, industry, food services and certification bodies 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 3 Audits from 1st of July 2024. From 1st of October 2024, IFS PACsecure version 3 audits will be mandatory.

0.2 IFS Objectives, Mission and Vision

The aim of IFS Certification is to assess whether the processing activities 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. IFS Audits are product and process focused. This ensures the development of high-quality products 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 cost reduction of long repetitive audits and additionally supports the 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 production site 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 and programs, audit 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 also applies to the IFS Management GmbH.

0.3 Coverage of the IFS PACsecure Standard

The IFS PACsecure Standard is applicable to packaging manufacturers and can only be used for companies producing, processing and/or converting packaging components and/or packaging materials intended as primary or secondary packaging.

For more details on the IFS Audit Scope, see chapter 2.2, Part 1.

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

0.4 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 – IFS PACsecure Audit Checklist (list of IFS PACsecure Audit Requirements)

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

Part 4 – Reporting, IFS Software and IFS Database.

The IFS PACsecure Standard is linked to the IFS PACsecure Doctrine. The doctrine provides additional rules and clarifications on the interpretation of some IFS PACsecure Requirements. Both documents are normative and shall be implemented following the defined dates, after the documents have been officially published.

0.5 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. That includes an annual review, to ensure the compliance with all relevant requirements. The working group members represent all stakeholders involved in the audit process: retailers, certification bodies, packaging industry, food industry, PAC Global, as well as service providers. Besides the annual review, the main objectives for the working groups are to share practical experiences, review changes or alignments of the IFS PACsecure Standard and clarification needs for the IFS PACsecure Doctrine, discuss the requirements of the audit report and decide on training needs.

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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 Audit. Moreover, it explains the principles of the IFS PACsecure Certification Process, including requirements to be applied by the audited companies and certification bodies.

1 The IFS PACsecure Certification Process

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.

The companies shall prepare well in advance for the IFS PACsecure Certification Process, which comprises of the different steps that are displayed in Annex 2.

The IFS Audit is the core part of the certification process, as the production site and its production processes will be challenged according to all specified requirements laid down in the IFS PACsecure Audit Checklist (Part 2), in order to assess compliance with the products and production processes.

An IFS Certification is a product and process certification. Therefore, the main part of this certification process consists of the IFS Audit. The auditor challenges the audited companies on the audit checklist to determine the level of compliance of processes and products. An audit is always focused on the following fundamental elements:

a. Product and process approach (PPA)

The product and process approach (PPA) implies the assessment of compliance with customer related specification(s) as well as the legal compliance of the products, depending on the countries of production and destination.

To ensure the PPA, IFS PACsecure Certifications are always specific to one production site. In addition, all products and processes of the relevant production site shall be included in the scope of the IFS PACsecure Audit.

During the IFS PACsecure Audit, the auditor shall collect objective evidence to evaluate the compliance with the IFS PACsecure Audit Requirements (see IFS PACsecure Audit Checklist, Part 2).

One of the key elements for conducting the IFS PACsecure Audit and to ensure high uniformity of the PPA implementation is to follow an audit trail. This audit trail consists of the following main steps:

- **Product sampling:**
  The selection of samples shall be risk-based but can also follow other 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 (sampled by the auditor on-site at the beginning or in advance of the audit) is essential and allows the IFS Auditor to follow a uniform path in order to obtain all necessary evidence. In addition, auditors shall perform a traceability test on the sampled product(s) during the IFS PACsecure Audit.

  Note: IFS has published guidelines (e.g. IFS Good Audit Practices (GAP) Guideline), which provide further information on topics to be checked and/or requested by the auditor from the audited production site during the IFS PACsecure Audit.

- **Overall on-site evaluation:**
  At least 50 % of the total IFS Audit duration shall be allocated to the on-site evaluation (within the production areas of the production site). This allows the auditor to comprehensively audit the products and the processes and shall be performed as soon as possible. For further information, see chapter 3.1, Part 1 and 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), including maintenance, hygiene, pest control and cleaning and disinfection activities,
  - Product development,
  - On-site laboratory,
  - Maintenance facilities,
  - Staff and sanitary facilities,
  - External areas.

  The auditor shall also use this time to evaluate the operating processes, through the following checks:
  - check the control measures defined for CCPs (if existing) and other control measures as well as their monitoring in order to cross-check them with the hazard and risk management system information
  - observe and interview employees
  - inspect product and processes characteristics
  - take further samples for cross-checking, when necessary
  - review formulas/configurations used during the manufacturing process
  - observe actual finished product dispatch and/or raw material delivery
  - assess the implemented product safety and quality management system in practice.

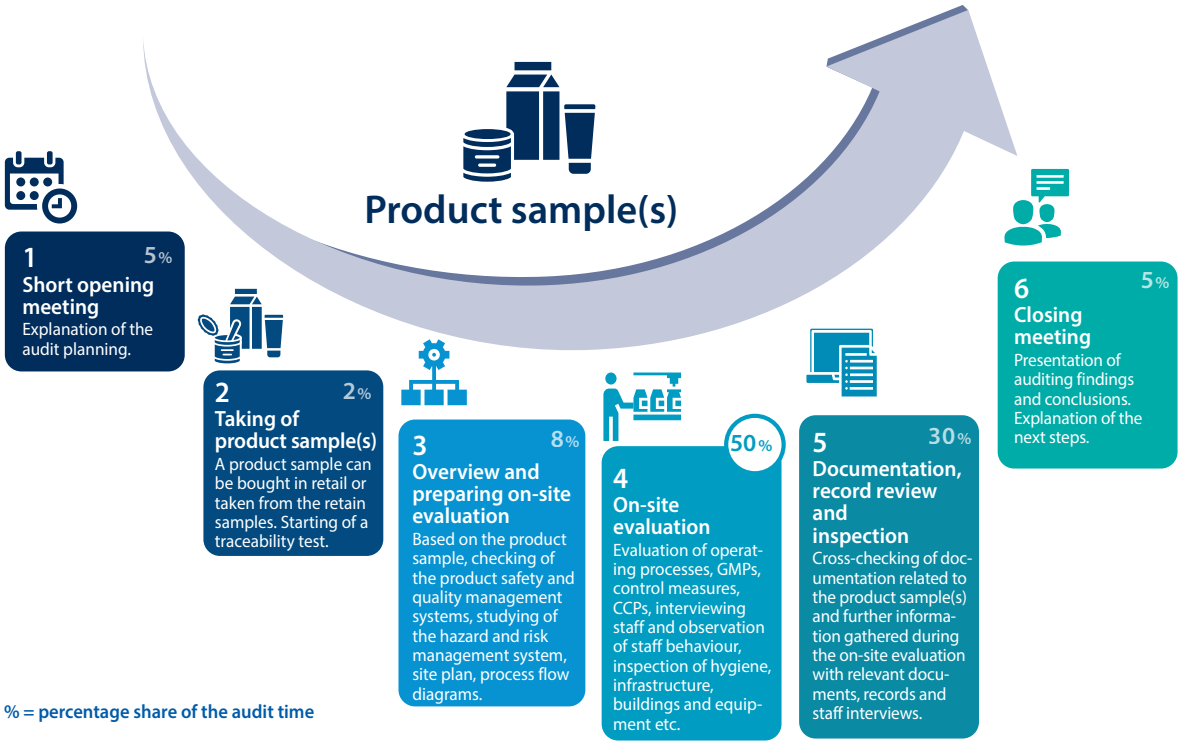
- **Documentation, record review and inspection:**
  The on-site evaluation is followed by a comprehensive documentation and record review/inspection, including cross-checking of related documents. This part of the audit aims at

verifying the information collected from the on-site evaluation and the evaluation of further requirements.
To master the IFS Audit trail, the auditors shall evaluate the production site's compliance in depth. Further explanations and examples are provided in the e-learning "IFS Product and Process Approach".

Summary of main steps is provided in the following chart (chart 1).

Note: This chart shows main steps of an announced IFS Audit. Steps 2 to 5 can be performed alternately. Percentages are given as a guidance.

Chart 1: The product and process approach of an IFS Audit



b. IFS Auditor Qualification

The IFS Auditor's specific expertise forms the crucial basis for the audit of the production site. Therefore, IFS Auditors are approved for specific product scope(s) to guarantee a high degree of quality and reproducibility of the audit findings. More information can be found in Part 3.

c. Annual certification cycle

The production site will go through a full IFS PACsecure Certification Process including a comprehensive IFS PACsecure Audit every year. This includes the audit of the full IFS PACsecure Audit Checklist (Part 2). If applicable, the implementation of the action plan from the last IFS Audit is also to be verified. More information on the certification cycle can be found in chapter 4.3, Part 1.

d. Certification by certification bodies accredited to the ISO/IEC 17065:2012 norm and contracted with IFS Management GmbH

Reliability of the certification is guaranteed through accredited, internationally recognised, independent, third-party certification bodies. Additionally, the certification bodies shall have signed a contract with IFS Management GmbH and shall comply with the specific rules described in Part 3.

e. Surveillance and harmonised rules by the IFS Standard Owner

As part of the IFS Quality Assurance activities, IFS has implemented procedures to monitor the performance of IFS approved certification bodies, IFS Auditors and IFS certified companies, the IFS Integrity Program, which 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 audited site shall be informed by its certification body about the procedures and rules of the IFS Integrity Program. More information on the Integrity Program can be found in chapter 5, part 1.

2 Before the IFS PACsecure Audit

In order to prepare the initial audit, the production site may perform a voluntary pre-audit to evaluate its current status and level. The pre-audit cannot be uploaded in the IFS Database and a different auditor shall perform the pre-audit to the one who performs the subsequent IFS Audit.

Any production site starting with new operations shall ensure that all requirements of IFS can be audited at the time of the initial audit. IFS recommends a minimum of three (3) months of operations before this first audit.

2.1 Making a contract with a certification body

In order to undertake an IFS PACsecure Audit, 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 certification bodies that have a valid contract with IFS Management GmbH is available by country on the IFS Website (www.ifs-certification.com).

A contract shall exist between the company and the certification body for the certification audit and shall include the following topics:

a. Certification process information

It shall include, at a minimum:

- Audit scope agreed between both parties. More information can be found in chapter 2.2, Part 1 and Annex 3.
- Audit duration. More information can be found in chapter 3.1, Part 1
- Information about the report and certificate details. More information can be found in chapters 1.2 and 1.4, Part 4.
- Reference to the IFS Integrity Program. More information can be found in chapter 5, Part 1.

- Mention that information about the company and its employees is stored in the IFS Database in line with the General Data Protection Regulation. More information can be found in chapter 3, Part 4.

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

The certification body shall ensure that the IFS Auditor is qualified for the product scopes of the audit, as well as the currently applicable version of the IFS Standard.
To assist the IFS PACsecure Auditor in preparing for the audit, 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 Audit, including decentralised structures.
- Cases where parts of the production activities or products are outsourced to a third-party on behalf of the IFS PACsecure certified production site.
- Overview of the exported products, including the different destination countries where the products are sold to.
- Under exceptional circumstances, any request for exclusion of some product groups. This will be carefully verified by the certification body in order to review if the exclusion is possible.
- History of certification status of IFS or any other GFSI recognised standards, for example type of certification/scope, date of the last certification audit (even if performed by another certification body), year of the last unannounced audit, if a certificate has been withdrawn in the past, etc.

More information on outsourced processes and exclusions can be found in chapter 2.2.1, Part 1 and Annex 4.

If the IFS PACsecure Audit is performed together with (an) other standard(s)/norm(s), all IFS Requirements shall be fulfilled (e.g. audit time schedule, audit duration, auditor competences, etc.).

c. Notifications to the certification body

During the certification cycle, the senior management of the production site shall ensure that the certification body is informed in due time about any changes that may affect the production site's ability to conform to the certification requirements (e.g. recall, alert on products, changes in organisation and management, important modification on the products and/or the production methods, changes in 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 the IFS PACsecure Audit Checklist (Part 2), requirement 1.2.6, some specific situations require a notification to the certification body within three (3) working days.

After receiving such information from the sites (limited to the three (3) specific situations, mentioned in the requirement 1.2.6 of the IFS PACsecure Audit Checklist), the certification body shall:

- Fill out the relevant extraordinary information form provided in the IFS Database in English and send it back to IFS Management GmbH within three (3) working days after receiving the information from the production site.
- Provide IFS Management GmbH a root cause analysis and progress report of the investigation within ten (10) working days (after submitting the form).

It is the certification body's responsibility to investigate each situation and decide any action on the IFS Certification Status.

d. Language of the IFS PACsecure Audit

The IFS PACsecure Audit shall be carried out in the working language of the production site. If there is a need for translation, the certification body shall provide a qualified interpreter not affiliated with the company. More information can be found in chapter 3.1.2, Part 3 and in the IFS PACsecure Doctrine.

2.2 Scope of the IFS PACsecure Audit

IFS PACsecure is applicable for the production, processing and/or conversion of packaging components and/or packaging materials, intended 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: IFS PACsecure is also applicable for packaging materials intended as secondary packaging in over-the-counter drugs/pharmaceutical products, only if these products 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.

The audit scope shall be agreed between both parties before the audit takes place.

It shall include the full activities of the site, including all production lines and products manufactured by the production site (both customer branded products and company's own branded products).

More information on the scope determination between IFS PACsecure and other IFS Standards can be found in Annex 1.

Certification is always site-specific (one legal entity, one address, one certificate), in relation to the actual processing activities of the site. Decentralised structures belonging to the same production site shall be audited and included in the audit scope to be able to gain a complete view of the processes. More information on the different types of production sites and information to be provided in the audit report and certificate can be found in chapter 2.2.2, Part 1.

The IFS PACsecure product scopes (from 1 to 7) shall be used to determine the audit scope. The selection of the product scope(s) depends on the finished products manufactured by the production site. The IFS PACsecure product scopes are laid down in Annex 3.

All applicable scopes shall be mentioned on the IFS PACsecure Certificate and Report.

The audit scope shall be described in detail in the audit report and on the certificate. It shall be clear, unambiguous, and shall fulfil the following rules:

- The different types of products shall be described in sufficient detail.
- The type of wrapping materials shall be described.
- The most characteristic processes that differentiates the product from others and that are not self-explanatory need to be clearly mentioned.
- The information about the intended use of products (primary and/or secondary packaging materials) shall be included.

The following elements shall not be mentioned in the scope:

- Certain activities of a production site are always part of the IFS PACsecure Audit and shall therefore not be mentioned specifically. Therefore, the following words shall not be mentioned in the scope description: storage, transport, sales, distribution, research, development and design. Labelling activities shall only be mentioned when they are an essential/relevant processing step of the production site e.g. if this is the only relevant processing step of the production of a partly outsourced product.
- Brand information is not allowed as it does not provide any information on the products and processes of the production site.
- Reference to claims is not allowed. Information on further claims can only be provided in the report.
- 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 which are listed in Annex 4.

The agreed scope shall be mentioned in the contract and it shall also be reviewed and confirmed by the auditor during the opening meeting of the IFS PACsecure Audit.

2.2.1 Outsourced processes and IFS PACsecure Audit Scope

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 site. This includes processes which are partly outsourced to a sister company within the same company group and applies to both customer branded products and the company's own branded products.

Note 1: Storage and/or transport activities carried out by a third-party are not part of the above defined partly outsourced processes and shall be evaluated according to the relevant chapters of the IFS PACsecure Audit Checklist (chapters 4.14 and 4.15, Part 2), especially to the requirements 4.14.4 and 4.15.6.

Note 2: From the IFS perspective, the difference between a raw material and a product coming from a partly outsourced process is based on the ownership:

- A raw material is purchased from a supplier (no ownership and legal responsibility before) and processed (further) by the IFS audited production site.
- A product from a partly outsourced process always belongs to the audited production site.

The following rules shall apply when a company has partly outsourced process(es):

- The requirements 4.4.5, 4.4.6 and 4.4.7 of the IFS PACsecure Audit Checklist (Part 2) apply and shall be audited by the auditor, to assess if the audited production site ensures control over such processes.
- The audit scope shall only mention the processes managed by the audited production site, not by the third-party.
- In the audit report of the audited production site (audit overview): a description of the partly outsourced processes and certification status of the third-party shall be provided.

- If the appointed third-party is IFS PACsecure certified, their COID (IFS Identification Code Number) can also be mentioned.
- On the certificate of the audited production site, the following sentence shall be added to the audit scope, beneath the description of products and processes: "Besides own production, the company has partly outsourced processes." More information on the IFS Certificate can be found in chapter 1.4, Part 4 and in the Annex 11.

b. Fully outsourced products and traded products

A **fully outsourced product** is a product manufactured, wrapped and labelled under the own company brand or customer brand by a different production site to the one being audited.

A **traded product** is a product manufactured, wrapped and labelled by and under a different company name to the production site being IFS PACsecure certified.

Fully outsourced products and traded products are, by nature, not covered by the IFS PACsecure Certification.

It is recommended that these activities are certified under IFS Broker or any equivalent GFSI recognised product safety certification standard based on the ISO/IEC 17065:2012 norm (e.g. a combined IFS PACsecure/IFS Broker Audit can be performed, see Annex 1).

Regardless whether these activities are certified or not, the following sentence shall be added to the certificate and in the company profile section of the audit report: "The company has own broker activities which are/are not IFS Broker/other GFSI recognised standard certified".

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

The IFS Audit is production site specific: one production site is subject to one audit 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).**

1. Single production site:

A single production site is a 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 site shall have one audit, one COID, one report and one certificate.

2. Multi-location production sites:

Multi-location production sites refer to a company with multiple production sites at different locations, which may have a head office/central management. Following rules apply in these two (2) cases:

a) Company with head office/central management

When the head office/central management also has additional processing activities, the site shall be audited and subjected to its own IFS PACsecure Certificate and Audit Report.

When the head office/central management does not have processing activities, it cannot be subject to an IFS PACsecure Certificate. The company can decide whether to organise a specific audit (which can also be remote in this case) for the activities managed by the head office/central management. This shall be defined in advance with the certification body, before the audit takes place:

- If no head office/central management audit is performed: the company shall ensure that all necessary information and responsible personnel from the head office/central management are available (when necessary) during the audit of each production site, to ensure that the auditor can audit centrally managed activities properly. For example, a representative from the head office/central management can attend the audit of the production sites, head office/central management documents are available on-site, etc.
- If a head office/central management audit is performed, the following rules apply:
  - The audit of the head office/central management shall always take place before the audit of each production site associated to each certification cycle.
  - The maximum period of time between the audit of the head office/central management and the audit of all production sites is twelve (12) months.
  - The certification body has to determine which parts of the head office/central management audit cover the site operation parts.
  - Each production site shall get an individual certificate and report.
  - The centrally managed activities, as well as the outcome of the audit shall be described in the audit report of each production site.
  - Deviations identified during the head office/central management cannot be partly solved in the audit reports of each production site. Deviations can be downgraded, for example, to a non-conformity, but neither fixed nor improved to a better scoring.
  - If a non-conformity has been raised during the audit of the head office/central management, all audited production sites are also affected and the certificates of these production sites shall be suspended. Only after a positive follow-up audit 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 audit of the production sites may also be necessary.
  - Both audit dates of the production site and head office/central management shall be visible in the audit report.
  - All COIDs of the production sites linked to the head office/central management shall be mentioned in each audit report.

b) Company without head office/central management

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

Note: A multi-location production site can individually choose whether it wants to be certified as part of multi-location production sites, as a single production site or not to be certified at all.

3. **Multi-legal entity production site:**
   a) If a production site has multiple legal entities at one physical location with the same scope, the following rules apply:
      - one audit shall be performed
      - the certificate and report shall be duplicated for each legal entity
      - each legal entity shall have its own COID.

   b) If 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, report and certificate
      - the audit duration shall be determined separately for each COID. A head office/central management audit can be appointed, which may allow a reduction of audit duration by maximum 0,5 days (as per multi-location approach).

   In both cases, if a contractual relationship between the legal entities exists, the COIDs of each legal entity shall be linked in the IFS Database. If the certificate of one legal entity is suspended/withdrawn, the certificates of all legal entities shall also be suspended/withdrawn, unless the certification body can demonstrate that the other legal entities are not affected.

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

2.3 Type of IFS PACsecure Audits

Different types of audits shall be conducted, depending on the certification status and cycle of the production site.

IFS Audit (full on-site):
An IFS PACsecure Audit shall always be performed on-site and during consecutive working days, for both announced and unannounced audit options.

IFS Split Audit:
Under exceptional circumstances (e.g. due to a widely acknowledge crisis) and when a full on-site audit is hardly possible, the company may agree with the certification body to perform an IFS Split Audit. The on-site part of this audit shall be performed first, followed by a remote part using ICT (Information and Communication Technologies). In order to perform an IFS Split Audit, the normative document "IFS Split Audit Protocol" shall be used, and sufficient justification shall be given in the IFS Audit Report. More information can be found in the IFS Split Audit Protocol.

2.3.1 Initial audit

Audit description:
There are two (2) types of initial audits:

a) "First" initial audit
The first initial audit refers to the very first IFS PACsecure Certification Audit of a production site during which all the requirements of the IFS PACsecure Audit Checklist shall be audited by the auditor. This type of audit is only applicable when there is no previous certification history available.

b) "New" initial audit
The new initial audit is the IFS PACsecure Audit performed:

- after an interruption in the certification cycle (see the chapter 4.3, Part 1) or
- after a failed recertification audit due to one or several non-conformity(ies) or a total score < 75% or
- after a failed follow-up audit or
- after a failed extension audit.

In this case, the following applies:

- the IFS PACsecure Certification history shall be checked to ensure that the rule on unannounced audit frequency is fulfilled (more information on unannounced audits can be found in chapter 2.4.2, Part 1).
- the audit report and action plan from the previous IFS PACsecure Audit shall be reviewed by the auditor, to check the implementation and effectiveness of corrections and corrective actions. This applies even if another certification body issued the audit report.

Note: If an initial IFS PACsecure Audit is failed, the IFS PACsecure Audit Report shall be uploaded in the IFS Database and this audit cannot be considered as a pre-audit.

For "first" initial audits and/or "new" initial audits performed according to a new version of the standard, all rules and requirements of the applicable version of the standard apply and shall be implemented and validated (e.g. through internal audits, senior management review, etc.) before the audit takes place. This also includes the requirements where an annual review is requested.

Audit options:
An initial audit can be performed announced or unannounced. More information on audit options can be found in chapter 2.4, Part 1.

2.3.2 Recertification audit

Audit description:
To maintain certification, the production site shall get recertified every year. Therefore, the recertification audit is a full audit of a production site, during which all the requirements of the IFS PACsecure Audit Checklist shall be audited by the auditor and lead to a renewal of the existing IFS PACsecure Certification.
The period during which a recertification audit shall take place is shown on the certificate and the audit shall be performed during this period in order to maintain the certification cycle.

It is the responsibility of the production site to renew their certification in due time. Therefore, all IFS PACsecure certified companies receive a reminder from the IFS Database three (3) months before certification expiration.

If the audit is not performed in due time, all IFS Database users with the respective production site in their favourites' list will receive an automatic e-mail notification.

The auditor shall review the action plan from the previous IFS PACsecure Audit to check the implementation and effectiveness of corrections and corrective actions. If the production site changes certification body, the production site shall update this information in the IFS Database and inform their new certification body so that the auditor can check the action plan from the previous audit.

If deviations are still present in the actual recertification audit, or if the scorings were lowered, the auditor shall assess the situation in accordance with chapter 5.11 of the IFS PACsecure Audit Checklist, Part 2.

The link between two (2) consecutive audits ensures a continuous improvement process.

Audit options:
A recertification audit can be performed announced or unannounced. More information on audit options can be found in chapter 2.4, Part 1.

2.3.3 Follow-up audit

Audit description:
A follow-up audit is required in a specific situation where the results from an initial or recertification audit did not allow a certificate to be issued due to one Major non-conformity and a total score ≥ 75%.

The follow-up audit is focused on the implementation of actions taken to solve the Major non-conformity and shall comply with the following rules:

- It shall be performed on-site.
- It shall generally be performed by the same auditor who performed the main (initial or recertification) audit.
- It shall be performed no earlier than six (6) weeks, and no later than six (6) months, after the main audit. If this deadline is not fulfilled or if the production site decides not to perform a follow-up audit, a new initial audit shall be performed.

Audit outcomes:
- If the follow-up audit is successful:
  - the positive outcome of the follow-up audit shall be provided in the audit report.
  - the updated report shall be uploaded in the IFS Database.
  - the certificate shall be issued at foundation level only, even if the final total score is ≥ 95%.
  - the certificate validity remains in the certification cycle, as described in chapter 4.3, Part 1.
- If the follow-up audit is failed:
  - the report of the failed follow-up audit shall be uploaded to the IFS Database.

- a new initial audit shall be performed and scheduled no earlier than six (6) weeks after the follow-up audit.

A detailed flow chart, with all steps, can be found in Annex 5.
The upload of a follow-up audit report is free of charge.

Audit options:
A follow-up audit can only be performed announced.

2.3.4 Extension audit

Audit description:
An extension audit is an additional audit to extend the current certification scope. This type of audit shall always be performed on-site. Furthermore, it shall be performed during the validity period of the existing certificate, in the following situations:

- If some production lines were not running during the main certification audit, involving product scopes and/or production/conversion processes and/or the hazard and risk management system (especially the CCPs) different to the ones audited during the initial/recertification audit.
- In case of seasonal products, which could not be audited during operation at the time of the main audit. During the following year, there will be one recertification and one extension audit, in order to ensure all products and processes are covered. The main audit shall always be performed when the most hazardous processing step is carried out.
- If significant changes occur to the production process and/or its environment between two (2) certification audits. This applies, for example, when new processes or products different to those included in the scope of the current certificate are introduced. In this case the following rules apply:
  - the certification body decides, based on a risk assessment, if an extension audit is necessary.
  - the risk assessment shall be based on hygiene, good manufacturing practices and product safety risks and shall be documented.

Audit outcomes:
The conditions to pass the extension audit are the same as for initial or recertification audits, but they will only be focused on specific requirements that have been audited. The original audit score on the IFS Certificate shall not be changed, however the certificate shall be withdrawn when the extension audit is failed.

The following two (2) outcomes are possible for an extension audit:

- The extension audit is successful, and the following shall be applied:
  - the certificate shall be updated with the new scope
  - the certificate shall keep the same expiry date as the certificate of the main audit
  - the updated certificate and extension audit report shall be uploaded in the IFS Database.
- The extension audit is failed in the following situations:
  - In the event of one or more non-conformity(ies)
- When the extension audit is failed the following consequences shall be enforced:
  - the full audit (including the main audit) is failed and
  - the current certificate shall be withdrawn.

The extension audit report shall be provided as an annex to the current audit report. The upload of an extension audit report is free of charge.

IFS provides the following example of a production site processing two kinds of products (A and B) at different periods of the year:

- The main audit is focussed on the processing activities of product A and on the documentation related to the processing of products A and B.
- After this audit, the certificate and the report shall specify: "Production of product A — production of product B will be checked during an extension audit" and an extension audit shall be performed later to verify the processing activities of product B on-site.
- After the extension audit, the certificate shall be updated specifying "Production of products A and B […]".
- Same annual procedure as above will apply each year.

Audit options:
An extension audit can only be performed announced.

2.4 IFS PACsecure Announced and Unannounced Audit options

Before scheduling and performing the IFS PACsecure Audit, the certification body shall decide and inform the production site whether the audit is conducted on an announced or unannounced basis, ensuring that at least one every third IFS PACsecure Audit is performed unannounced, starting 1st January 2021 (regardless of the IFS PACsecure Standard Version).

Certification bodies shall contact their customers in advance to set a date for an announced audit or to register them for an unannounced audit.

2.4.1 Announced audit option

The announced audit is conducted at a time and date agreed between the production site and the selected certification body and shall be performed on consecutive days. An announced recertification audit shall be scheduled at earliest eight (8) weeks before the audit due date and at latest two (2) weeks after the audit due date (anniversary date of the initial audit).

2.4.2 Unannounced audit option

The unannounced audit shall be performed within a time window of [– 16 weeks before audit due date; + two (2) weeks after audit due date] and shall take place without prior notification of the date to the production site, to ensure the unannounced character of the audit.

All IFS Checklist Requirements shall be implemented before the audit time window starts.

A site that has undergone an unannounced audit will obtain the IFS Star Status which will be visible on the IFS Database and IFS Certificate. The status will be withdrawn once an announced audit takes place.

An unannounced audit shall be performed at least once every third IFS PACsecure Audit, starting 1st January 2021.

A failed announced audit does not count towards the "at least every third audit unannounced rule". It is up to the certification body to decide together with the production site if the next audit should be unannounced due to customer requirements or if it can be announced. An unannounced audit counts for this rule no matter if the result is passed or failed.

If the certification cycle is interrupted where an unannounced audit was due, the next certification audit (=new initial audit) shall be conducted unannounced.

The certification body shall:

- decide in which year the first mandatory unannounced audit will be performed and inform the production site at least six (6) months before the audit due date.
- ensure that this frequency is fulfilled, even if the production site (COID) changes its certification body.

Apart from this minimum mandatory frequency, unannounced audits may be performed more frequently based on the production site's decision.

Note: In case of different IFS Standards, the unannounced certification frequency counts separately.

The site is responsible to inform the certification body about the following information at latest four (4) weeks before the start of the audit time window (to allow the certification body to register it in the IFS Database):

- Name(s) of the on-site person(s) to be contacted at the production site.
- If needed, blackout period of a maximum of ten (10) working days when the production site is not available for audit, as well as non-operating periods. The ten (10) working days can be split into a maximum of three (3) periods.
- If the site produces seasonal products, the expected seasonal production dates shall be notified and the time window [–16 weeks, + two (2) weeks] does not apply. Providing a blackout period is not permitted in this situation and the unannounced audit shall take place at any time during this seasonal production period.

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

The registration of unannounced audits for multi-location production sites with a head office/central management shall comply with the following rules:

- The head office/central management shall either undergo an announced or unannounced audit.
- The audit of the head office/central management shall always take place before the audit of each production site and shall be performed before the start of the unannounced audit time window of the production site(s).

- When the head office/central management undergoes an announced audit: the announced audit of the head office/central management and unannounced audit of the production site shall not be performed on consecutive days (e.g. if the head office/central management is located within one of the production sites, there shall be two (2) different audits: an announced one for the centrally organised processes and an unannounced one for the production site).
- When the head office/central management undergoes an unannounced audit: unannounced audits of the head office/central management and the production site can be organised to take place on the same day (e.g. if the head office/central management is located within one of the production sites, there can be one unannounced audit for centrally organised processes and for the production site. This audit shall start with the production processes).

The overview of the audit types and options is given in the below chart (chart 2).

Chart 2: Audit types and options

			Execution mode of the IFS Audit			
			IFS Full On-site Audit		IFS Split Audit	
			IFS Audit Options			
	Audit type	Explanation	Announced	Unannounced	Announced	Unannounced
At least every third (3) audit shall be performed unannounced	Initial audit	**First initial:** Audit of a production site that has no previous IFS Certification history.	☑	☑	☑ (not recommended)	☑ (not recommended)
		New initial: Audit that is performed after interruption of cycle or after a failed audit.	☑	☑	☑	☑
	Recertification audit	Audit to renew the existing certificate after re-evaluating all requirements.	☑	☑	☑	☑
	Follow-up audit	Audit to be conducted when one Major non-conformity was scored during the main audit and the total score is ≥ 75%.	☑	☒	☒	☒
	Extension audit	Audit to extend the current certification scope resulting from the initial/recertification audit.	☑	☒	☒	☒

2.5 Planning an IFS PACsecure Audit

- For an announced audit, the first audit 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 audit.
- For an unannounced audit, the certification body decides about the year when an unannounced audit will take place and the site shall provide the needed information for the registration to the unannounced option at latest four (4) weeks before the start of the audit time window. All audit days shall be within the unannounced audit time window to ensure the status of unannounced audit.

2.5.1 Drawing up an audit time schedule

The certification body shall provide the production site with the audit time schedule, which shall:

- Include appropriate details on the audit scope
- Include audit duration
- Be sufficiently flexible to respond to any unexpected event which may arise during the on-site evaluation part of the audit
- Take the review of the audit report and action plan from the previous audit into consideration
- Specify the production site's products or product ranges that shall be audited
- In case of audit team: indicate which auditor performs which part of the audit. Information about the audit date and time for each auditor shall be provided in the IFS Database.
- In case of IFS Split Audit: indicate the dates and time ICT will be used to evaluate the checklist requirements.
- If the IFS PACsecure Audit is performed together with another standard/norm: indicate when and which part of each standard/norm has been audited.

For an announced audit, the time schedule shall be sent to the site before the audit, to ensure the availability of responsible persons on the day of the audit.

For an unannounced audit, it shall be shared during the opening meeting. It might also be modified or adapted due to the availability of the participants to be audited and the current processing times.

3 IFS PACsecure Audit realisation

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

- The audit shall take place at a time when the products included in the audit scope are being processed/converted (in order to audit all processing steps).
- The production lines shall be operational during the IFS Audit.

If some production lines are not operating during the IFS Audit, and the products and/or production/conversion processes and/or the hazard and risk management system (especially the CCPs) are different from those in operation, two (2) options are possible:

- The production line(s) can run later during the audit and are included in the scope of the "main" audit.
- The production line(s) cannot run later during the audit and an extension audit shall be performed. More information on extension audits can be found in chapter 2.3.4, Part 1.

3.1 Audit duration

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

- size of the site,
- type of production,
- audit scope,
- number of production lines involved,
- total number of employees (maximum total number of people on-site, including part time workers, shift workers, temporary staff, administrative people, on-site outsourced staff, etc.), considering the maximum total number of employees possible over a year,
- number of deviations and/or non-conformities found in the previous audit,
- etc.

In all cases, the minimum duration of an IFS PACsecure Audit shall be two (2) days (16 hours) without audit preparation and reporting times. One audit day is equivalent to eight (8) hours (without lunch break) and shall never exceed ten (10) hours.

For an audit team, a minimum of two (2) hours shall be added to the determined audit duration. This additional time shall be allocated to the team and not to an individual auditor for common tasks (e.g. opening and closing meetings, discussion about audit findings, etc.).

Note: If the IFS PACsecure Audit is combined and/or integrated with another standard(s)/norm(s), the certification body shall ensure that all requirements for IFS PACsecure Audit duration are fulfilled and that the overall duration is higher than the IFS PACsecure Audit duration.

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

The rules to extend or reduce the IFS PACsecure Audit duration are detailed in the IFS PACsecure Doctrine. The certification body/auditor shall justify the decision for a reduction in the IFS Audit Report.

The only acceptable reduction reasons are those defined in the IFS PACsecure Standard and its related Doctrine. A combination of different reasons for reduction, including in the case of a combined IFS Audit, is not possible.

The IFS Integrity Program will regularly review the justifications for audit time reduction, to ensure they are relevant and aligned with the above rules.

At least 50% of the total IFS Audit duration shall be allocated to the on-site evaluation (within the production areas of the production site) to allow the auditor to comprehensively audit the products and the processes. This can be decreased to 1/3 if a site has simple processes and the total audit duration after reduction, is equal to or less than 1,5 days (for clarification of simple processes and rules to reduce audit duration, see IFS PACsecure Doctrine). In any case, the certification body / auditor shall justify the decision for a reduction to the on-site evaluation in the IFS Audit Report.

In addition to the determined audit duration, following time shall be added, at a minimum:

- two (2) hours for audit preparation
- 0,75 days (six (6) hours) for audit report writing.

3.2 Audit performance

The audit shall be scheduled based on the following steps:

- Opening meeting. The opening meeting and the evaluation of the existing product safety and quality management system shall be kept short, to allow the auditor to start the on-site evaluation as soon as possible (typically 30 minutes after entering the site).
- Evaluation of existing product safety and quality management system, to be achieved by checking documentation (hazard analysis and risk management 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 control measures defined for CCPs (if existing) and other control measures to be cross-checked with the hazard analysis and risk management system information.
- Documentation, 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 audit.
- Closing meeting: During the closing meeting, at the end of the audit, the auditor (or lead auditor for an audit 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 audit.

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

Note: During the audit, the IFS Auditor shall make detailed notes regarding all evaluations against the IFS PACsecure Standard, which will be used as the basis for the audit report.

IFS requires certification bodies/auditors to provide a mandatory document which reflects and confirms the actual presence of the auditor(s) and audited production site representative(s) during the audit. This document shall:

- state the start and end time of each audit day.

- be signed by a representative of the company, auditor(s), and if applicable from trainee(s), auditor under observation, witness auditor, interpreter, technical expert or any other observer present, latest on the last day of the audit.

This document shall be part of the audit 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 an IFS PACsecure Requirement has been met, the auditor shall evaluate all requirements classified either as regular or as KO requirements in the IFS PACsecure Audit Checklist (Part 2).

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. When evaluating each requirement, the auditor shall evaluate if the requirement is met.

In doing so, the auditor shall also evaluate the effectiveness of the measures that a company has taken to implement a requirement. If the measures taken are not effective in the sense that they result in a negative impact on product safety, in a breach of the legal requirements of the production and/or destination countries, or in a breach of customer agreements, the auditor shall evaluate this as a deviation or non-conformity.

In the IFS PACsecure Standard, there are six (6) scoring possibilities and the option of non-applicability. Points are awarded for each requirement according to the following chart (chart 3):

Chart 3: IFS Scoring System

Result	Explanation	Points
A	Full compliance.	20 points
B (deviation)	Almost full compliance.	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 issued 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.
N/A Not applicable	The requirement is not applicable. N/A can apply to any requirement, except for KO requirements numbers 1, 3 and 5 to 10. The auditor shall provide an explanation in the report.	Not included in the calculation of the total score.

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 implemented by the production site to reach compliance.

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

1) 1.2.1 Governance and commitment
2) 2.3.9.1 Monitoring system of each CCP
3) 3.2.2 Personal hygiene
4) 4.1.3 Customer agreement

5) 4.2.1.3 Raw material specifications

6) 4.12.1 Foreign material risk mitigation

7) 4.18.1 Traceability

8) 5.1.1 Internal audits

9) 5.9.1 Procedures of recalls, withdrawals and incidents

10) 5.11.3 Corrective actions

Scoring of KO requirements is explained in the following chart (chart 4).

Chart 4: Scoring of a KO requirement

Result	Explanation	Points
A	Full compliance.	20 points
KO B (deviation)	Small part of the requirement is not implemented, with no impact on product safety, legality, and customer requirements.	0 point
C (deviation)		"C" scoring is not possible
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.

If the auditor raises one or several Major and/or KO non-conformity(ies), certification cannot be granted and, if this is a recertification audit, the current IFS Certificate shall be withdrawn, under the following rules:

- It shall be withdrawn in the IFS Database by the certification body as soon as possible, and at latest two (2) working days after the last audit day.
- In the IFS Database, the certification body shall provide explanations in English about the reasons for withdrawing the current certificate, including the requirement number of the non-conformity(ies). These explanations shall provide the same details as those described in the action plan.

Note: All IFS Database users with the respective production site 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 withdrawn.

More information on failed audits can be found in chapter 4.2.1.1, Part 1.

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

The total score is calculated as follows:
Total number of points = (total number of IFS PACsecure Requirements (points) – requirements evaluated as N/A (points)) × twenty (20)
Final score (in %) = number of points awarded/total number of points.

The auditor shall provide explanations in the audit report for:

- requirements defined as compulsory fields, even if the requirements are scored with A,
- all requirements scored with B, C, D,
- Major/KO non-conformity/ies,
- requirements audited as not applicable.

4 Post IFS PACsecure Audit Actions

4.1 Action plan

The auditor and/or certification body shall issue the action plan (with the list of findings) to the company at latest within two (2) weeks from the last audit date. A provisional score and report can be available upon request.
The action plan shall be used by the company as a basis for drawing up corrections and corrective actions for the issued deviations and non-conformities. More information can be found in Annex 7.

4.1.1 Company's completion of the action plan

The company shall provide the following in the action plan:

- Evidence of implementation of corrections and proposed corrective actions for all deviations (B, C, D), KO B, 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 5).

Chart 5: Timescale for corrections and corrective actions

TIMESCALE	
Corrections **Provided and implemented within four (4) weeks**	**Corrective actions** **Provided within four (4) weeks, but may be implemented later**
Evidence of implementation shall be provided to the certification body within a maximum of four (4) weeks after the receipt of the action plan for completion.	Relevant for a sustainable and successful implementation (may take longer than the deadline for issuing the certificate, needs to be justified by the company). Implemented before the recertification audit, at the latest.

Examples of acceptable evidence for the implementation of corrections:

- Training records
- Updated procedures with traceable modifications
- Before and after pictures
- Evidence (e.g. e-mail) of communication of documents to the relevant personnel
- Internal audit or inspection report
- Invoices of repairs. Offers of repairs are not accepted, as it is only proof of the intention of correction, not evidence of correction
- New monitoring procedure (e.g. for a damaged infrastructure)
- For an updated document, it may be necessary to get evidence of training and/or communication related to the updated document for the company personnel, in case other personnel/department has to work with it
- For an updated form, based on its importance and frequency of use, it may be necessary to send a completed form to the certification body/auditor.

The company shall forward the completed action plan, including evidence of implementation of corrections, to the certification body/auditor within maximum four (4) weeks of having received the action plan.

Corrections and corrective action(s) shall be translated into English.

4.1.2 Validation of the action plan

The auditor or a representative of the certification body shall validate:

- the relevance of the corrections, corrective actions and of their implementation dates
- the evidence of implementation of corrections
- the corrective actions

in the allocated column of the action plan, before the issuance of the final audit report.

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

The action plan and related 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). Unclarity or doubts about the findings and the related scorings need to be clarified between the auditor and the IFS Reviewer. The technical review shall include, at a minimum, all tasks of an IFS Reviewer (Annex 12, IFS Reviewer Definition).

Based on the result of the technical review, the nominated reviewer can recommend 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 audit.

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

Chart 6: Scoring and issue of certificate

Audit 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 within four (4) weeks of receiving the action plan with the list of findings.	Report including action plan provides status	Yes, certificate at higher level, 12-month validity. The certificate shall only be issued when the corrections are implemented.
Total score is ≥ 75 % and < 95 %	Passed at IFS PACsecure foundation level after receipt of the action plan	Send completed action plan within four (4) weeks of receiving the action plan with the list of findings.	Report including action plan provides status	Yes, certificate at foundation level, 12-month validity. The certificate shall only be issued when the corrections are implemented.
Maximum one Major and total score is ≥ 75%	Not passed, unless further actions taken and validated after follow-up audit	Send completed action plan within four (4) weeks of receiving the action plan with the list of findings. Follow-up audit maximum six (6) months after the audit date.	Report including action plan provides status	Certificate at foundation level, if the Major non-conformity is effectively solved during the follow-up audit. The certificate shall only be issued when the corrections are implemented.
> one Major and/ or total score is < 75 %	Not passed	Actions and new initial audit to be agreed upon	Report including action plan provides status	No
At least one KO requirement scored with D	Not passed	Actions and new initial audit to be agreed upon	Report including action plan provides status	No

4.2.1.1 Specific management of the audit process in case of one or several non-conformity/ies and/or score < 75%

Specific rules shall apply, depending on the type and number of non-conformity(ies) issued and the total score.

- **If only one Major non-conformity is issued, with a total score ≥ 75%:**
  - a follow-up audit is possible. More information on the follow-up audit can be found in chapter 2.3.3, Part 1.
- **If more than 1 Major, or 1 or more KO with D non-conformity/ies and/or total score is <75%:**
  - the IFS PACsecure Audit is failed, the certificate will not be issued, and the following rules apply:
    - For a recertification audit: the current certificate shall be withdrawn.
    - The deadline for withdrawing the current certificate is:
      - 2 (two) working days if the audit is failed due to one or several non-conformity(ies).
      - 2 (two) working days after the certification decision if the audit is failed due to a total score < 75% with no non-conformity(ies) raised.
    - The audit shall be completed, and all requirements shall be evaluated in order to give the company a full overview of its situation.
    - The action plan is recommended to be completed for improvement purposes.
    - A full new initial audit shall be performed no earlier than six (6) weeks after the audit where the non-conformity(ies) was/were issued.

Note: any failed IFS PACsecure Audit shall not be considered as a pre-audit.

More information on failed audits and the certificate withdrawal process can be found in chapter 4.3.1, Part 1 and in Annexes 5, 6 and 8.

4.2.1.2 Deadlines for issuing the IFS Certificate.

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 audit report, the action plan and the certificate shall then be uploaded to the IFS Database between six (6) and eight (8) weeks from the last audit day, based on the following timeframe:

- Auditor sending to the company the action plan: maximum two (2) weeks from the last day of audit
- Company completing the action plan and providing evidence of corrections: maximum four (4) weeks
- Certification body performing the technical review, making the certification decision, issuing the report/certificate and to upload them to the IFS Database: maximum two (2) weeks.

More information can be found in Annex 2.

4.3 Certification cycle

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 audit date + eight (8) weeks –1 day + 1 year.

The time window to schedule the recertification audit is:

- [– eight (8) weeks; +two (2) weeks] from the last day of initial audit (audit due date) for an announced audit.
- [– 16 weeks before last day of audit due date; +two (2) weeks after last day of audit due date], for an unannounced audit.

The date of the recertification audit is calculated from the initial audit date and not from the issue date of the certificate. This allows the certificate validity to remain the same, even if the recertification audit date changes every year and does not correspond exactly to the anniversary/due date.

If the recertification audit is not scheduled in due time, or if the steps of the certification process were not completed in time, a break in certification will occur and a new initial certification cycle will be initiated.

The previous audit report and certificate remain visible in the IFS Database for a further three (3) months (after the end of certificate validity). If the recertification audit takes place later than the above-mentioned three (3) months, the certification of the company will not be visible anymore and the COID will automatically be set to an inactive status in the IFS Database.

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

An IFS Certificate shall be withdrawn by the certification body in the situations such as:

- When any information indicates that the products/processes may no longer comply with the requirements of the certification system, especially in case of non-conformity(ies) identified during the audit (main or follow-up audit) or when access is denied (apart from force majeure).
- In case the production stopped and moved to a new location.
- In case of cancellation of certification contract (between the certification body and the company).

Note: Concerning the rules described above, it is within the discretion of the certification body to withdraw certificates.

An IFS Certificate shall be suspended by the certification body in the situations such as:

- In case of pending investigations by the certification body, following a product safety incident or other event.
- For the certificates of all companies linked to a head office/central management, when a non-conformity is issued during the audit of the head office/central management.
- In case of non-payment for the current audit by the audited company.

If the suspension is lifted, the certification body shall make all necessary modifications to public information, authorisations for use of brands, etc., in order to ensure transparency 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 audit report

Audit reports shall remain the property of the company and shall not be released, in whole or part, to a third-party without the company's prior consent (except where required by law, accreditation bodies and/or GFSI monitoring activities). The consent for the distribution of the IFS PACsecure Audit 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 safely and securely store a copy of the IFS PACsecure Audit Report and associated documentation including the auditor's notes for a period of five (5) years. More information on the access conditions to information about the audit reports in the IFS Database can be found 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 ensure the quality of the IFS Standards by reviewing IFS Audit Reports of certified companies and also by using several measures to analyse the performance of certification bodies and auditors. Furthermore, the IFS Integrity Program aims to ensure that market participants do not gain a competitive advantage by not complying with IFS rules. The majority of the IFS Integrity Program activities follow a risk-based approach (risk-based monitoring), with a smaller portion based on complaints and/or whistle-blowers (complaint management). The IFS Integrity Program strengthens the reliability and confidence of the IFS Standards by monitoring their implementation in practice.

The main procedures of the IFS Integrity Program are described in Annex 4 of the "IFS Framework Agreement on the auditing and certification of the International Featured Standards (IFS)" between IFS Management GmbH and the certification body. These procedures have been developed by 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 Audits shall accept the IFS Integrity Program procedures before proceeding to conduct any IFS Audits.
Certification bodies are obliged to inform their customers applying for an IFS Audit about the content of the current version of Annex 4 of the IFS Framework Agreement and to include enforceability in their contracts.

5.1 IFS Integrity Program activities

The IFS Integrity Program is mainly involved in the following activities:

5.1.1 IFS Database Analysis

Each report uploaded in the IFS Database is automatically checked against defined parameters, such as qualification of auditor(s) and audit duration.

Noticeable discrepancies are clarified with the certification bodies. For this purpose, the IFS Integrity Program might request comprehensive and detailed statements.

Furthermore, a risk-based evaluation of the uploaded data is carried out for preparation of IFS Integrity Certification Body Office Audits.

5.1.2 IFS Integrity On-site Checks

IFS Integrity On-site Checks are carried out to evaluate IFS certified sites and can be organised risk-based or following complaints. In general, the Integrity On-site Checks are carried out unannounced (announcement 30 minutes before the start). In some special cases, they might also be performed on an announced basis (generally announced up to 48 hours before). In case of announced Integrity On-site Checks, certification bodies can accompany the checks. However, prior contact with the selected sites is prohibited.

Production sites with a valid IFS Certificate shall accept an unannounced/announced Integrity On-site Check and shall give access and support to the commissioned integrity auditor. The acceptance of the IFS Integrity Program is part of the requirements of all IFS Standards.

If, during an IFS Integrity On-site Check, a Major or KO non-conformity is identified based on objective evidence, this has the same impact on the current IFS Certificate as during a regular IFS Audit.

If the production site denies the IFS Integrity Auditor access to the production site, this needs to be considered as a breach of the contract, which typically leads to the withdrawal of the current IFS Certificate.

For each Integrity On-site Check, a report is prepared and is only made available to the company, the responsible certification body and upon request to authorities, accreditation bodies and GFSI. In case of complaint-based Integrity On-site Checks, the report may also be shared with the complainant.

5.1.3 IFS Integrity Certification Body Office Audits

In order to ensure the correct implementation of all procedures described in the IFS Standards and respective normative documents, the IFS Integrity Program carries out regular office audits at certification bodies (Integrity Certification Body Office Audits). During these office audits, performance of certification bodies and their personnel are checked by reviewing report samples and information from the database. During these Integrity Certification Body Office Audits, certain

detected issues could also lead to integrity witness audits of IFS Auditors or to Integrity On-site Checks at companies certified by the respective certification body.

5.1.4 IFS Integrity Witness Audits

IFS Integrity Witness Audits are a routine part of the IFS Integrity Program Activities; they can be initiated by the risk-based approach or complaint-based. At least one Integrity Witness Audit is done after every certification body office audit. Companies shall enable witness audits as part of regular IFS Audits. For organisational reasons, Integrity Witness Audits can be announced on very short notice.

Note: IFS Integrity On-site Checks, Integrity Witness Audits and Integrity Certification Body Office Audits carried out as part of the Integrity Program are conducted by IFS Integrity Auditors employed or commissioned by the IFS Management GmbH. Integrity Auditors are completely independent from the audited companies and the certification bodies.

5.2 IFS Complaint Management

Retailers or any other interested parties (including whistle-blowers) 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.

All complaints are treated confidentially. The IFS Integrity Program staff will neutrally evaluate all complaints. 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. To clarify whether a complaint is justified, one or several of the above-mentioned IFS Integrity Program activities may be used.

If relevant, the complainant will be informed about the result of the analysis.

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.

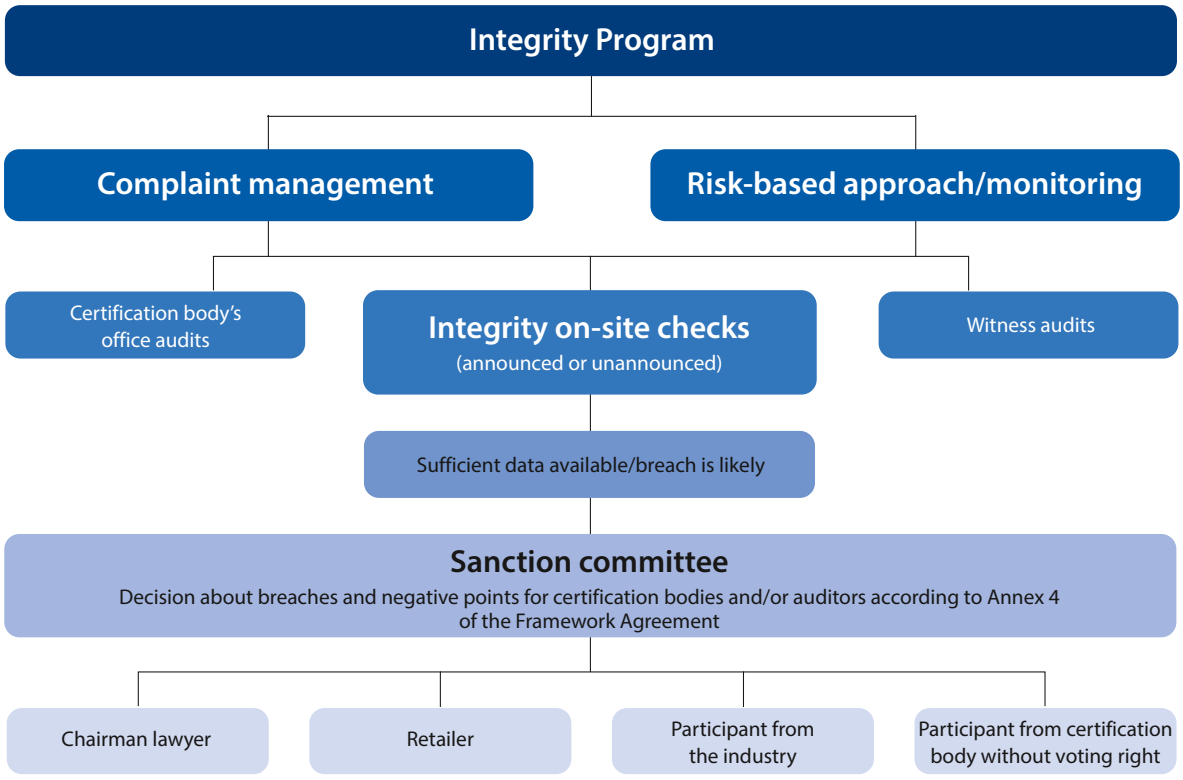
Sanctions and/or penalties will be issued to the certification body and/or its auditors if the sanction committee concludes that a breach has been committed. The type of sanction and/or penalty depends on the severity of the breach.
For each final breach ruling, a certification body and/or an auditor 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 (more information can be found in Annex 4 of the IFS Framework Agreement).

IFS Management GmbH will inform the responsible 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 7).

Chart 7: Summary of IFS Integrity Program activities



6 IFS Logos

The copyright of IFS PACsecure and the registered trademark are 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 audited company by the certification body and checked by the auditor during the audit. The results of this check shall be described in the company profile of the audit 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 respective logo can be used from the announcement of the achieved IFS Certification until the end of the certification validity.
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 audited production site and company have to immediately stop including the IFS

Logos on their documents and/or website. In case of exclusion regarding the audit scope, 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 Audit. Exclusion details can be provided upon request." It is also possible to list only those products that fall under the respective IFS Certification.

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

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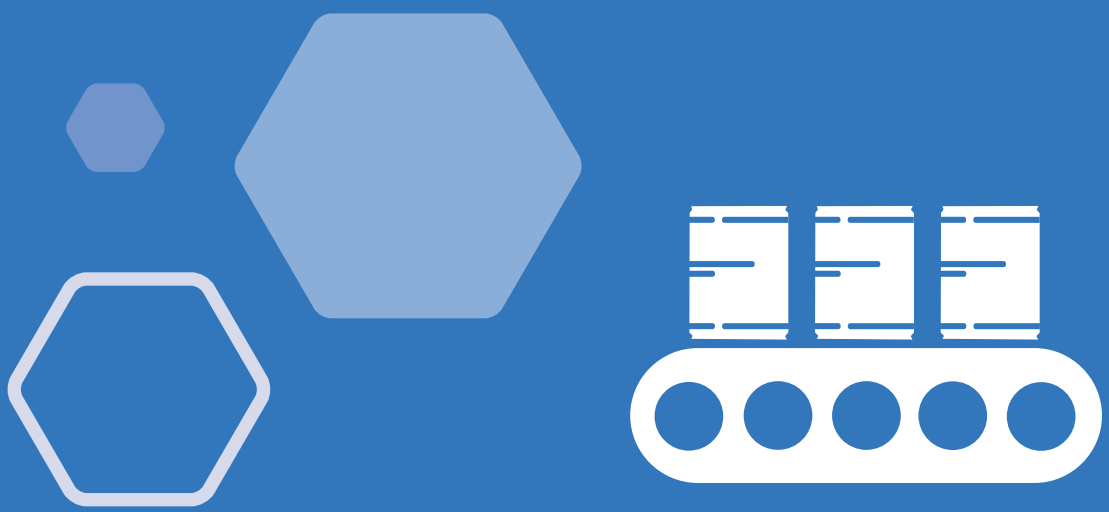

PART 2
IFS PACsecure Audit Checklist – List of IFS PACsecure Audit Requirements

0 General clarifications

0.1 About the guidance for industry and auditors

- The purpose of the guidance is to help companies implementing the requirements and auditors auditing those, alike. However, the implementation of IFS Requirements depends on the companies' specifics and risk assessment, and therefore the guidance can only have explanatory character. The content of the guidance is not normative nor legally binding.
- 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 audit to the situation of each site.

0.2 About the requirements

- Requirements with a "*" require compulsory information for the IFS PACsecure Audit Report (see "Overall summary" in Annex 10).

Req. No.	IFS PACsecure version 3 requirement	Guidance
1	**Governance and commitment**	
1.1	**Policy**	
1.1.1*	The senior management shall develop, implement and maintain a corporate policy, which shall include, at a minimum: • product requirements • customer focus • product safety culture • sustainability. The corporate policy shall be communicated to all employees.	• 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 to 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 to relevant interested parties as appropriate? ***Additional explanation/information*** • *The term "product requirement" comprises product safety, product quality, legality and authenticity (see also glossary for product requirement definition).* • *Sustainability is included in IFS PACsecure even if it´s a product safety and quality standard, in order to initiate/develop awareness of this topic in companies.*
1.1.2	The corporate policy shall be broken down into specific objectives for the relevant departments with defined responsibilities and timelines. These shall be known and shall be effectively implemented. Objectives about product safety culture shall include, at a minimum, communication about product safety policies and responsibilities, training, employee feedback on product safety related issues and performance measurement.	• Is the content of corporate policy adapted to specific and measurable objectives? • What objectives are addressed for product requirements, customer focus, product safety culture, and sustainability? • Are the objectives clearly formulated and measurable? • How are the objectives attained? • What is the timeframe for attaining the objectives? • Who is responsible for the attainment of objectives? • What kind of mechanisms are implemented to measure whether the objectives have been attained?
1.1.3	All relevant information related to product requirements shall be communicated effectively and in a timely manner to the relevant personnel.	• How is relevant information related to product requirements communicated to concerned personnel?

Req. No.	IFS PACsecure version 3 requirement	Guidance
1.2	Corporate structure	
1.2.1*	**KO No. 1: The senior management shall ensure that employees are aware of their responsibilities related to product requirements, the product safety and quality management system and that mechanisms are implemented and maintained to monitor the effectiveness of their operation. Such mechanisms shall be identified and documented.**	• How does senior management ensure that employees know their responsibilities related to product requirements? • Are employees aware of how they contribute to the effectiveness of the product safety and quality management system? • Are employees aware of the implications of not conforming with product requirements or with the product safety and quality management system requirements? • How does senior management take accountability for the effectiveness of the product safety and quality management system? • Which mechanisms are implemented by senior management to monitor how effectively these operations are carried out by employees?
1.2.2	The senior management shall provide sufficient and appropriate resources to meet the product and process requirements, including those related to the product safety and quality management system.	• How were the necessary resources defined? • How does the company ensure that 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. with senior management in a crisis situation)? • In what manner (coordination/communication) and in what form (resources) is the hazard and risk management team supported by senior management? • Is the hazard and risk management team known throughout the company? How has this been communicated?
1.2.3*	The personnel responsible for product safety and quality management shall have a direct reporting relationship to the senior management. An up-to-date organisational chart showing the company structure shall be documented, maintained, and known by the relevant personnel.	• How is the organisation structured? • Is an organisational chart available? • What version is the current organisational chart and when was it issued? • Who is(are) the person(s) responsible for the product safety and quality management report? • To whom does the personnel responsible for the product safety and quality management report?

Req. No.	IFS PACsecure version 3 requirement	Guidance
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 and/or changes to existing procedures, what actions are taken to ensure that processes are known by the relevant personnel?
1.2.5*	The senior management shall implement and maintain a system to ensure that the company is kept informed of all relevant legal and regulatory requirements, scientific and technical developments, industry codes of practice, product safety and product quality issues, and that they are aware of factors that can influence product defence and product fraud risks.	• 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 keep informed and updated on relevant information? • If changes occur, who checks the implementation of these changes? • How does the company's management ensure that all relevant legal and regulatory product requirements are implemented and known by the relevant persons? • How does the company's management ensure that purchased products, services and manufactured products comply with all relevant legal and regulatory requirements?

Req. No.	IFS PACsecure version 3 requirement	Guidance
1.2.6*	The senior management shall ensure that the certification body is informed of any changes that may affect the company's ability to conform to the certification requirements. This shall include, at a minimum: • any legal entity name change • any production site location change. For the following specific situations: • any product recall • any product recall and/or withdrawals decided by authorities for product safety and/or product fraud reasons • any visit from authorities which results in mandatory action connected to product safety, and/or product fraud which is related to the IFS PACsecure Standard scope the certification body shall be informed within three (3) working days.	• Has the company made changes to 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 decided by an official order, and/or a visit from authorities which results in mandatory action connected to product safety, and/or product fraud? 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?

Req. No.	IFS PACsecure version 3 requirement	Guidance
1.3	**Management review**	
1.3.1*	The senior management shall ensure that the product safety and quality management system is reviewed. This activity shall be planned within a 12-month period and its execution shall not exceed 15 months. Such reviews shall include, at a minimum: • a review of objectives and policies, including elements of product safety culture • results of audits and site inspections • positive and negative customer feedback, including customer audit results • process compliance • product fraud assessment outcome • product defence assessment outcome • compliance issues • status of corrections and corrective actions • notifications from authorities.	• 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?
1.3.2	Actions from the management review shall be aimed at supporting improvement. The management review shall assess follow-up actions from previous management reviews and any change that could affect the product safety and quality management system. The management review shall be fully documented.	• 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? • What is the effectiveness of the measures taken in the previous year? • How was the status monitored during the year? • What improvements have been identified and what improvements have been achieved? • Is it possible to designate an aim to support improvement from the existing data?

Req. No.	IFS PACsecure version 3 requirement	Guidance
1.3.3	The senior management shall identify and review (e.g. by internal audits or on-site inspections) the infrastructure and work environment needed to ensure product requirement compliance at least once within a 12- month period, or whenever significant changes occur. This shall include, at a minimum: • buildings • supply system • machines and equipment • transport • staff facilities • environmental conditions • hygienic conditions • workplace design • external influences (e.g. noise, vibration). Based on risks, the results of the review shall be considered for investment planning.	• How often is this review performed? • When is the infrastructure and work environment evaluated? • Does the infrastructure evaluation include internal flows (work, materials, waste, personnel, water, etc.)? • Who evaluated the infrastructure and work environment? • What was the result of the evaluation? • What risks were identified according to the results of the review? • What are the related investments for the near future?
2	**Product safety and quality management system**	
2.1	**Quality management**	
2.1.1	**Document management**	
2.1.1.1	A procedure shall be documented, implemented and maintained to control documents and their amendments. All documents which are necessary for compliance with product requirements and customer requirements shall be available in their latest version. The reason for any amendments to documents, critical to those requirements, shall be approved by authorised personnel and recorded.	• 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/information*** *The control of documents comprises: the creation, review, approval, release, distribution, access, usage, storage, retrieval, security, control of changes, retention, and disposal of documents.*

Req. No.	IFS PACsecure version 3 requirement	Guidance
2.1.1.2	The product safety and quality management system shall be documented, implemented and maintained, and shall be kept in one secure location. This applies to both physical and/or digital documented systems.	• Where is documentation concerning the product safety and quality management system kept? • Are the documents related to the product safety and quality management system stored securely?
2.1.1.3*	All documents shall be 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 documents made available to the employees? • How are document changes communicated to relevant employees? • Are there any distribution lists for documents? ***Additional explanation/information*** *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).*
2.1.2	**Records and documented information**	
2.1.2.1	Records and documented information shall be legible, properly completed, genuine, and available on request. They shall be easily accessible; maintained in a way that subsequent manipulation or amendment by unauthorised persons is prohibited; securely stored and protected from loss, intentional adulteration and/or misuse.	• Are records plausible? • Are records legible? • How and where are records filed? • How is quick access to 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?

Req. No.	IFS PACsecure version 3 requirement	Guidance
2.1.2.2*	All records and documented information shall be kept in accordance with legal and customer requirements. If no such requirements are defined, records and documented information shall be kept for a minimum of one year after the converting time. For products which have no converting time, the duration of record and documented information keeping shall be justified and this justification shall be documented.	• Where are records stored? • Who is responsible for the storage of records? • How long are records kept? • Are customer requirements defined in relation to a record-keeping duration? • On what basis was the storage time for records defined? • For products with no specified converting time, is the definition for record storage time justified? • How is data-backup carried out?
2.1.2.3	A system shall be implemented and maintained to ensure that only authorised personnel have access to create or amend records and documented information (e.g. password protection for records documented electronically).	• How are amendments to records carried out? • Who is authorised to make amendments? • How are amendments authorised? ***Additional explanation/information*** *An example for controlling access to create or amend records documented electronically is by password protection.*
2.2	**Product safety and quality management**	
2.2.1	**Hazard and risk management system**	
2.2.1.1*	The basis of the company's product safety and quality management system shall be a fully implemented, systematic and comprehensive hazard and risk management system, based on the Codex Alimentarius principles or other applicable internationally-recognised industry guidelines. It shall take into account good manufacturing practices, good hygiene practices and any legal and regulatory requirements of the production and destination countries which may go beyond such principles or guidelines. The hazard and risk management system shall be specific and implemented at the production site.	• What principles are the company's hazard and risk management system based on? • Does every site/plant have a separate hazard and risk management system? • What specific legal and regulatory requirements are taken care of in the hazard and risk management system? • Are the applicable legal and regulatory requirements related to the production and destination countries included?

Req. No.	IFS PACsecure version 3 requirement	Guidance
2.2.1.2*	The hazard and risk management system shall cover all raw materials, product contact wrapping materials, products or product groups as well as every production/conversion process from incoming goods up to the dispatch of finished products, including product development.	• Does the hazard and risk management system cover raw materials, wrapping materials, products or product groups as well as every process (including outsourced processes) 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 and risk management system?
2.2.1.3	The hazard and risk management system shall be based upon scientific literature, or technical verified information related to the manufactured products and processes, or expert advice obtained from other sources, which may include: trade and industry associations, independent experts and authorities. This information shall be maintained in line with any new technical process development.	• Is the hazard and risk management 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 and risk management 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?
2.2.1.4	In the event of changes to raw materials, wrapping materials, production/conversion processes, formulas/configurations, infrastructure and/or equipment, the hazard and risk management system shall be reviewed to ensure that product requirements are complied with.	• How often is this review performed? • How are product development/product modification and the hazard and risk management system interconnected? • Have changes occurred since the last review? If so, what were the changes? Was the hazard and risk management system reviewed due to the changes?

Req. No.	IFS PACsecure version 3 requirement	Guidance
2.3	**Application of a hazard and risk management system**	
2.3.1	**Assemble a hazard and risk management team**	
2.3.1.1	The hazard and risk management team shall be multidisciplinary and include operational staff. Personnel appointed as team members shall have appropriate knowledge of hazards and risks associated to products and processes.	• Who are the 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?
2.3.1.2	Those responsible for the development and maintenance of the hazard and risk management system shall have received appropriate training in the development and application of the hazard and risk management system. An internal team leader shall be designated.	• Were those responsible trained in the application of the hazard and risk management system? • When was the last training course held? • What was the content of the training course? • How was the knowledge verified?
2.3.2	**Product description**	
2.3.2.1	A full description of the product shall be documented and maintained and shall contain all relevant information on product requirements, which includes, at a minimum: • composition (raw materials, rework, reprocessing, recycled materials, plant-based materials, functional additives, etc.) • physical, sensory, chemical, functional and microbiological characteristics • legal requirements in regard to product safety and quality • processing methods/ technologies • wrapping and labelling • durability (converting time) • conditions for storage, method of transport and distribution.	• Is there a documented and maintained complete product description 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?

Req. No.	IFS PACsecure version 3 requirement	Guidance
2.3.3	**Identify intended use and users of the product**	
2.3.3.1	The intended use of the product shall be described in relation to the expected use of the product by the customer, and also by the end consumer when: • products are intended to be sold to the end consumer • there is no subsequent transformation process that changes the characteristics and/or intended use of the product after it is sold to the customer. When the end consumer shall be considered, possible misuse and vulnerable groups shall be taken into account.	• What is the intended use of the product(s) by customers? • Where the end consumer is concerned, what is the intended use of the product(s) by the end consumer? Has misuse and vulnerable groups been taken into account? • Are there any restrictions for usage? ***Additional explanation/information*** *Examples of products with no changes after they are sold to the customers: pizza boxes, hamburger clamshell, etc.*
2.3.4	**Construct flow diagram**	
2.3.4.1	A flow diagram shall be documented and maintained for each product, or product group, and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall identify every step and each control measure defined for a CCP and other control measures. It shall be dated, and in the event of any change, shall be updated.	• Are flow diagrams available for all products? • Are the flow diagrams dated? • Are control measures defined for CCP's (if existing) and are other control measures identified in the flow diagrams? • Are flow diagrams up-to-date?
2.3.5	**On-site confirmation of the flow diagram**	
2.3.5.1	Representatives of the hazard and risk management team shall verify the flow diagram through on-site verifications, at all operation stages and shifts. Where appropriate, amendments to the diagram shall be made.	• Based on which criteria are the flow diagrams checked? • Are the flow diagrams verified on-site?

Req. No.	IFS PACsecure version 3 requirement	Guidance
2.3.6	**Conduct a hazard analysis and risk assessment for each step**	
2.3.6.1	A hazard analysis and risk assessment shall be conducted for all possible and expected physical, chemical (including radiological and allergens) and biological hazards. The hazard analysis and risk assessment shall include hazards linked to the materials in contact with the product, wrapping materials, work environment, and any other risk related to the product requirements.	• Does a hazard analysis and risk assessment exist for each step? • Are all hazards and relevant risks included? • Which biological, physical and chemical hazards (including radiological and allergens) can be expected? • How was the hazard analysis performed?
2.3.6.2	The hazard analysis and risk assessment shall consider the likelihood of the occurrence of hazards and risks and the severity of their adverse effects. Consideration shall be given to control measures designed and applied for controlling each significant hazard or risk identified.	• Does a hazard analysis exist for all product groups including harm and likelihood? • Which controls are relevant in regard to the significant hazard or risk identified?
2.3.7	**Determining critical control points (CCP) and other control measures**	
2.3.7.1	Determining whether the step at which a control measure is applied is a CCP in the hazard and risk management system shall be facilitated by using a decision tree or other tool(s) which demonstrates a logical reasoned approach. The determination of CCP's shall be justified and documented.	• How were the CCPs determined? • Which CCPs were defined? • How many CCPs exist? • Are the determination of CCP's justified and documented? ***Additional explanation/information*** *Critical Control Points shall be determined only for those steps at which a control measure is applied to prevent, eliminate, or reduce to an acceptable level those hazards identified as significant for product safety.*

Req. No.	IFS PACsecure version 3 requirement	Guidance
2.3.8	**Establish validated critical limits for each CCP**	
2.3.8.1*	For each CCP, measurable or observable critical limits shall be defined and validated to identify when a process is out of control. Validation of critical limits established for each CCP shall be documented.	• Is a critical limit defined for each CCP? • Which critical limits are defined? • How were the critical limits defined? • How were the critical limits validated? ***Additional explanation/information*** *In case no CCP has been determined, this requirement can be scored as N/A.*
2.3.8.2	For control measures, other than those defined for CCPs, appropriate limits shall be established.	• Is a clear limit defined for control measures, other than those defined for CCPs? • How were the limits determined?
2.3.9	**Establish a monitoring system for each CCP**	
2.3.9.1*	**KO No. 2: Specific monitoring procedures in terms of method, frequency of measurement or observation and recording of results, shall be documented, implemented and maintained for each CCP, to detect any loss of control at that CCP. Each defined CCP shall be under control. Monitoring and control of each CCP shall be demonstrated by records.**	• How are CCPs monitored? • How are losses of control recorded and assessed? • How is the monitoring of each CCP documented? (date, time, signature responsible person, measured value) • Who is responsible for the documentation? • How long are the records kept? • Where are the records kept? ***Additional explanation/information*** *In case no CCP has been determined, this requirement can be scored as N/A.*
2.3.9.2	Records of CCP monitoring shall be verified by a responsible person within the company and maintained.	• Who is responsible for reviewing CCP monitoring records? • When how and who checks the results of the monitoring? • How long are CCP surveillance records kept? ***Additional explanation/information*** *In case no CCP has been determined, this requirement can be scored as N/A.*
2.3.9.3	The operative personnel in charge of the monitoring of control measures defined for CCPs and other control measures shall have received specific training/ instruction.	• Which persons or functions supervise which control measures? • How are the training/instruction planned? • What training or instruction is provided to monitor the control measures? • Is the person responsible for monitoring aware of what measures need to be taken in case the limits are not under control?

Req. No.	IFS PACsecure version 3 requirement	Guidance
2.3.9.4	Control measures, other than those defined for CCPs, shall be monitored, recorded and controlled by measurable or observable criteria.	• How are control measures, other than those defined for CCPs monitored? • Are methods, frequency of measurement or observation, and results of monitoring documented? • How are losses of control recorded and assessed? • Who is responsible for the monitoring of control measures, other than those defined for CCPs? • Has the person responsible for monitoring received proper training for these activities? • Is the person responsible for monitoring aware of what measures need to be taken in case the limits are not under control? • How long are the records kept? • Where are the records kept?
2.3.10	**Establish corrective actions**	
2.3.10.1	In the event that the monitoring indicates that a particular control measure defined for a CCP or any other control measure related to product safety is not under control, corrective actions shall be documented and implemented. Such corrective actions shall also take any action relating to non-conforming products into account and identify the root cause for the loss of control of CCPs.	• What are the corrective measures for each CCP and other control measures related to product safety? • When were corrective actions taken? • Where are the corrective actions documented? • Who documents the corrective actions taken? • How is the effectiveness of corrective actions taken evaluated? • Have the causes of the corrective actions occurred repeatedly? • Is the company's management informed in case of ineffective corrective actions at the CCP?

Req. No.	IFS PACsecure version 3 requirement	Guidance
2.3.11	**Validate the hazard and risk management system and establish verification procedures**	
2.3.11.1	Procedures of validation, including revalidation after any modification that can impact product safety, shall be documented, implemented and maintained to ensure that the hazard and risk management system is suitable to effectively control the identified hazards and risks.	• Are validation procedures implemented? • How are the objectives/acceptance criteria of the validation determined? • Are CCPs and other control measures validated? When were they validated? • Are revalidation procedures undertaken after any modifications that can impact product safety?
2.3.11.2*	Procedures of verification shall be documented, implemented and maintained to confirm that the hazard and risk management system is working correctly. Verification activities of the hazard and risk management system, for example: • internal audits • testing • sampling • deviations and non-conformities • complaints shall be performed at least once within a 12-month period or whenever significant changes occur. The results of this verification shall be recorded and incorporated into the hazard and risk management system and shall be communicated to and reviewed by the senior management.	• Are verification procedures implemented to ensure that the hazard and risk management system is working correctly? • Are the verification criteria defined? • How often is the hazard and risk management system verified? • What was the date and result of the last verification? • What kind of activities were considered in the last verification? • Does the hazard and risk management system reflect the results of the verification? • Is the company's management informed of the results of the verification?

Req. No.	IFS PACsecure version 3 requirement	Guidance
2.3.12	**Establish documentation and record keeping**	
2.3.12.1	Documentation and records related to the hazard and risk management system, for example: • hazard analysis and risk assessment • determination of control measures defined for CCPs and other control measures • determination of critical limits • processes • procedures • outcome of control measures defined for CCPs and other control measure monitoring activities • training records of the operative personnel in charge of the monitoring of CCPs and other control measures • observed deviations and non-conformities and implemented corrective actions shall be available.	• Which hazard and risk management system related documents exist? • Do these documents include processes, procedures and results?
3	**Resource management**	
3.1	**Human resources**	
3.1.1	All personnel performing work that affects product requirements shall have the required competence, appropriate to their role, as a result of education, work experience and/or training.	• How are the competencies determined? • How is it ensured that new employees have the right capabilities for the job?
3.1.2	The responsibilities, competencies and job descriptions, including deputies in case of absences, for all job titles with an impact on product requirements shall be documented, implemented and maintained. Assignment of key roles shall be defined.	• Where are defined responsibilities, competencies and job descriptions, including deputies in case of absences, for each job title kept? • 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?

Req. No.	IFS PACsecure version 3 requirement	Guidance
3.2	**Personal hygiene**	

3.2.1*	Risk-based requirements relating to personal hygiene shall be documented, implemented and maintained and shall include, at a minimum, the following topics:
	• coverage of hair and beards
	• protective clothing (including their condition of use in production areas and staff facilities)
	• hand washing, disinfection and hygiene
	• eating, drinking, smoking/ vaping or other use of tobacco
	• actions to be taken in case of cuts or skin abrasions
	• fingernails, false nails/eyelashes, personal belongings (including medicines), use of scented products, and prohibited use of jewellery
	• identification and notification of infectious diseases and conditions impacting product safety via a medical screening procedure, subject to legal restrictions in the country of operation.
		• Do the rules regarding personal hygiene include all topics listed and are they risk-based?
		• 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/information
		• *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 personal hygiene rules defined based on risks are:*
		  ◦ *The use of gloves are 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).*
		  ◦ *The usage of headgear is required. 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).*
		  ◦ *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.*

Req. No.	IFS PACsecure version 3 requirement	Guidance
3.2.2*	**KO No. 3: The requirements for personal hygiene shall be understood and applied by all relevant personnel, contractors and visitors.**	• How are the hygiene requirements communicated to personnel, contractors and visitors? • How is it ensured that personnel, contractors and visitors know, understand and follow the relevant hygiene rules?
3.2.3	Compliance with personal hygiene requirements shall be monitored on a risk-based frequency.	• How are employees monitored during work? • Is the frequency of monitoring risk-based?
3.2.4	A risk-based program shall be implemented and maintained to control the effectiveness of hand hygiene.	• Does the company have a program to control the effectiveness of hand hygiene? • Is the program risk-based in relation to products and processes?
3.2.5	Cuts and skin abrasions shall be covered with a coloured plaster/ bandage that shall not pose contamination risks. Plaster/ bandage shall be waterproof and coloured differently from the product colour. Where appropriate: • plasters/bandages shall contain a metal strip • single use gloves shall be worn.	• What colour 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?
3.2.6	Adequate protective clothing shall be provided in sufficient quantity for each employee.	• Is protective clothing given to the personnel? If so, how many sets of clothing are provided? • What are the rules regarding protective clothing? • How often is an employee supposed to change their protective clothing?
3.2.7	When required, all protective clothing shall be thoroughly laundered in-house by approved contractors or by employees. This decision, including frequency of laundry, shall be documented and based on risks. Requirements related to laundry shall ensure a minimum of the following: • sufficient segregation of dirty and clean clothing at all times • avoidance of contamination until use. The effectiveness of laundering shall be monitored.	• What kind of protective clothing is provided and is it laundered? How frequently? • How is protective clothing laundered? • Is the decision on who washes the protective clothing risk-based? • 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 laundering monitored?

Req. No.	IFS PACsecure version 3 requirement	Guidance
3.2.8	In case the personnel, contractors and/or visitors have any health issues, infectious diseases or conditions that may have an impact on product safety, these shall be immediately reported, and actions shall be taken to minimise contamination risks.	• 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?
3.3	**Training and instruction**	
3.3.1*	Documented training and/or instruction programs shall be implemented and maintained with respect to the product and process requirements and the training needs of the employees, based on their job, and shall include: • training objectives • training contents • training frequency • employee tasks • languages • competent trainer/tutor A procedure or program shall be documented, implemented and maintained to prove the effectiveness of the training and/or instruction programs.	• Who is responsible for training? • Which trainings were conducted last year? • Is there any evidence for trainings carried out in-house and externally? • Is evidence of trainer competencies kept? • How are foreign/temporary employees trained/instructed? • Who participates in the training sessions? • How does are training needs identified? • 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 programs shall apply to all personnel, including seasonal and temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained/instructed in accordance with the documented training/instruction programs.	• 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 introductory training plan implemented for all relevant employees?

Req. No.	IFS PACsecure version 3 requirement	Guidance
3.3.3	Records of all training/instruction events shall be available, stating: • list of participants (including their signature) • date • duration • contents of training • name of trainer/tutor.	• When did the last training take place? • Is all training evidence comprehensive? • Do all records contain all necessary information?
3.3.4	The contents of training and/or instruction shall be reviewed and updated when necessary. Special consideration shall be given to these specific topics, at minimum: • product safety culture • product requirements • product fraud • product defence • product/process modifications • complaints and non-conformities related to product compliance and its impact on customers (and consumers, if applicable) • feedback from the previous documented training/instruction program.	• 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? • Are the listed topics included in the contents of training and/or instruction?
3.4	**Staff facilities**	
3.4.1*	Adequate staff facilities shall be provided and shall be proportional in size, equipped for the number of personnel, and designed and controlled to minimise product safety risks. Such facilities shall be maintained in a way to prevent contamination.	• 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? ***Additional explanation/information*** *Examples of staff facilities are: changing room, smoking area, dining room, etc.*
3.4.2	Product contamination risks by food and drink and/or foreign materials shall be minimised. Consideration shall be given to food and drink from vending machines, canteen and/or brought to work by personnel.	• May employees bring food and other materials from home? • May employees take medicine to their workplace? • Does a hazard analysis exist regarding foreign material from staff facilities?

Req. No.	IFS PACsecure version 3 requirement	Guidance
3.4.3	Changing rooms shall be located to allow direct access to the areas where exposed products (e.g. not covered or protected by wrapping) are handled. When infrastructure does not allow it, alternative measures shall be implemented and maintained to minimise product contamination risks. Outdoor clothing and protective clothing shall be stored separately unless alternative measures are implemented and maintained to prevent contamination risks.	• Do locker rooms have direct access to areas where processing activities are carried out? • If changing rooms have no direct access to processing areas, what kind of measures have been implemented? • 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 contamination risk to areas where products are handled. The toilets shall be equipped with hand washing facilities. The facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.	• Is direct access from the toilets to an area where products are handled restricted and the possibility of contamination risk avoided?
3.4.5*	Hand hygiene facilities shall be provided and shall address, at a minimum: • adequate number of wash basins • suitably located at access points to and/or within production areas • designated for cleaning hands only. The necessity of similar equipment in further areas (e.g. storage area), shall be based on risks.	• Are there enough hand hygiene facilities available at access points to and/or within production areas? • Is there a necessity for similar equipment in further areas (e.g. storage areas)? If so, how is it defined? • Are there signs/pictograms advising personnel to wash hands in each relevant area?
3.4.6	Hand hygiene facilities shall provide: • running potable water at an adequate temperature • adequate cleaning and disinfection equipment • adequate means for hand drying.	• Are all hand hygiene facilities provided with adequate cleaning and disinfection equipment and adequate means for hand drying? • Are all hand washing facilities provided with running potable water at an adequate temperature?

Req. No.	IFS PACsecure version 3 requirement	Guidance
3.4.7	Where the processes require a higher hygiene control, the hand washing equipment shall provide in addition: • hand contact-free fittings • hand disinfection • waste container with hand contact-free opening.	• Are there processes where a higher hygiene control is required? If so, which controls? Are they risk-based defined? How frequently are they carried out?
3.4.8	The necessity of cleaning and disinfection facilities for boots, shoes and further protective clothing shall be based on risks.	
4	**Operational processes**	
4.1	**Customer focus and contract agreement**	
4.1.1	A procedure shall be implemented and maintained to identify the fundamental needs and expectations of customers. The feedback from this process shall be used as input for the company's continuous improvement.	• 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 used towards continuous improvement? • Do the identified needs have an influence on the production process?

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4.1.2	The requirements between the company and its customers shall be defined, agreed upon and reviewed concerning their acceptability before the supply agreement is concluded. All requirements related to product safety and quality within the customer agreement, and any revision of these clauses, shall be communicated to, and implemented by each relevant department.	• Does the company have defined written supply agreements with customers?
		• Has the customer defined specific requirements for purchased products?
		• Who conducts the review of requirements?
		• 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/information
		• *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*
		  ◦ *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).*
		• *Regarding customer property, the controls should comprise, at minimum, its identification, verification and protection. Also, in the case of loss, damage, or any issue with this property, the company shall inform the customer and take corrective actions.*

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.1.3*	**KO No. 4: Where there are customer agreements related to:** • **product formula/configuration (including raw material characteristics)** • **process** • **technological requirements** • **testing and monitoring plan** • **wrapping** • **labelling** **these shall be complied with.**	• How does the company verify and ensure these customer agreements are fulfilled? ***Additional explanation/information*** • *In case there are no customer agreements, the requirement can be scored as N/A.* • *"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 the printing process).* • *Examples of customer agreements 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.*
4.1.4	In accordance with customer requirements, the senior management shall inform their affected customers, as soon as possible, of any issue related to product safety or legality, including deviations and non-conformities identified by competent authorities.	• How is it ensured that customers are informed about any issue related to product safety or legality?

Req. No.	IFS PACsecure version 3 requirement	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 documented, implemented and maintained and shall include, where required, the acceptance of the customer(s). The procedure shall include: • the management of customers' specifications and the protection of its information, if existing • the formal agreement of specifications, formulas/configurations, where required by customers • the update of finished product specifications in case of any modification related to: ◦ raw materials ◦ formula/configuration ◦ processes which impact the finished products ◦ wrapping materials which impact the finished products • how to communicate the information and its changes inside the company and, when applicable, to the customer.	• 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 defined, how are customer specifications and the protection of this information managed?
4.2.1.2*	Specifications shall be documented, implemented and maintained for all finished products. They shall be up to date, unambiguous and in compliance with legal and customer requirements.	• Are specifications available for all finished products? • How does the company ensure that specifications comply with legal and customer requirements? • How is it identifiable that specifications are up to date?
4.2.1.3*	**KO No. 5: Specifications shall be documented, implemented and maintained for all raw materials. Specifications shall be up to date, unambiguous and in compliance with legal requirements and, if defined, with customer requirements.**	• Are specifications available for all raw materials? • How does the company ensure that specifications comply with legal requirements and, if defined, with customer requirements? • How is it identifiable that specifications are up to date?

Req. No.	IFS PACsecure version 3 requirement	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*	Where products are requested to be labelled and/or promoted with a claim or where certain methods of treatment or production are excluded, control measures shall be implemented and maintained to verify and ensure compliance with such a statement.	• Does the customer have specific requirements related to the exclusion of certain methods of treatment or production, or the absence of specific components or raw materials? • Have these specific requirements been included in specifications? • Has the company implemented procedures to verify and ensure these specific customer requirements? • How are these specific customer requirements verified and ensured by the company? • What kind of tests/analysis and scientific evidence are available to support claims? ***Additional explanation/information*** • *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.* • *The veracity and accuracy of claims shall be validated through studies and/or tests/analysis, throughout the converting time of the products (see also glossary for claim definition).* • *In case there are no specific customer requirements, nor claims, the requirement can be scored as N/A.*

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.3	**Product development, product modification, and/or modification of production/conversion processes**	
4.3.1	For the development of products and/or processes, a hazard analysis and risk assessment shall be conducted. In the case of modification of products and/or processes, the hazard analysis and risk assessment shall be reviewed and, when applicable, necessary changes shall be made.	• Is a hazard analysis and risk assessment available for new developments? • Is the hazard analysis and risk assessment (related to chapter 2) reviewed in case of modifications? ***Additional explanation/information*** *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 to enhance 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*	A procedure shall be documented, implemented and maintained to ensure that the finished product complies with current legislation of the destination country/ies, and customer requirements.	• What kind of procedure has been implemented to ensure product legislation compliance? • Export goes to which countries? • Which countries have special requirements?
4.3.3*	The development or modification of products and/or processes shall result in specifications about formula/configuration, rework, wrapping materials, manufacturing processes (including printing) and process parameters which comply with product and customer requirements. This includes factory trials, product testing/analysis and process monitoring. The progress and results of the development/modification of products and/or processes shall be recorded.	• Are specifications developed about formula/configuration, rework, wrapping materials, manufacturing processes (including printing) and process parameters which comply with product and customer requirements? • What product testing/analysis and process monitoring are made while a product is developed and/or a process is modified? • Is the developed product submitted to a trial run and product testing? • Are records of progress and results of the product development/modification and modification of production/conversion process available?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.3.4	When the company has printing processes, a system to manage the development, modification and usage of artwork shall be implemented and maintained. This system shall comprise the following elements, at a minimum: • responsibilities and activities related to the management of artwork and customer-approved reference material between the company and customer • approval of final artwork, product concepts, printing specifications and the identification of critical information, by the customer, when applicable • usage and storage conditions of approved artwork master, customer-approved reference material and printing materials, in order to avoid degradation, misuse and loss • management of renewal, changes and obsolescence of artwork masters, customer-approved reference material and printing materials, including their disposal.	• 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 for the customer identified? • What kind of control activities are in place to ensure the approved artwork, printing equipment, and printing specifications correspond to the product to be printed? • How are the renewal, changes and obsolescence of artwork masters, customer-approved reference material and printing materials managed? • If the company has no printing processes, this requirement can be scored as N/A. ***Additional explanation/information*** • *If the company has no printing processes, this requirement can be scored as N/A.* • *Some examples of critical information are: food ingredient list(s), allergens, claims, identification code, among others.*
4.3.5	Converting time tests or appropriate validation through physical, sensory, chemical, functional and microbiological evaluation shall be carried out and consideration shall be given to product formula/ configuration, wrapping material, manufacturing, declared conditions and intended use. The converting time shall be defined in accordance with this evaluation.	• Are converting time tests executed? • What kind of evaluations and validations are carried out? • How is the converting time determined? • How are converting time recommendations and/or product use information established? • How are converting time requirements taken into consideration during product development?
4.3.6	Recommendations for handling and/or use of products related to product safety and/or quality shall be validated and documented where appropriate.	• 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?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.4	**Purchasing**	
4.4.1*	A procedure for the sourcing of raw materials, semi-finished products and wrapping materials and the approval and monitoring of suppliers shall be documented, implemented and maintained. This procedure shall include, at a minimum: • raw materials and/or suppliers' risks • required performance standards (e.g. certification, origin, etc.) • exceptional situations (e.g. emergency purchase) and, based on risks, additional criteria shall be included, for example: • audits performed by an experienced and competent person • analyses/testing results • supplier reliability • complaints • supplier questionnaire.	• Has the company implemented the required procedure? • 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 suppliers monitored? • Are suppliers graded? • How is the qualification of suppliers ensured? • Which criteria are included in the suppliers' risks? • Which supplier has analysis certificates? • How is supplier reliability assessed and measured? • Does the supplier reliability system include complaints and non-conformities? • What kind of performance standards are requested?
4.4.2	The purchased materials shall be assessed, based on risks and suppliers' status, for product safety, product quality, legality, and authenticity. The results shall be the basis for the testing and monitoring plans.	• Which risks are identified? • How often are assessments made? • Which criteria are defined to determine the suppliers' status? • How does the company assess the conformity of the products purchased? • How is the authenticity of products checked? • How is the supplier status identified? • What kind of testing and monitoring plans have been defined? • What kind of impact does the supplier status have on the determination of frequency and the scope of testing and monitoring plans?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.4.3*	The purchasing services which, based on risks, have an impact on product requirements, shall be evaluated to ensure they comply with defined requirements. This shall consider, at a minimum: • the service requirements • the supplier's status (according to its assessment) • the impact of the service on the finished products.	• Which risks are identified? • How often are assessments made? • How is the impact of the service on the finished product determined? • How does the company assess the conformity of the services purchased? • At what frequency are the purchased services assessed? • How is the supplier status identified? • What kind of impact does the supplier status have on the schedule of assessments?
4.4.4*	Where a part of production/ conversion process (including wrapping and labelling) is outsourced, this shall be documented in the product safety and quality management system and such processes shall be controlled to guarantee that product requirements are not compromised. Control of such outsourced processes shall be identified and documented. When required by the customer, there shall be evidence that they have been informed and have agreed to such outsourced process.	• Does the company have (an) outsourced process(es)? • Is/are the outsourced process(es) included in the product safety and quality management system? • What are the hazards/risks 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)?

4.4.5	An agreement shall be documented and implemented, covering the outsourced processes and describing any arrangements made in connection with it, including in-process controls, testing and monitoring plans.	• Is there a documented and implemented agreement 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 there defined mechanisms implemented and a time frame for informing of any issue related to product compliance?
		  ◦ Are in-process controls, testing and monitoring plan, traceability and documents for the delivery included?

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4.4.6	Suppliers of the outsourced processes shall be approved through: • certification to IFS PACsecure or other GFSI recognised production of food packaging certification standard, or • documented supplier audit, performed by an experienced and competent person, which shall include, at a minimum, requirements for product safety, product quality, legality and authenticity.	• Is the supplier of outsourced processes certified to IFS PACsecure or another equivalent GFSI standard certification? If so: ◦ Does the company request the renewal of the supplier certificate on a regular basis? ◦ How does the company verify 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 any other equivalent GFSI standard certification: ◦ Has the company conducted audits to the supplier? ◦ Does the audit include, at a minimum, requirements for product safety, product 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 experience and competencies defined for the person who perform supplier audits? Is there evidence that defined requirements are fulfilled? ***Additional explanation/information*** *IFS Food Progress assessments at intermediate level are accepted as documented supplier audits. The frequency of the documented supplier audit shall be justified by risk assessment,* *if not performed within 12 month.*
4.4.7	The sourcing of materials and supplier assessments shall be reviewed at least once within a 12- month period or whenever significant changes occur. Records of the reviews and the consequential actions of the assessment shall be documented.	• 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?

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4.5	**Product wrapping**	
4.5.1*	Based on risks and intended use, key parameters for the wrapping materials shall be defined in detailed specifications complying with the current relevant legislation and other relevant hazards or risks. The suitability of the wrapping materials in contact with products shall be validated and monitored by means of the relevant test/ analysis, for example: • sensory tests • functional test • storage and distribution tests • chemical analysis • migration test results.	• What materials are used for product wrapping? • Which are the key parameters identified? • Are key parameters for the wrapping materials risk-based determined? • 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 in contact with products checked and verified?
4.5.2	For all wrapping material which could have an impact on products, declarations of compliance, which attest conformance with legal requirements shall be documented and maintained. In the event that no specific legal requirements are applicable, evidence shall be documented and maintained to ensure that wrapping materials are suitable for the intended use. This applies for wrapping material which could have an influence on raw materials, semi-finished and finished products.	• When required by legislation, are declarations of compliance in place? • Does the company have evidence available to demonstrate the suitability of wrapping materials?

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4.5.3	Used wrapping material and labelling shall correspond to the product being wrapped and shall comply with agreed customer product specifications. Labelling information shall be legible and indelible. When applicable, special consideration shall be given to these specific issues: • label reprints • label and/or wrapping rework activities • suitability of reused containers or wrapping materials • information to be added on labels when special transport or storage conditions for products are used. This shall be monitored and documented at least at the start and end of a production run as well as at every product changeover.	• What kind of control activities are taken to avoid mistakes and wrong information in label reprints and rework activities? • How is container reuse 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*	Potential adverse impact on product safety and/or product quality from the factory environment (e.g. ground, air) shall be investigated. Where risks have been identified (e.g. extremely dusty air, strong smells), control measures shall be implemented, maintained and reviewed for effectiveness at least once within a 12-month period or whenever significant changes occur.	• Does a location investigation exist? • Can a location have a negative influence on product safety and product quality? • What kind of control measures have been established if potentially damaging materials/ substances are nearby? • Is efficiency of control measures regularly reviewed? • Who reviews the efficiency of the established control measures? • How is efficiency of established control measures reviewed?
4.7	**Factory exterior**	
4.7.1	All external areas of the factory shall be clean, tidy, designed and maintained in a way to prevent contamination. Where natural drainage is not effective, an adequate drainage system shall be installed.	• Are factory exteriors tidy? • Are factory exteriors designed and maintained in a way to prevent contamination? • 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?

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4.7.2	Outdoor storage shall be kept to a minimum. Where goods are stored outside, it shall be ensured that there are no contamination risks or adverse effects on product safety and quality.	• 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 flow**	
4.8.1	A site plan covering all buildings of the production site shall be documented, implemented and maintained, and shall describe, at a minimum, the process flow of: • finished products • semi-finished products, including rework • wrapping materials • raw materials • personnel • waste • water.	• Is the site plan available? • Does the site plan 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 defined, implemented, maintained, reviewed and where necessary, modified to ensure that microbiological, chemical and physical contamination risks of raw materials, wrapping materials, semi-finished and finished products are avoided. The risk of cross-contamination, mix-ups and mixing, shall be minimised through effective control measures.	• 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 control measures has the company implemented to minimise the identified risks? • How is the effectiveness of control measures checked?
4.8.3	In the case where areas sensitive to microbiological, chemical and physical risk(s) have been identified, they shall be designed, operated and monitored to ensure product safety is not compromised.	• Are there sensitive areas? • What sensitive areas were defined? Which risks were identified? • What kind of controls are implemented? ***Additional explanation/information*** *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?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.9	**Production and storage premises**	
4.9.1	**Constructional requirements**	
4.9.1.1*	Premises where products are prepared, treated, processed and stored, shall be designed, constructed and maintained to ensure product safety.	• Are the premises designed, constructed and maintained 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 meet production requirements in a way to prevent contamination, reduce condensation and mould growth, facilitate cleaning and if necessary, disinfection.	• Are walls clean? • How often are walls maintained and cleaned?
4.9.2.2	The surfaces of walls shall be maintained in a way to prevent contamination and be easy to clean; they shall be impervious and wear-resistant to minimise product contamination risks.	• Are wall surfaces impervious and wear-resistant?
4.9.2.3	The junctions between walls, floors, and ceilings shall be designed to facilitate cleaning and if necessary, disinfection.	• Are junctions and corners clean?
4.9.3	**Floors**	
4.9.3.1	Floor coverings shall be designed and constructed to meet production requirements and be maintained in a way to prevent contamination and facilitate cleaning and if necessary, disinfection. Surfaces shall be impervious and wear-resistant to minimise product contamination risks.	• Are floors clean? • Are floor coverings impervious and wear-resistant? • How often are floors maintained and cleaned?
4.9.3.2	The hygienic disposal of water and other liquids shall be ensured. Drainage systems shall be designed, constructed and maintained in a way to minimise product contamination risks (e.g. entry of pests, transmission of odours, among others) and shall be easy to clean.	• How is water and other liquids disposal ensured? • How often are gullies maintained and cleaned?

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4.9.3.3	In product handling areas, machinery and piping shall be arranged to allow waste water, if possible, to flow directly into a drain. Water or other liquids shall reach drainage without difficulty to minimise product contamination risks. Stagnation of puddles shall be avoided.	• Are there water or other liquid puddles on the floors of production areas? • 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 designed, constructed and maintained to minimise the accumulation of dirt and condensation, and shall not pose any physical and/or microbiological contamination risks.	• How often are ceilings and overhead fixtures maintained and 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.	• Are false ceilings accessible? • How often are false ceilings maintained and 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 way to prevent contamination and shall be easy to clean.	• Can dirt accumulate on windowsills? • How often are windows and other openings maintained and cleaned?
4.9.5.2	Where there are contamination risks, windows and roof glazing shall remain closed and fixed during production.	• Are windows kept open?
4.9.5.3	Where windows and roof glazing are designed to be opened for ventilation purposes, they shall be fitted with easy to clean protective barriers to prevent any contamination.	• Are windows sealed with insect gratings? • Is the integrity of gratings regularly reviewed?

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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 way to prevent contamination and be easy to clean. They shall be designed and constructed with materials which avoid: • splintering parts • flaking paint • corrosion.	• Are doors damaged? • How often are doors maintained and cleaned?
4.9.6.2	External doors and gates shall be constructed to prevent the access of pests.	• Do external doors prevent pests entering the production areas? Do they remain closed?
4.9.6.3	Plastic strip curtains separating areas shall be maintained in a way to prevent contamination and be easy to clean.	• Are plastic strip curtains damaged? • How often are plastic strip curtains maintained and cleaned?
4.9.7	**Lighting**	
4.9.7.1	All production/conversion, storage, receipt and dispatch areas shall have adequate levels of light according to the activities carried out.	• Is there a legal requirement applicable regarding lighting? • Which criteria are 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	Adequate natural and/or artificial ventilation shall be designed, constructed and maintained 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?
4.9.8.2	If ventilation equipment is installed, filters and other components shall be easily accessible and monitored, cleaned or replaced as necessary.	• How is ventilation equipment maintained and cleaned? • How are air filters monitored and cleaned?

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4.9.8.3	Air conditioning equipment and artificially generated airflow shall not compromise product safety and quality.	• What kind of hazards/risks has the company identified and assessed? If hazards/risks has been identified, what kind of controls has been implemented? • Are there production areas with under-/over-pressurization?
4.9.8.4	Dust extraction equipment shall be designed, constructed and maintained 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 for hand washing, cleaning and disinfection, or as material in the process shall be of potable quality at the point of use and supplied in sufficient quantity.	• Where does the water supply come from? (city supply, well water, tanker)? • Is water demand always covered? • For what purpose is water used in the company (staff facilities, cleaning procedures, raw material)? • Is water treated on-site (water hardness correction, chlorination, sterilization, filtration …)? • Are local legal requirements available?
4.9.9.2	The quality of water (including recycled water), steam or ice shall be monitored following a risk-based sampling plan.	• 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 monitoring and sampling plan for water risk-based determined? • Is water analysed according to legal requirements (own water supply, outside supply)? Do results comply with standards?
4.9.9.3	Recycled water, which is used in the process, shall not pose contamination risk.	• In which processes is recycled water used? • How is recycled water quality controlled? • Are local legal requirements on hand? • Is water analysed according to legal requirements? • Do results comply with standards?
4.9.9.4	Non-potable water shall be transported in separate, properly marked piping. Such piping shall neither be connected to the potable water system nor allow the possibility of reflux to prevent contamination of potable water sources or the factory environment.	• Is the drinking water system completely separated from the 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?

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4.9.10	**Compressed air and gases**	

4.9.10.1*	The quality of compressed air that comes in direct contact with products, or wrapping materials in contact with products, shall be monitored based on risks. Compressed air shall not pose contamination risks.	• Is compressed air used in direct contact with products or on 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 hazards/risks has the company identified and assessed?
		  ◦ In regard to the identified and assessed hazards/risks, what kind of controls has the company implemented?

4.9.10.2	If gases are used in direct contact with products, or with wrapping materials in contact with products, evidence shall be documented and maintained to ensure their safety and quality for the intended use.	• For which products/processes is gas used and what for? • What are the characteristics relevant for product safety and quality? How is this monitored? • Is there a declaration of compliance for gases?
4.10	**Cleaning and disinfection**	
4.10.1*	Risk-based cleaning and disinfection schedules shall be validated, documented, implemented and maintained. These shall include: • objectives • responsibilities • the products used and their instructions for use • dosage of cleaning and disinfection chemicals • the areas and timeslots for cleaning and disinfection activities • cleaning and disinfection frequency • Cleaning In Place (CIP) criteria, if applicable • documentation requirements • hazard symbols (if necessary).	• 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/information*** *Cleaning schedules can include SSOP's.*
4.10.2	Cleaning and disinfection activities shall be implemented and shall result in effectively cleaned premises, facilities and equipment.	• How are the cleaning and disinfection activities validated? • How is their adequate implementation monitored?

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4.10.3	Cleaning and disinfection activities shall be documented and such records shall be verified by a responsible designated person in the company.	• Where are the cleaning and disinfection activities documented? • 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 competent personnel shall perform cleaning and disinfection activities. The personnel shall be trained and retrained to carry out the cleaning and disinfection schedules.	• Which are the competencies defined for personnel in charge of performing cleaning and disinfection activities? • How often are they trained? • Who trains them? • Are these trainings documented?
4.10.5*	Cleaning and disinfection equipment shall be suitably designed and defined for the intended use, identified, used and stored in a way that avoids contamination.	• How can the intended use of cleaning and disinfection equipment be identified? • What kinds of control activities are in place to avoid the contamination of cleaning and disinfection equipment? • Where is cleaning and disinfection equipment stored?
4.10.6	Safety Data Sheets and instructions for use shall be available on-site for cleaning and disinfection chemicals. Personnel responsible for cleaning and disinfection activities shall be able to demonstrate their knowledge of such instructions.	• 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?
4.10.7	The effectiveness of the cleaning and disinfection activities shall be verified. The verification shall rely on a risk-based sampling schedule and shall consider one or several actions, for example: • visual inspection • rapid testing • analytical testing methods. Resultant actions shall be documented.	• 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?

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4.10.8	Cleaning and disinfection schedules shall be reviewed and modified in the event that changes occur to products, processes or cleaning and disinfection equipment, if necessary.	• When are cleaning and disinfection procedures validated? • Who adapts cleaning and disinfection procedures? • How often are cleaning and disinfection schedules changed?
4.10.9	Cleaning and disinfection chemicals shall be labelled, used and stored in a way that avoids contamination. Access to cleaning and disinfection chemicals shall be limited to authorised personnel.	• Are the cleaning and disinfection chemicals labelled? • What kinds of control activities are in place to ensure cleaning and disinfection chemicals are used according to instructions and intended use, to avoid contamination? • Where are cleaning and disinfection chemicals stored?
4.10.10	Where a company hires a third-party service provider for cleaning and disinfection activities in production areas, all above-mentioned requirements shall be documented in the service contract.	• Are cleaning and/or disinfection activities executed by external service providers? • 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, trainings, etc.), in order to prevent any negative impact on products? ◦ In the case that external personnel are absent from work, what kind of actions are taken by the third-party service provider and the company? ◦ Are measures 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 competencies are defined for the responsible person? ***Additional explanation/information*** *If no third-party service provider has been hired, the requirement can be scored as N/A.*

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.11	**Waste management**	
4.11.1*	A waste management procedure shall be documented, implemented and maintained to prevent cross contamination.	• Has the company implemented a waste management procedure? • What kind of waste was defined by the company? • What controls are defined to manage the waste and avoid cross-contamination? • How is the waste collected and stored?
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 is product waste and other waste removed from packaging material handling areas? • Who is responsible for waste removal?
4.11.4	Waste collection containers shall be marked, suitably designed and maintained, easy to clean, and where necessary, disinfected.	• What kind of waste is there? • What waste is collected in separate containers? • When appropriate, are hands free openings in use? • 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 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?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.11.6*	A procedure to manage and control the disposal and/or destruction of trademark materials/products shall be documented, implemented and maintained. The procedure shall comply with legal requirements and customer agreements, when applicable. The disposal and/or destruction of trademark materials/products shall be recorded and shall be included in the traceability system of the company.	• What kind of system is in place to control the disposal and/or destruction of trademark materials/products? • What kinds of waste disposal and/or destruction records exist for trademark materials/products? • Who is responsible for waste disposal and/or destruction of trademark materials/products? • How is traceability ensured?
4.12	**Foreign material and chemical risk mitigation**	
4.12.1*	**KO No. 6: Based on risks, procedure(s) shall be documented, implemented and maintained to prevent contamination with foreign materials. Contaminated products shall be treated as non-conforming products.**	• What kinds of foreign material and chemicals may be found? • Where are sources of foreign material and chemicals identified? • Are staples/clips used? How are knives and cutting devices controlled? • How is foreign material contamination avoided? • Are implemented procedures to prevent contamination based on risks? • How are contaminated products handled? • How are isolated products identified/checked? What actions are taken regarding the product?
4.12.2	The products being processed shall be protected against physical contamination, which includes but is not limited to: • environmental contaminants • oils or dripping liquids from machinery • dust spills. Special consideration shall also be given to product contamination risks caused by: • equipment • pipes • walkways • platforms • ladders. If, for technological characteristics and/or needs, it is not possible to protect the products, appropriate control measures shall be implemented and maintained.	• Which foreign body hazards were identified? • How was classified the risk of the different foreign bodies identified? • How are the products protected against physical hazards? • What control measures are implemented? • Have the effectiveness of control measures been evaluated?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.12.3	All chemicals within the facility shall be fit for purpose, labelled, stored and handled in a way not to pose any contamination risk. Safety Data Sheets and instructions for use shall be available on-site.	• What kind of chemicals are used in the facility? • Are chemicals labelled? • What kinds of controls are in place to ensure chemicals are used according to instructions and intended use with the aim to avoid contamination? • Where are chemicals stored? • Are current safety data sheets available for all chemicals? • How are instructions for the use of chemicals transmitted to personnel in charge? • Where and when can the instructions be inspected?
4.12.4	Where metal and/or other foreign material detectors are required, they shall be installed to ensure maximum efficiency of detection to prevent subsequent contamination. Detectors shall be subjected to maintenance to avoid malfunction at least once within a 12-month period, or whenever significant changes occur.	• Where are the foreign material detectors installed? • How are the metal parts found in the product? • What effect does the shape, position and type of metal have on 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 process conditions?
4.12.5	The accuracy of all equipment and methods designed to detect and/or eliminate foreign materials shall be defined. Functionality tests of such equipment and methods shall be carried out on a risk-based frequency. In case of malfunction or failure, the impact on products and processes shall be assessed.	• How often is detector accuracy checked? • Who checks functionality and accuracy of equipment? • What are the defined actions to be taken when a detector is defective? • Are corrective actions verified? • Are operational defects documented?
4.12.6	Potentially contaminated products shall be isolated. Access and actions for the further handling or testing of these isolated products shall only be carried out by authorised personnel.	• Are contaminated products automatically isolated? • Who may handle and/or has access to isolated products? • How are isolated products handled?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.12.7	In areas where raw materials, wrapping materials, semi-finished and finished products are handled, the use of glass and/or brittle materials shall be excluded; however, where the presence of glass and/or brittle materials cannot be avoided, the risks shall be controlled and the glass and/or brittle materials shall be clean and pose no risks to product safety.	• Does a hazard analysis exist concerning contamination through glass/brittle material? • Where is glass/brittle material used in the plant? • How is glass/brittle material protected from breakage?
4.12.8	Risks-based control measures shall be implemented and maintained for the handling of all kinds of containers used in production/ conversion processes (including wrapping materials) which are made of glass or brittle material. After this process step, there shall be no further contamination risks.	• What control measures are implemented?
4.12.9	Procedure(s) shall be documented, implemented and maintained describing the control measures to be taken in case of glass breakage and/or brittle materials. Such control measures shall include identifying the scope of goods to be isolated, designation of authorised personnel, cleaning and if necessary, disinfection of the production environment and releasing the production line for continued production.	• What measures are taken in case of glass breakage? • What should be taken into account? • Who cleans the production environment? • Who assess potential product contamination? • Are contaminated products isolated? • Who permits continuation of production?
4.12.10	Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.	• Is every glass/brittle material breakage documented? • Where is glass/brittle material breakage documented? • Are there exceptions to documentation? • Are exceptions justified?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.12.11	Where visual inspection is used to detect foreign materials, these shall be carried out in accordance with defined procedures, and by competent and trained personnel. Operative changes shall be performed at a risk-based frequency to maximise the effectiveness of the process.	• How are visual inspections carried out? • Which influences shall be taken into account? • At what frequency are the operative changes carried out? • How has the effectiveness of the process been checked?
4.12.12	In areas where raw materials, wrapping materials, semi-finished and finished products are handled, the use of wood shall be excluded; however, where the presence of wood cannot be avoided, the risks shall be controlled, and the wood shall be clean and pose no risk to product safety.	• 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 condition (clean, free from splinters or other sources of physical contamination)? • Who inspects the wooden tool and how often is its condition inspected? • Are pallets checked to verify that they are clean, sound, dry, free from damage and contamination?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.13	**Pest monitoring and control**	
4.13.1	Site premises and equipment shall be designed, built and maintained to prevent pest infestation.	• Is there evidence of potential favourable pest infestation conditions?
4.13.2*	Risks-based pest control measures shall be documented, implemented and maintained. They shall comply with local legal requirements and consider, at a minimum: • factory environment (potential and targeted pests) • type of raw material/finished products • site plan with area for application (bait map) • constructional designs susceptible for pest activity, for example ceilings, cellars, pipes, corners • identification of the baits on-site • responsibilities, in-house/external • agents used and their instructions for use and safety • frequency of inspections • rented storage, if applicable.	• How is pest control organised? • Which pests are being controlled? • Which kind of baits are used? • Is product contamination being prevented when baits/traps/insect exterminators and chemical agents are used (no negative influence)? Who is responsible for pest control? • Is there a map which shows all pest monitoring/control stations/devices, each of which should be numbered and regularly monitored? • What is the inspection schedule?

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4.13.3	Where a company hires a third-party service provider for pest control, all above-mentioned requirements shall be documented in the service contract. A competent person at the company shall be appointed to monitor the pest control measures. Even if the pest control service is outsourced, responsibilities for the necessary actions (including ongoing supervision of pest control measures) shall remain within the company.	• 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?
		• If a third-party service provider for pest control activities is hired:
		  ◦ 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 issues or infectious diseases, or any others measures (e.g. access restrictions, training, etc.) in order to prevent any negative impact on products?
		  ◦ In the case that external personnel are absent from work, what kind of actions are taken by the third-party service provider and the company?
		  ◦ Are measures 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 monitoring and verification activities? What are the defined competencies 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 measures shall be taken.	• 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 measures 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 a plague to the responsible person?

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4.13.5	Baits, traps and insect exterminators shall be fully functioning, sufficient in number, designed for purpose, placed in appropriate positions and used in a way to avoid contamination.	• Where are electrical fly killers installed? • Are all fly killers connected and working correctly?
4.13.6	Incoming deliveries shall be inspected on arrival for the presence of pests. Any findings and actions taken shall be recorded.	• Are incoming goods inspected for pest contamination? • Where is this documented? • Is pest presence documented? • What kind of actions are taken when pests are found? • Where are these actions documented?
4.13.7	The effectiveness of pest control measures shall be monitored, including trend analysis, to allow timely appropriate actions. Records of this monitoring shall be available.	• How is the effectiveness of pest control measures monitored? • Are pest monitoring and control outcomes/data analysed with aims to allow appropriate actions/ improvements?

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4.14	**Receipt and storage of goods**	
4.14.1*	All incoming goods, including wrapping materials, shall be checked for compliance with specifications and a determined risk-based monitoring plan. Records of those inspections shall be available.	• What goods (including semi-processed products) are inspected when received? • What is checked when received? • Is receipt documented? • Who performs these checks?
4.14.2*	A system shall be implemented and maintained to manage the storage of raw materials, semi-finished and finished products. It shall consider, at a minimum: • identification of all products • control measures to ensure the storage conditions correspond to product specification and minimise contamination risks or any other negative impact • usage of products in accordance with the principles of First In/ First Out and/or First Expired/ First Out • how to proceed when the defined converting time or expiry date of products is exceeded • how to manage incoming goods, including wrapping materials, which have no established converting time or expiry date.	• What kind of control measures are carried out to ensure the storage conditions correspond to product specifications? • 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 established converting time or expiry date?
4.14.3	Adequate storage facilities shall be available for the management and storage of working materials, equipment, tools, process aids and additives. The personnel responsible for the management of storage facilities shall be trained.	• How are working materials, equipment, tools, process aids, and additives stored? • Who uses chemicals and takes them out of storage? • Are the equipment and tools in good clean condition?

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4.14.4	Where a company hires a third-party storage service provider, the service provider shall be certified to IFS Logistics or any other GFSI recognised certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own storage practices shall be fulfilled and this shall be defined in the respective contract.	• 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 hired has no IFS Logistics Certification, nor an equivalent GFSI standard certification:
		  ◦ 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?
		  ◦ In the case that external personnel are absent from work, what kind of actions are taken by the third-party service provider and the company?
		  ◦ Are measures 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 monitoring and verification activities? What are the defined competencies for the responsible person?
		
		Additional explanation/information
		If no third-party service provider has been hired, the requirement can be scored as N/A.

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.15	**Transport**	
4.15.1*	The containers and vehicles used to transport goods shall be suitably designed and defined for the intended use, maintained in a way to prevent contamination, and shall protect the products from adverse weather conditions and external influences. The conditions inside the containers and vehicles related to the absence of, for example: • strange smells • adverse humidity • pests • foreign materials (e.g. wood splinters, stones, organic contaminants, etc.) • mould • surfaces shall be checked before loading and documented to ensure compliance with the defined conditions. The actions taken shall be recorded.	• Are transport vehicles and containers suitable for intended purposes? • What is checked before loading? • Where is inspection documented/recorded? • What actions are taken in case of deviations/ non-conformity?
4.15.2	Where goods shall be transported at certain conditions, these shall be ensured and documented before loading and during transport.	• Are products being loaded which require certain conditions (e.g. humidity during paper transportation)? • 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 the destination in good condition?
4.15.3	Procedures to prevent contamination during transport, including loading and unloading, shall be documented, implemented and maintained. Different categories of goods (e.g. products, wrapping materials, etc.) shall be considered, if applicable.	• May goods be transported alongside non packaging material products? • How is contamination prevented?

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4.15.4	Risk-based hygiene requirements for transport vehicles and equipment used for loading/ unloading (e.g. hoses of silo installations) covering product and process needs shall be documented, implemented and maintained. Compliance with these requirements shall be monitored, and actions taken shall be recorded.	• Are transport vehicles cleaned? • Where are cleaning procedures documented?
4.15.5	The loading/unloading area shall be appropriate for their intended use. They shall be constructed in a way that: • the risks of pest intake are mitigated • products are protected from adverse weather conditions • accumulation of waste is avoided • condensation and growth of mould are prevented • cleaning and if necessary, disinfection can be easily undertaken.	• How is the reception of goods organised? • How is loading organised?

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4.15.6	Where a company hires a third-party transport service provider, the service provider shall be certified to IFS Logistics or any other GFSI recognised certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own transportation practices shall be fulfilled and this shall be defined in the respective contract.	• If a third-party transport service provider is hired:
		  ◦ Does the third-party transport service provider have an IFS Logistics Certification or an equivalent GFSI standard certification?
		• If the third-party transport service provider hired has no IFS Logistics Certification, nor an equivalent GFSI standard certification:
		  ◦ 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?
		  ◦ In the case that external personnel are absent from work, what kind of actions are taken by the third-party service provider and the company?
		  ◦ Are measures 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 monitoring and verification activities? What are the defined competencies for the responsible person?
		
		Additional explanation/information
		• *If no third-party service provider has been hired, the requirement can be scored as N/A.*
		• *If the company decides that its products can be sent via parcel service, it shall ensure that the integrity and safety of the product is not compromised during the whole distance and that general terms and conditions are respected. The company shall conduct a risk assessment and controls based on the worst-case scenario.*

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4.16	**Maintenance and repair**	
4.16.1*	A maintenance plan shall be documented, implemented and maintained, that covers all critical equipment (including transport, production and storage premises) to ensure product requirements. This applies both to internal maintenance activities and service providers. The plan shall include responsibilities, priorities and due dates.	• How is maintenance organised? • Where are maintenance procedures documented? • Which equipment is 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 shall be kept.	• How is it ensured that maintenance and repair work does not affect product safety? • How are lighting fixtures repaired? • Where are repair works documented? • What rules are in place for reactivating equipment once 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 from lubricants being used/applied during production process and maintenance? • Are application methods validated regarding prevention of product contamination?
4.16.4	Failures and malfunctions of premises and equipment (including transport), that are essential for product safety and quality shall be identified, documented and reviewed to enable prompt actions and to improve the maintenance plan.	• 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 to avoid compromising product safety and quality. Such work shall be identified, documented and a short-term deadline set for eliminating the issue.	• Are temporary repairs allowed? • Where are these documented? • How quickly shall temporary repairs be completely mended? • Who is responsible for verifying this?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.16.6	Where a company hires a third-party maintenance and repair service provider, all the company requirements regarding material, equipment and operational rules shall be defined, documented and maintained in the service contract or agreement, to prevent any product contamination.	• 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 issues or infectious diseases, 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 monitoring and verification activities? What competencies are defined for the responsible person? ***Additional explanation/information*** *If no third-party service provider has been hired, the requirement can be scored as N/A.*

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.17	**Equipment**	
4.17.1*	Equipment shall be suitably designed and defined for the intended use. Before commissioning new equipment, compliance with product requirement and customer requirements shall be validated.	• Is equipment suitably designed and were they checked before start-up?
4.17.2	For all equipment and tools which could have an impact on the product, evidence shall be documented and maintained to demonstrate compliance with legal requirements. In the event that no specific legal requirements are applicable, evidence shall be documented and maintained, for example: • certificate of conformity • technical specifications • manufacturer's self-declaration to demonstrate that they are suitable for the intended use.	• Which evidence is available to ensure the equipment and tools which come into direct contact with products are suitable for the intended use?
4.17.3	Equipment shall be located to allow effective cleaning, disinfection and maintenance operations.	• Is equipment suitably designed and is it checked before start-up? • What rules exist for the start-up of new equipment? • Is new equipment immediately considered in maintenance plan? • Does an equipment installation plan exist?
4.17.4	All product equipment and related tools shall be identified, controlled, maintained, stored and transported in a way that does not compromise product safety and product quality (e.g. damage, mixing, printing errors).	• Are product equipment and related tools identified and controlled? • Are product equipment and related tools in good condition?
4.17.5	In the event of changes to equipment, the process characteristics shall be reviewed to ensure that product requirements and customer requirements, are complied with.	• What happens in case of equipment failure?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.18	**Traceability**	
4.18.1*	**KO No. 7: A traceability system shall be documented, implemented and maintained that enables the identification of product lots and their relation to batches of raw materials and wrapping materials in contact with products and/or materials carrying legal and/or relevant product safety information. The traceability system shall incorporate all relevant records of:** • **receipt** • **production/conversion processes at all steps** • **use of rework** • **distribution.** **Traceability shall be ensured and documented until delivery to the customer.**	• How is the finished product batch identified? • Does the traceability system defined by the company include the relation between finished product batches, raw materials, production/ conversion processes and controls? • How is traceability ensured? • What products come from which supplier? • Is there a list available with all current suppliers? • Can rework be completely traced? • How is rework documented?
4.18.2*	The traceability system, including mass balance, shall be tested at least once within a 12-month period or whenever significant changes occur. The test samples shall reflect the complexity of the company's product range. The test records shall demonstrate upstream and downstream traceability (from delivered products to raw materials, and vice versa).	• When was the last test carried out to verify the traceability system? • The samples were 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	The traceability from the finished products to the raw materials and to the customers shall be performed within four (4) hours maximum. Test results, including the timeframe for obtaining the information, shall be recorded and where necessary actions shall be taken. Timeframe objectives shall be in compliance with customer requirements, if less than four (4) hours are required.	• Are there customer requirements for the timeframe? • Have timeframes been respected during own traceability exercises?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.18.4	Labelling of semi-finished or finished product lots shall be made at the time when they are directly wrapped to ensure their traceability. Where they are labelled at a later time, the temporarily stored semi-finished or finished products shall have a specific lot labelling.	• When is batch labelling done? • What is the batch labelling code? • When are labels applied to product units? ***Additional explanation/information*** *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.*
4.18.5	If required by the customer, identified representative samples of the manufacturing lot or batch number shall be stored appropriately and kept until expiration of the recommended converting time of the finished product and, if necessary, for a determined period beyond this date.	• 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 there an implemented sample bank? • How are these samples managed?

Req. No.	IFS PACsecure version 3 requirement	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 also be 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/information*** *Some examples of allergens present in raw materials are soy-based grease, nut-based oils, starch-based glues, among others.*
4.19.2*	Risks-based control measures shall be implemented and maintained to ensure that: • all allergen entry routes are identified • potential cross-contamination of products by allergens is minimised. The potential cross-contamination risks related to the environment, transport, storage, raw materials, equipment, personnel (including contractors and visitors), cleaning and disinfection activities, process flow (from receipt of goods to dispatch) and rework shall be considered • the declaration of allergens are in accordance with legal and customer requirements, if existing. Implemented control measures shall be monitored.	• Do legal and/or customer requirements related to the declaration of allergens in final products exist? • Are control measures implemented and maintained to minimise potential cross-contamination risks? • How are control measures monitored?
4.19.3	The control measures shall be reviewed at least once within a 12-month period or whenever significant changes occur. If necessary, the control measures shall be revised/updated accordingly.	• How often are control measures reviewed? • Are control measures and monitoring requirements changed, and if so, why? • What criteria are defined for control measures to be reviewed in addition to the 12-month period, i.e. when changes to risk could occur? • Is the effectiveness of control measures reviewed? If so, how is this undertaken?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.20	**Product fraud**	
4.20.1	The responsibilities for a product fraud vulnerability assessment and mitigation plan shall be defined. The responsible person(s) shall have the appropriate specific knowledge.	• Who is responsible for product fraud mitigation activities? • How is it ensured that the responsible person has the appropriate knowledge? ***Additional explanation/information*** *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 product fraud vulnerability assessment, including assessment criteria, shall be documented, implemented and maintained. The scope of the assessment shall cover all raw materials, wrapping materials and outsourced processes, to determine the risks of fraudulent activity in relation to substitution, mislabelling, adulteration or counterfeiting.	• 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, outsourced 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?
4.20.3	A product fraud mitigation plan shall be documented, implemented and maintained, with reference to the vulnerability assessment, and shall include the testing and monitoring methods.	• What are the testing, monitoring methods and controls applied to mitigate the risk of potential product fraud activity identified within the vulnerability assessment? • How is the product fraud mitigation plan defined? • Are testing, monitoring methods and controls regularly reviewed for suitability and effectiveness? • Who monitors, and where necessary takes action when issues are identified during controls? • Are testing, monitoring methods and controls appropriately and consistently applied in accordance with identified risks?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.20.4*	The product fraud vulnerability assessment shall be reviewed at least once within a 12-month period or whenever significant changes occur. If necessary, the product fraud mitigation plan shall be revised/updated accordingly.	• How often is a vulnerability assessment undertaken? • Are control and monitoring requirements changed, and if so, why? • Which criteria are defined for additional product fraud vulnerability assessments within the 12-month period? • Is the effectiveness of the product fraud mitigation plan reviewed? If so, how is this undertaken?
4.21	**Product defence**	
4.21.1	The responsibilities for product defence shall be defined. The responsible person(s) shall have the appropriate specific knowledge.	• Who is responsible for the product defence program? • How is it ensured that the responsible person has the appropriate knowledge? • 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 defined? • Was this communicated to the members of the company and how?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.21.2*	A product defence assessment, including assessment criteria, shall be documented, implemented and maintained to identify potential threats and define product defence measures. This shall include, at a minimum: • legal requirements • customer requirements • site security conditions • identification of critical areas and/or practices and policy of access by employees • visitors and contractors • how to manage external inspections and regulatory visits • any other appropriate control measures.	• Are legal/customer product defence requirements applicable to the company? • Based on legal requirements in the country, is it required to apply for formal registration because of where the plant is located, or the country where the product is sold? 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 product defence assessment? • Is the product defence assessment in line with legal and/or customer needs and/or expectations? • What areas have been identified as critical? • What are the implications if a major breach is identified? • In case of external inspections and regulatory visits: ◦ Is there a documented procedure that defines the criteria to be followed 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 specify what to do and how to proceed if a supervisory authority 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?

Req. No.	IFS PACsecure version 3 requirement	Guidance
4.21.3	A product defence plan shall be documented, implemented and maintained, with reference to the product defence assessment, and shall include the testing and monitoring methods.	• What kind of policies and control activities are in place to control the entrance of employees, visitors and contractors to critical or high-risk areas? • How is the company alerted to a breach of product defence? • Is there a way 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 a product defence breach been detected? • What kind of control activities have been implemented? • Are there tests to verify whether measures against tampering are properly applied and fully working? • 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?
4.21.4	The product defence plan shall be tested for effectiveness and reviewed at least once within a 12-month period or whenever significant changes occur. If necessary, the product defence plan shall be revised/updated accordingly.	• What criteria does the company consider when determining the frequency to review the product defence plan, in addition to the fixed 12-month period? • Was the product defence plan updated due to the product defence assessment review?

Req. No.	IFS PACsecure version 3 requirement	Guidance
5	**Measurements, analyses, improvements**	
5.1	**Internal audits**	
5.1.1*	**KO No. 8: An effective internal audit program shall be documented, implemented and maintained and shall ensure, at a minimum, that all the requirements of the IFS Standard are audited. This activity shall be planned within a 12-month period and its execution shall not exceed 15 months. The company shall have a risk assessment in place where activities, which are critical to product safety and quality shall be audited more frequently.** **It shall also apply to off-site storage locations owned or rented by the company.**	• How is the internal audit program organised? • Is there an audit plan? • Is the internal audit program risk-based determined? • Which critical activities to product safety and quality are identified? • How often are internal audits performed? ***Additional explanation/information*** *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)*
5.1.2	The auditors shall be competent and independent from the audited department.	• Who are the auditors? • Which are the competencies defined for auditors? • Do the auditors have any connection with the audited area/department? ***Additional explanation/information*** *Some examples of alternatives to fulfil the independent criteria might be:* • *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.*
5.1.3	Internal audits shall be documented and results communicated to the senior management and to persons responsible for the concerned activities. Compliances, deviations and non-conformities shall be documented and communicated to the relevant persons.	• How are internal audit results communicated to the persons in charge of the process(es) where compliances, deviation(s) and/or non-conformity(ies) were identified? • Is the communication immediate and in sufficient time for actions to be taken? • How are internal audit results communicated to the senior management?

Req. No.	IFS PACsecure version 3 requirement	Guidance
5.2	**Site factory inspections**	
5.2.1*	Site factory inspections shall be planned and carried out for certain topics, like for example: • constructional status of production and storage premises • external areas • product control during processing • hygiene during production/ conversion processes and within the infrastructure • foreign material hazards • personal hygiene. The frequency of inspections shall be based on risks and on the history of previous results. Inspections and resulting actions shall be documented.	• How often do site inspections take place and who performs them? • 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	**Process validation and control**	
5.3.1	The criteria for the validation and control of the process shall be defined. The validation of the process parameters shall be performed using the collected data that is essential for product safety and quality. If substantial modifications occur, a revalidation shall be carried out.	• Which criteria are defined for validation? • Which criteria are defined for the control of the process? • 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?
5.3.2	Process parameters which are essential to ensure the capability of consistently producing conforming products shall be monitored, recorded continuously and/or at appropriate intervals and secured against unauthorised access and/or change.	• What kind of parameters has the company defined as essential to ensure the production of conforming products? • Have these parameters been validated? • At what frequency are these 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?

Req. No.	IFS PACsecure version 3 requirement	Guidance
5.3.3*	All rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.	• How is it ensured that rework complies with specifications or other legally required documentations? • Where is rework documented? • Who reviews rework results? • Who decides on the release of reworked items?
5.3.4	Procedures shall be documented, implemented and maintained for prompt notification, recording and monitoring of process deviations. Where necessary, appropriate actions shall be taken, and these shall be recorded.	

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

Req. No.	IFS PACsecure version 3 requirement	Guidance
5.4	**Calibration, adjustment and checking of measuring and monitoring devices and inspection equipment**	
5.4.1*	Measuring and monitoring devices required to ensure compliance with product requirements shall be identified and recorded. Their calibration status shall be recorded. Measuring and monitoring devices shall be agreed with the customer, or conform to accepted industry standards (e.g. spectrophotometers, lighting in print inspection cabinets, pantone patterns), and legally approved, if required by current relevant legislation.	• What kinds of measuring and monitoring devices exist? • What is demanded of measuring and monitoring devices? • How are measuring and monitoring devices identified? • What monitoring device is relevant for which kind of measurement? • Do calibrated devices exist? • How is the calibration status of a measuring device identified?
5.4.2*	All measuring devices shall be checked, monitored, adjusted and calibrated at defined intervals in accordance with recognised standard/methods and within relevant limits of the process parameter values. The results shall be documented. When inspection equipment is used to control parameters relevant for compliance with product requirement, the method and accuracy to control the parameter values and its limits shall be defined. The continuous operation and efficiency of the inspection equipment to control the parameters under the values and limits defined shall be monitored.	• How are measuring device checks organised? • Are measuring devices regularly checked, monitored, adjusted and 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 equipment: • What kind of equipment is used? • Which are the inspection parameters? • How is the equipment monitored to be fully functioning equipment? • How is the effectiveness of equipment verified? ***Additional explanation/information*** *Some examples of inspection equipment is:* • *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).*

Req. No.	IFS PACsecure version 3 requirement	Guidance
5.4.3	All measuring and monitoring devices and inspection equipment shall be used exclusively for their defined purpose. Where the results of measurements or the status of the device/equipment indicate a malfunction or failure, the device in question shall be immediately repaired or replaced. Where a malfunction has been identified, the impact on processes and products shall be assessed to identify whether non-conforming products have been processed.	• What actions are taken when measurement results are uncertain? • How are devices/equipment with malfunctions/ failures identified?
5.5	**Quantity control monitoring**	
5.5.1*	Compliance criteria to control lot quantity shall be defined. A system on frequency and methodology for quantity control shall be implemented and maintained to meet legal requirements of the destination country/ies, and customer specifications.	• 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	Quantity control monitoring shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing lot. The results from this monitoring shall be compliant with defined criteria for all products ready to be delivered.	• Is a sampling plan implemented? • How was the size of sampling and the frequency of checks determined?

Req. No.	IFS PACsecure version 3 requirement	Guidance
5.6	**Product testing and environmental monitoring**	
5.6.1*	Risk-based testing and monitoring plans for internal and external analyses shall be documented, implemented and maintained to ensure that product requirements and specific customer requirements are met. The plans shall cover a minimum of: • raw materials • semi-finished products (if applicable) • finished products • wrapping materials • contact surfaces of processing equipment • relevant parameters for the control of the process and environmental monitoring. All test results shall be recorded.	• Are the testing and monitoring plans for internal and external analyses risk-based determined? • Which products are encompassed in the inspection plan (raw materials, semi-finished and finished products, wrapping materials, environmental tests)? • 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? How frequently?
5.6.2*	Based on risks, the criteria for environmental monitoring program shall be documented, implemented and maintained.	• What kind of hazards/risks has the company identified? • What criteria are defined for environmental monitoring?
5.6.3*	Analyses, which are relevant for product safety, shall preferably be performed by laboratories with appropriate accredited programs/methods (ISO/IEC 17025). If the analyses are performed internally or by a laboratory without appropriate accredited programs/methods, the results shall be cross-checked with test results from laboratories accredited to these programs/methods (ISO/IEC 17025) at least once within a 12-month period, or whenever significant changes occur.	• Is there an analytical laboratory on-site? Is it accredited to ISO/IEC 17025? • Are internal lab results verified by an accredited lab? • Which external laboratories are used? Are these accredited to ISO/IEC 17025?

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5.6.4	Procedures shall be documented, implemented and maintained to ensure the reliability of the results from internal analyses, based on officially recognised analysis methods. This shall be demonstrated by ring tests or other proficiency tests.	• How is it ensured that internal analytical methods are appropriate? • Are ring tests performed?
5.6.5	Results of analyses shall be evaluated in a timely manner by competent personnel. Immediate corrections shall be implemented for any unsatisfactory results. Based on risks and legal requirements, the frequency for review of the testing and monitoring plan results shall be defined in order to identify trends. When unsatisfactory trends are identified, the impact on processes and products as well as the need for actions shall be assessed.	• Who reviews analytical results? • How are analytical results verified? • Are trends investigated? • Are actions introduced when results are unsatisfactory?
5.6.6	Where internal analyses or controls are undertaken, these shall be carried out in accordance with defined procedures, performed by competent and approved personnel, in defined areas or laboratories using appropriate equipment.	• 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?
5.6.7	When it is relevant for the monitoring of products requirements and/or required by the customer, internal sensory tests shall be carried out. These tests shall be in accordance with specifications and related to the impact on respective parameters of product characteristics. The results of these tests shall be documented.	• When and how are sensory tests performed?

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5.6.8	The testing and monitoring plans/ programs shall be reviewed and updated, based on results, changes to legislation or issues that may have an impact on product requirements.	• What was the last review of the testing and monitoring plan/program? • How was the review executed? • How does the company update the testing and monitoring plan/program in case of legislation changes? • Are product fraud topics included for the testing and monitoring plan/program review?
5.7	**Product release**	
5.7.1*	A procedure for quarantine (blocking/hold) shall be documented, implemented and maintained to ensure that only raw materials, semi-finished, finished products and wrapping materials complying with product requirements and customer requirements, are processed/converted and delivered.	• Does the company have a quarantine and release procedure? • What criteria are 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 documented, implemented and maintained for the management of complaints. The procedure shall consider, at a minimum: • product complaints by customers and when applicable, by consumers • any written notification from the competent authorities – within the framework of official controls –, any ordering action or measure to be taken when non-compliance is identified • raw materials complaints by the company to its suppliers.	• How does the company handle complaints? • Is a prompt reaction to every complaint ensured? • Which complaints have 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 individually?
5.8.2*	All complaints shall be recorded, be readily available and assessed by competent staff. Where it is justified, actions shall be taken immediately.	• 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?

Req. No.	IFS PACsecure version 3 requirement	Guidance
5.8.3	Complaints shall be analysed with a view to implementing actions to avoid the recurrence of the deviations and/or non-conformities.	• How are complaints analysed and how often? • Who manages complaint statistics? • Is there a breakdown for different reasons for a complaint? • 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 of the deviations and/or non-conformities? • Who is responsible for the process?
5.8.4	The results of complaint data analysis shall be made available to the relevant responsible persons.	• To whom is complaint statistics data presented?
5.9	**Management of product recalls, product withdrawals and incidents**	
5.9.1*	**KO No. 9: An effective procedure shall be documented, implemented and maintained for the management of recalls, withdrawals, incidents and potential emergency situations with an impact on product requirements. It shall include, at a minimum:** • **the assignment of responsibilities** • **the training of the responsible persons** • **the decision-making process** • **the nomination of a person, authorised by the company and permanently available, to initiate the necessary process in a timely manner** • **an up-to-date alert contact list including customer information, sources of legal advice, available contacts** • **a communication plan including customers, authorities, and where applicable, consumers.**	• Has the company implemented a procedure? • How does the company evaluate that the procedure is implemented? • Which are the defined actions? • Are the responsibilities clearly defined within the defined actions? • Are the responsible personnel trained? • Who is the person nominated for initiating the necessary process? Is this person permanently available? How are potential absences covered (vacations, sick leave, etc.)? • Is an up-to-date alert contact list available? • Does the company have an internal/external communication plan considering who, what, how, restrictions, timelines, etc.)?

Req. No.	IFS PACsecure version 3 requirement	Guidance
5.9.2*	The procedure shall be subject to internal testing for recall/withdrawal, by covering the end-to-end process. This activity shall be planned within a 12-month period and its execution shall not exceed 15 months. The outcome of the test shall be documented, reviewed for continuous improvement, and where necessary, actions shall be taken.	• How does the company evaluate that the procedure is effective? • How often is effectiveness of the procedure tested? • Is the update of contact data verified? • Are corrective actions taken in case the procedure is not effective?
5.10	**Management of non-conforming products**	
5.10.1*	A procedure shall be documented, implemented and maintained for the management of all non-conforming raw materials, semi-finished products, finished products, processing equipment and wrapping materials. This shall include, at a minimum: • defined responsibilities • isolation/quarantine procedures • risk assessment • identification including labelling • decision about the further usage like release, rework, reprocessing, blocking, quarantine, rejection/disposal.	• What procedures exist for the management of non-conforming products? • How are non-conforming products identified? • What rules exist for product isolation/quarantine? • 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 cross-contamination with the isolation/quarantine area(s)? (e.g. between products with/without allergens compounds; between contaminated product destined for disposal and the one intended for rework, etc.)
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-conforming products are identified, immediate actions shall be taken to ensure that product requirements are complied with.	• What procedures are implemented with non-conforming products? • Who makes decisions about non-conforming products?

Req. No.	IFS PACsecure version 3 requirement	Guidance
5.10.4	Finished products that are out of specification shall not be placed on the market unless written approval of the customer is available. When out of specification products shall be destroyed, records of this shall be maintained.	• How are out of specification products destroyed? Are records available? • If the customer allowed the release of out of specification products, is there written evidence of this approval?
5.11	**Management of deviations, non-conformities, corrections and corrective actions**	
5.11.1*	A procedure for the management of corrections and corrective actions shall be documented, implemented and maintained for the recording, analysis, and communication to the relevant persons of deviations, non-conformities and non-conforming products, with the objective to close the deviations and/or non-conformities and avoid recurrences via corrective actions. This shall include a root cause analysis, at least for deviations and non-conformities related to safety, legality, authenticity and/or recurrence of deviations and non-conformities.	• Has the company implemented a procedure for the management of corrections and corrective actions? • How does the company evaluate that the procedure is implemented?
5.11.2	Where deviations and non-conformities are identified, corrections shall be implemented.	• What discrepancies and/or non-conformities have occurred recently?
5.11.3*	**KO No. 10: Corrective actions shall be formulated, documented and implemented as soon as possible to avoid the further occurrence of deviations and non-conformities. The responsibilities and the timescales for corrective actions shall be defined.**	• What corrective actions has been implemented? • Where are corrective actions documented? • Who is responsible for corrective actions? • How long may it take to implement corrective Actions?
5.11.4	The effectiveness of the implemented corrections and corrective actions shall be assessed, and the results of the assessment documented.	• Where are corrective actions documented? • How are corrective actions verified?

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PART 3
Requirements for accreditation bodies, certification bodies and auditors
IFS Accreditation and Certification Process

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.

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 an IFS Training Session ("IFS PACsecure Standard for auditors" e-learning 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 "IFS PACsecure Standard for auditors" e-learning course with the main emphasis on Part 1 (IFS PACsecure Certification Protocol), Part 3 (requirements for accreditation bodies, certification bodies and auditors), Part 4 (audit report, certificate) of the IFS PACsecure Standard, the IFS PACsecure Doctrine and the IFS Auditor Examination Process.

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

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

- Accompanying IFS PACsecure Auditors during registered IFS PACsecure Audits (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 annual IFS Certification Body Conference, IFS Calibration Training, "IFS PACsecure Standard for auditors" e-learning course; or by being trained internally by an accreditation body leader who has taken part in the IFS Training/Certification Body Conference)
- Have taken part in an HACCP 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.

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

For renewal assessments, 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 IFS Product Scopes shall be considered within the accreditation witness assessments.

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:

- 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 number of certificates totaling up to 200, 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 number of auditors totaling up to 20, 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 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, certification bodies shall stop performing IFS Audits and issuing IFS Certificates. To recover accreditation after a withdrawal, 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.

Accreditation bodies shall inform IFS if a certification body has its accreditation in relation to an IFS Standard suspended or withdrawn.

2 Requirements for the certification bodies

Certification bodies intending to perform IFS PACsecure Audits 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 Audit (including the first audit(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 In-house 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

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) audits including the accreditation witness assessment before achieving accreditation status. All audits (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 audits 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 Audit. 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 audited 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 Audits or the content of IFS Audit Reports, the IFS Offices require the certification body to provide a statement on the cause and the measures identified to rectify the problem within ten (10) working days.

- If the complaint relates to administrative errors, e.g. in IFS Audit Reports, IFS Certificates or in the IFS Database, the IFS Offices ask the certification body to provide a statement and rectify the problem within five (5) working days. 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 8). Furthermore, the decision can only be made by a different person than the one who performed the audit.

Chart 8: 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 audit. The review shall be documented.
Certification decision	By the certification body (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 working exclusively for the certification body or a committee with no involvement of the person who performed the audit.

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 IFS Recertification Audits) will be necessary.

2.6 Certification body responsibilities for IFS PACsecure Auditors, IFS PACsecure Reviewers, IFS PACsecure In-house 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 auditors and reviewers to the level required by the IFS Standard. Therefore, certification bodies have the following responsibilities:

- To manage witness audits/assessments (by accreditation bodies, Integrity Program, and certification body through the monitoring program and sign-off audits).

- To ensure that auditors or audit teams are qualified for the full scope of the audit 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 audit performance of every auditor by an on-site witness audit at least once every two (2) years (see more details in chapter 3.1.5, Part 3). All information related to the fulfilment of requirements for maintenance of approval shall be kept up to date in the IFS Database.
- To witness auditors who are already IFS Auditors but new to the certification body when starting to perform IFS Audits for them (this witness audit can count as the regular monitoring audit so that the next regular monitoring audit 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 audited during the previous two (2) years).
- To ensure that no auditor shall perform more than three (3) consecutive IFS PACsecure Audits at the same production site (this only applies for full audits, irrespective of the time between them; this does not apply for follow-up audits, extension audits, audits that have been participated in as a trainee).
- To ensure that all auditors and reviewers have a valid contract with the certification body.
- To obtain signed confirmation from the auditors for each audit, 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 audited, currently or within the last two (2) years.

  This confirmation can be covered by a general confirmation of an auditor working as a permanent employee for the certification body.
- To ensure that at least one member of the certification body staff is responsible for certification body in-house IFS Trainings. This approved IFS PACsecure In-house Trainer shall have taken part in the "IFS PACsecure Standard for auditors" e-learning 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, etc. 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,
  - audit practices according to the IFS Good Audit Practices guideline,
  - failures in reports and findings,
  - exercises to calibrate criteria regarding the IFS Scoring System.

  The IFS PACsecure In-house Trainer is responsible for the content of the training and shall lead at least part of the training. Topics such as legislation, audit 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 as a face-to-face meeting or via online session(s). The signature list, agenda and material 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 audit report and associated documentation including auditor's notes are stored safely and surely for a period of five (5) years.

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

Every certification body shall have a minimum of one contracted auditor, one contracted reviewer, one approved IFS In-house Trainer and an IFS responsible person (contact person for IFS). In case of any changes, the certification body shall inform the IFS Offices.

3 Requirements for IFS PACsecure Auditors, IFS PACsecure Reviewers, IFS PACsecure In-house Trainers and IFS PACsecure Witness Auditors

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

3.1 Requirements for IFS PACsecure Auditors

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

Exclusive auditors shall have submitted all relevant information about their competencies to the certification body and the certification body shall have assessed and confirmed their competencies before they register them as new exclusive auditors in the IFS Database.

Non-exclusive auditors are fully responsible for their own application as IFS Auditor and shall register themselves as 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.

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 Examination.

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

All auditors shall have agreed to 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 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.
- 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) Work experience

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

- Functions related to packaging manufacturing activities (e.g. quality assurance, product safety, R&D …) in the packaging industry or in retail
- Packaging safety auditing
- Packaging safety inspection or enforcement.

Experience from consultancy in relation to packaging manufacturing activities may be recognised as a maximum of one year towards the work experience, if it can be proven by customer contracts, invoices, orders or confirmations.

c) Qualification

The candidate shall have:

- Taken part in a recognised lead auditor course (e.g. IRCA, IFS) with a duration of at least 40 hours.
- Taken part in a food hygiene and HACCP course, with a duration of at least two (2) days/16 hours

d) General audit experience

- **If the candidate has 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 five (5) years. The following types of audits are accepted as valid general audit experience:
  - GFSI recognised certification audits in related scope
  - Second party audits recognised by IFS
  - IFS Progress PACsecure Assessments (intermediate level or at least eight (8) hours assessment duration).
- **If candidate has no audit experience:** In case the candidate has no own audit experience, the candidate shall participate in three (3) IFS PACsecure audits or any of the above-mentioned packaging safety audits accepted as valid general audit experience, in the following order and tasks assigned:
  - first audit: inactively participate as a shadow observer

- second and third audits: participate actively in the audits under supervision and responsibility of an experienced IFS Lead Auditor.

The trainee and IFS Lead Auditor shall never separate during the audits.
The audit schedules for the second and third audits shall reflect the parts the trainee is auditing. These schedules shall be made available to the IFS Offices on request.

- **Combination of audit experience and no audit experience:** A combination of own audit experience and trainee audits is possible as long as the above-mentioned requirements for the type of audits and supervision during trainee audits are complied with.
- **For all candidates:** Audit number four (4) and five (5) shall be a full IFS PACsecure Audit where active participation as a trainee under the supervision and responsibility of an IFS approved auditor is required. The audit schedules for these audits shall reflect the parts the trainee is auditing. These schedules shall be made available to the IFS Offices on request. The audits are accepted for product scope extensions and can be performed in any product scope.

The audits shall have been carried out at different production sites. A maximum of three (3) audits at the same site are accepted.

The candidate shall have performed or observed at least one (1) audit when applying for the written exams. Audit four (4) and five (5) shall only be performed after the candidate passed the written exams. The general audit experience shall be completed before the sign-off audit will be performed.

The full approval process from passing the written exams until being activated in the IFS Database shall take no longer than two (2) years.

Chart 9: General audit experience plus sign-off audit

N° of audit/ assessment	Tasks/Role	Possible audit/assessment types
1	Performed audit as lead or co-auditor OR participation as a trainee (no active participation)	• Full packaging safety audit (GFSI recognised certification audits in related scope and/or recognised second party audits) and/or IFS Progress PACsecure Assessment (intermediate level or at least eight (8) hours assessment duration) shall have been performed by the auditor in the packaging industry OR • IFS PACsecure Audit (only possible as a trainee)
Written exams(1) can be taken after audit 1		
2 - 3	Performed audits as lead or co-auditor OR active participation as a trainee in the audits/assessments under supervision and responsibility of an experienced lead auditor	• Full packaging safety audit (GFSI recognised certification audits in related scope and/or recognised second party audits) and/or IFS Progress PACsecure Assessment (intermediate level or at least eight (8) hours assessment duration) shall have been performed by the auditor in the packaging industry OR • IFS PACsecure Audit (only possible as a trainee)
Written exams(1) need to be passed before audit 4 and 5		
4 – 5	Active participation in the IFS Audits under the supervision and responsibility of an approved IFS Auditor	• IFS PACsecure Audit
6	Auditor under observation in the **sign-off audit**(2)	• IFS PACsecure Audit, in a company where the audit scope matches the product scopes the "auditor under observation" is applying for
(1) See "IFS Examination Process" in chapter 3.1.3, Part 3 (2) See glossary in Annex 12		

e) Specific and practical knowledge per product scope

For each applied product scope (see Annex 3 for product scopes), one of the following options shall be met:

- Option 1:
  At least one (1) year professional experience in the packaging industry in relation to packaging manufacturing activities (quality assurance, product safety, production, R&D…) for each

applied product scope. Experience from consultancy related to the packaging manufacturing activities may be recognised as a maximum of six (6) months towards work experience, if it can be proven by customer contracts, invoices, orders or confirmations.

- Option 2:
  At least five (5) audits belonging to the following categories:
  - GFSI recognised certification audits in related scope (of which trainee audits are also accepted if evidence of attendance is available)
  - IFS Progress PACsecure Assessments (Intermediate Level or at least eight (8) hours assessment duration)
  - Second party audits recognised by IFS

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. six (6) months of work experience plus three (3) audits or equivalent combinations).

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

Chart 10: Possible combinations to obtain product scope(s) 1, 2, and/or 7:

To obtain	Option 1	Option 2
Scope 1 Flexible plastic	A minimum of two (2) audits on scope 1 AND Three (3) audits on scope 1 and/or 2	A minimum of six (6) months of work experience in scope 1 AND Three (3) audits on scope 1 and/or 2
Scope 2 Rigid plastic	A minimum of two (2) audits on scope 2 AND Three (3) audits on scope 2 and/or 1	A minimum of six (6) months of work experience in scope 2 AND Three (3) audits on scope 1 and/or 2
Scope 7 Other packaging components	A minimum of two (2) audits on scope 7 AND Three (3) audits in any other product scope where these materials are included in the manufacturing of the final product and are part of it.	A minimum of six (6) months 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 manufacturing of the final product and are part of it.

The auditor shall have participated in all steps of the audits (on-site audit and auditor's on-site decision-making processes). Audits shall have been preferably carried out at different production sites, with a maximum of two (2) audits at the same production site.

f) Language

If auditors wish to perform audits in language(s) different to their mother tongue, they shall be able to provide evidence of fluency in this/these other language(s) and provide the following evidence to IFS Offices:

- Acceptance of language certificates comparable to the CEFR (Common European Framework of Reference for Languages) level B2 and higher,

OR

- Two (2) years work experience in the packaging sector in the respective country

OR

- At least ten (10) audits performed in the respective language of the country (trainee audits are not accepted) that include writing reports in this language without an interpreter

OR

- For initial approval only: successful completion of the general written exam in the respective language without an interpreter.

g) IFS e-learning training courses

The candidate shall have:

- Taken part in the "IFS Product and Process Approach" e-learning course
- Taken part in the "IFS PACsecure Standard for Auditors" e-learning course. The "IFS PACsecure Standard for Auditors" 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.

If the auditor's CV does not meet the above-mentioned requirements, IFS may reject the auditor's examination application.

For exclusive auditors, the auditor's CV shall be confirmed by a person from the certification body. Non-exclusive auditors shall confirm the correctness and completeness of the data provided in their CV themselves.

Note: 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.

All requirements for approving auditors shall be assessed by the certification body, according to ISO/IEC 17065:2012 norm.

3.1.3 IFS Examination Process and sign-off audit

Auditors who comply with the requirements mentioned in chapter 3.1.2, Part 3, can then take part in the IFS PACsecure Examination Process, which comprises:

- The general written IFS PACsecure Exam (independent of product scopes the auditor is confirmed for).
- The written IFS PACsecure product scope exam(s) (dependent on the product scopes the auditor is confirmed for).

Note: Detailed regulations for IFS Examination ("IFS Examination Regulation" document) and international IFS Examination schedules are provided by IFS and are available on the IFS Website.

Upon successful completion of IFS Examination Process and fulfilment of the required general audit experience (see chapter 3.1.2 d), the auditor shall be signed off during their first IFS PACsecure Audit acting as lead auditor under observation of the fully qualified witness auditor (see also glossary for sign-off audit definition).

The sign-off audit shall be:

- performed in a company where the audit scope matches the product scope(s) the "auditor" is going to be approved for
- witnessed by an IFS PACsecure Witness Auditor who is approved for all product scope(s) of the audit.

The report of the sign-off audit shall be documented in the template provided by IFS.

Once the IFS Witness Audit Report of the successfully 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 Auditor Certificate will be issued for the auditor. The IFS Auditor Certificate mentions the duration of validity, the product scope(s) the auditor is approved for and the auditor's languages.

Starting from the day of activation, the auditors are allowed to perform IFS PACsecure Audits for the product scope(s) they have been approved for by IFS Offices. The certificate validity starts from the date of activation in the IFS Database and is based on the date the IFS Examination is successfully passed. The validity 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 IFS Examination on 20.10.2024, the auditor certificate will be valid until 31.12.2026.

3.1.4 Conversion option for auditors approved for other GFSI recognised certification standards in related scope, accredited to ISO/IEC 17065:2012 norm, to become approved for IFS PACsecure Standard

The candidate shall:

- Be approved for at least two (2) years for the referenced GFSI recognised certification standard in related scope accredited to ISO/IEC 17065:2012 norm
- Take part in the IFS e-learning training courses (see chapter 3.1.2 g)
- Pass the written IFS PACsecure Exam. Product scope(s) will be accepted based on their approval for the referenced GFSI recognised certification standards.
- Perform a sign-off witness audit.

3.1.5 Maintenance of auditor's approval

The auditor's approval shall be reassessed before the end of validity of their auditor's certificate. To maintain their approval, the exclusive auditor shall fulfil the following requirements:

- Every year: to have taken part in a one (1) day/eight (8) hours in-house training by the certification body (see specifications on this training in chapter 2.6, Part 3). This is applicable from the year the IFS Examination is passed.
- Every year: to have performed a minimum of five (5) IFS PACsecure Audits as a lead or co-auditor. This is applicable from the first full year following the approval as an IFS PACsecure Auditor.
- Every two (2) calendar years: to have attended and successfully completed a two (2) day IFS 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 IFS Examination was passed.

- Every two (2) calendar years: to be assessed by the certification body during a full IFS PACsecure Audit (on-site monitoring witness audit), in order to evaluate their competencies. This audit 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 IFS Standard Audit or GFSI recognised certification standard audit in related scope accredited to ISO/IEC 17065:2012 norm. The witness auditor shall not be part of the audit (as a team member). For the on-site witness audit performed during an IFS PACsecure Audit, the witness auditor shall fulfil the requirements to act as an IFS PACsecure Witness Auditor, as defined in chapter 3.4. The certification body shall specify the name of the witness auditor in the IFS Audit Report. A comprehensive witness report using the IFS Witness Report template shall be available to demonstrate the outcome of the witness audit.

Non-exclusive auditors are responsible for maintaining their own IFS PACsecure approval.

To maintain their approval, the non-exclusive auditor shall fulfil 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 in-house training with **each certification body** the non-exclusive auditor is linked to in the IFS Database.
- Every two (2) years: to be assessed by **each certification body** during a full IFS PACsecure Audit (on-site monitoring witness audit).

Note 1: The monitoring witness audits should, over time, reflect the scopes an auditor is approved for.

Note 2: If the witness audit is performed during another GFSI recognised certification standard audit in related scope, the witness auditor shall witness the auditor during the full determined audit duration. Apart from this before mentioned rule, the rules for witness auditor and reporting format for the respective standard apply.

Note 3: Successfully completed witness assessments from accreditation bodies or witness audits from the IFS Integrity Program during IFS PACsecure Audits can replace the witness audits from the certification body.

Note 4: For an audit team, the lead auditor can only be witnessed if the audit team did not split during the audit.

All results of the monitoring process of approved IFS PACsecure Auditors, as well as internal and external trainings, shall be assessed by the certification body, according to ISO/IEC 17065:2012 norm.

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.

Note: In case of any extraordinary situation, (e.g. emerging market), where the regular rules cannot be complied with, it is mandatory to contact the IFS Auditor Management for a case by case decision.

IFS manages auditor reapproval every two (2) years:

- If all requirements are fulfilled, IFS re-issues a new auditor certificate which is valid for two (2) more years.

- If not all of them are fulfilled, the auditor's certificate will not be maintained, and the auditor shall successfully participate in the general written IFS PACsecure Exam again.

Example of situation where all requirements are fulfilled:

- Date of passed initial IFS Examination: 25th May 2024
- Date of end of validity for IFS Auditor Certificate (initial approval): 31st December 2026
- The auditor shall participate in an IFS Calibration Training between 1st January and 31st December 2026.
- The auditor is authorised to perform IFS Audits from the day of activation in the IFS Database until 31st December 2026.
- In 2026, if the auditor has:
  - taken part in the IFS Calibration Training (e.g. on 8th and 9th September 2026) and
  - fulfilled all other rules mentioned in chapter 3.1.5.
- The new end of validity date for IFS PACsecure Auditor Certificate (reapproval) is: 31st December 2028.

3.1.6 Specific situation of temporarily inactive auditor

If an auditor needs to take a timeout (i.e. a break from their 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 chapter 3.1.5 to maintain auditor approval 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 they can resume their activity as an IFS PACsecure Auditor. If not, the auditor will lose their IFS PACsecure Approval, and the auditor shall successfully participate in the general written IFS PACsecure Exam again.

In case of a standard version change during this temporary time-out, the auditor shall fulfil the requirements for approved auditors when a new version is released (see chapter 3.5, Part 3).

3.1.7 Scope extension for approved IFS PACsecure Auditors

Auditors may, during the validity of their IFS 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 at least partly new experiences different to that provided for initial application. The auditor shall in addition pass the corresponding written IFS PACsecure product scope exam, organised by IFS Offices.

Note 1: IFS PACsecure Audits which were performed under the supervision of a witness auditor, can count for the witness auditor to apply for a product scope extension. Participation in an IFS PACsecure Audit as technical expert or interpreter can also count to apply for a product scope extension.

Note 2: To be able to use the performed IFS Audit as evidence for a scope extension request in the case of an audit team, the auditors shall stay together during the whole IFS Audit.

3.1.8 Further rules and explanations concerning the non-exclusive approach

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

A non-exclusive auditor will be linked to a certification body in the IFS Database by uploading the witness audit performed by the certification body.

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

Loan agreements for individual audits and IFS Working Group Agreements are not possible for non-exclusive auditors.

3.1.9 General rules about audit teams

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

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

- An IFS Audit Team consists of IFS PACsecure Auditors whose combined profile (product scope(s)) complies with the scope of the audited production site.
- A lead auditor shall always be appointed.
- Lead and co-auditor(s) shall always be approved for at least one product scope of the audit scope.
- A minimum of two (2) hours shall be added to the determined audit duration. This additional time shall be allocated to the team for common tasks (e.g. opening and closing meetings, discussion about audit findings, etc.) and not to an individual auditor.
- The remaining time can be split, as long as the auditor approval for product scope(s) are always covered during the audit. If the lead or co-auditor(s) does not individually have all product scopes necessary for the audit, they have to remain together during all parts of the audit where the approval of both auditors are necessary. Only an auditor with all relevant product scopes is allowed to perform the respective parts of the audit separately.

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

3.2 Requirements for IFS PACsecure Reviewers

An IFS PACsecure Reviewer shall be:

- an approved IFS PACsecure Auditor, or
- an IFS Auditor for any IFS Product Standard having taken part at the "IFS PACsecure Standard for Auditors" eLearning course, or
- an IFS Pure Reviewer (if not an IFS PACsecure Auditor).

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

The following section details the requirements for being approved as a 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 food hygiene and HACCP course, with a duration of at least two (2) days/16 hours.

d) General audit experience
The candidate shall have attended to two (2) full IFS PACsecure Audits (as observer).

e) Language
If the candidate wishes to review audit reports in language(s) different from their mother tongue, they shall be fluent in this/these 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) IFS e-learning training courses
The candidate shall have:

- Taken part in the "IFS Product and Process Approach" e-learning course
- Taken part in the "IFS PACsecure Standard for Auditors" e-learning course.

g) In-house training
The candidate shall have taken part in a one (1) day task related in-house training, organised by the certification body.

Once the reviewer has fulfilled the above-mentioned requirements and this has been approved by IFS, they will be activated as an IFS PACsecure Pure Reviewer in the IFS Database and a personal IFS Reviewer Certificate will be issued.

Starting from the day of activation, the IFS PACsecure Reviewer is allowed to perform technical reviews of IFS PACsecure Audit 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 IFS PACsecure Pure Reviewer's approval shall be reassessed before the end of validity of their reviewer's certificate.

To maintain their approval, the reviewer shall fulfil the following requirements:

- Every year: to have taken part in a one (1) day/eight (8) hours in-house training by the certification body (see specifications on the training in chapter 2.6).
- Every two (2) years: to have taken part (as observer) at one full IFS PACsecure Audit.
- Every two (2) calendar years: to have attended and successfully completed a two (2) days IFS Calibration Training, organised by IFS. The first mandatory IFS Calibration Training shall be completed in the second calendar year following the date of the initial approval.

Non-exclusive pure reviewers are responsible for maintaining their own IFS Pure Reviewer approval.

To maintain their approval, the non-exclusive pure reviewer shall fulfil the same requirements as for exclusive pure reviewers, with the following variants (**in bold**):

- Every year: to have taken part in a one (1) day/eight (8) hours in-house training with **each certification body** the non-exclusive pure reviewer is linked to in the IFS Database.
- Every two (2) years: to have taken part (as observer) at one full IFS PACsecure Audit for **each certification body**.

Note: When starting with a new certification body, a pure reviewer shall take part in a one-day task related in-house training by the certification body.

3.3 Requirements for IFS PACsecure In-house Trainers

At least one IFS PACsecure auditor shall be appointed by the certification body as an IFS PACsecure In-house Trainer (see chapter 2.6)

The IFS PACsecure In-house Trainer shall be fluent in English and in the language(s) used when conducting their trainings. The decision if a trainer's language skills are sufficient to carry out a training in a proper way, in the respective language, is the responsibility of the certification body.

The maintenance of IFS PACsecure In-house Trainer is linked to the maintenance of IFS PACsecure Auditor qualification.

In addition, the IFS PACsecure In-house Trainer shall:

- Every year: to carry out or take part in a one (1) day/eight (8) hours in-house training by the certification body.
- Continuously: to stay informed about any new information concerning the IFS PACsecure Standard (provided by IFS to their certification body).

When a new IFS Doctrine is published: to train all approved IFS PACsecure Auditors and IFS PACsecure Reviewers on all changes and new information from the IFS Doctrine before they perform any new audit or technical review (this training can be done face-to-face, online or by webinar).

3.4 Requirements for IFS PACsecure Witness Auditors

A person qualifying as an IFS PACsecure Witness Auditor shall fulfil the following requirements:

a) Qualification and experience

- To be an experienced IFS PACsecure Auditor (to have already performed at least ten (10) full IFS Audits as lead auditor),

OR

- To be an experienced IFS Food or IFS HPC Auditor [to have already performed at least ten (10) full IFS Audits as lead auditor] who has taken part in the "IFS PACsecure Standard for Auditors" e-learning course.

b) Language

The witness auditor shall be approved for the language(s) in which the audit is performed.

c) IFS e-learning training course

The candidate shall have taken part in the IFS Witness Auditor e-learning course (provided by IFS).

Once the previous requirements are fulfilled, the candidate shall be appointed by the certification body as a witness auditor.

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.

The witness auditor shall provide comprehensive witness audit reports, using the IFS template in case of IFS Witness Audit, which shall be made available to IFS on request.

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

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

3.6 Overview of requirements for initial approval and maintenance of approval

and the tasks of each IFS related role in a certification body

The following chart (chart 11) 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 11: Overview of 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, Part 3)	• Professional Education • Work experience • Qualifications • General audit experience • Specific knowledge per product scope • IFS e-learning training courses • Passed IFS Examination • Sign-off audit	• Every year: one (1) day in-house training by the certification body • Every year: five (5) IFS PACsecure Audits. • 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 IFS Standard Audit or GFSI recognised certification standard audit in related scope accredited to ISO/IEC 17065:2012 norm • Every two (2) years: IFS Calibration Training, organised by IFS	• Perform IFS Audits • Review IFS Audit Reports) if they did not perform the audit themselves)

Function/ role in certification body	Profile/requirements for initial approval	Requirements for maintenance of approval	Task
IFS PACsecure Reviewer (see chapter 3.2, Part 3)	IFS PACsecure Auditor, IFS Food or IFS HPC Auditor who has taken part in the "IFS PACsecure Standard for Auditors" e-learning course, or IFS PACsecure Pure Reviewer: • Professional Education • Work experience • Qualifications • General audit experience (as observer or performed themselves) • IFS e-learning training courses • One-day task related in-house training organised by the certification body.	IFS PACsecure Pure Reviewers • Every year: one (1) day in-house training by the certification body • Every two (2) years: one (1) IFS PACsecure Audit as observer • Every two (2) years: IFS Calibration Training, organised by IFS	Review IFS PACsecure Audit Reports (technical tasks) To check, at a minimum: • the overall consistency of the IFS Audit Reports • if the findings are well described and matching the evaluation • if the corrections and corrective actions as well as the deadlines for implementation proposed by the audited company have been validated by the auditor (or by a representative of the certification body) and are relevant
IFS PACsecure In-house Trainer (see chapter 3.3, Part 3)	IFS PACsecure Auditor appointed by the CB.	• Linked to the maintenance of approval as IFS PACsecure Auditor • Every year: one (1) day in-house training (attend or conduct) • Continuously: check and communicate the IFS updated information provided by IFS. • In case of a new doctrine: train all approved IFS PACsecure Auditors and IFS PACsecure Reviewers on all changes and new information from the IFS Doctrine, before they perform any new audit or technical review	• Train auditors and reviewers • Generate content of the training program for all IFS PACsecure Auditors and Pure Reviewers of the certification body • When a new IFS Doctrine is published, train all approved IFS PACsecure Auditors and Pure Reviewers before they perform any new audit or technical review (this training can be done face-to-face, online or by webinar)

Function/ role in certification body	Profile/requirements for initial approval	Requirements for maintenance of approval	Task
IFS PACsecure Witness Auditor (see chapter 3.4, Part 3	• Experienced IFS PACsecure Auditor [at least 10 performed IFS Audits], OR an experienced IFS Food or HPC Auditor [at least 10 performed IFS Audits] who has taken part in the "IFS PACsecure Standard for Auditors" e-learning course • IFS Witness Auditor e-learning course provided by IFS	• Linked to the maintenance of approval as IFS PACsecure Auditor	• Perform witness audits according to IFS Requirements on behalf of the certification body including on-site witness audit and reporting • **Note:** only IFS Auditors approved as IFS PACsecure Witness Auditors and covering the full scope of the witness audit shall perform sign-off audits

PART 4

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PART 4
Reporting, the IFS Software and the IFS Database

0 Introduction

After performance of an IFS PACsecure Audit, a detailed and well-structured audit report shall be completed. The language of the report shall be the working language of the company. In special cases defined by the certification bodies, where the native language of the retailers or purchasers is different to the working language of the company, an English version of the report could also be prepared. If the report is written in a different language to English, the company profile, the overall summary of compulsory information tables and the audit scope shall be translated in English.

Note: For any combined audit (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 Audit Report shall be prepared according to the following format:

- the audit overview (chapter 1.1, Part 4)
- the main content (chapter 1.2, Part 4).

1 Reporting

1.1 Minimum requirements for the IFS Audit Report: audit overview (ANNEX 9)

Cover page
The cover page of the IFS Audit Report shall include:

- name and/or logo and address of the certification body
- IFS PACsecure Logo
- name of the audited site and legal authorisation number, if applicable
- GS1 GLN(s) (Global Location Numbers) related to the site(s) that has/have been covered during the audit, if applicable
- dates(s) of the audit
- announced or unannounced audit status
- certification body's accreditation details.

Audit overview
The audit overview of the IFS Report shall include the following mandatory information:

- **Audit details**
  - name of the lead auditor, reviewer (person in charge of the technical report review), co-auditor, trainee and witness auditor, if applicable
  - audit date(s) (in case of a follow-up audit, the date of the follow-up audit shall additionally be specified)
  - duration of the audit (start and end time for each audit day)
  - previous audit dates (start and end time for each audit day)
  - name of the certification body and the auditor who performed the previous audit
  - name and address of the audited 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.
- **Audit scope**
  - detailed description of processes and products, including the information about the intended use of products (primary and/or secondary packaging materials)
  - code(s)/number(s) of product scope(s).
- **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
  - description of multi-location production sites, if applicable (see chapter 2.2.2, Part 1).
- **Final audit result**
  - final audit result with level and percentage (in case of a follow-up audit, specify that a follow-up audit has taken place and that the Major non-conformity has been solved or not)
  - timeframe in which the recertification audit shall be performed or if it will be unannounced.
- **Observations regarding non-conformities (D evaluation of KO requirement(s) and Majors)**
  In case of a follow-up audit, additional explanations shall be provided on requirement for which the Major non-conformity has been solved.
- **Comments concerning follow-up of corrections and corrective actions**
  Description of corrections and corrective actions from the previous audit (both that have been sustainably and efficiently implemented or not).

- **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 audit 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. The company profile, which includes compulsory information, shall be translated into English.

1.2 Minimum requirements for the IFS Audit Report: main content (ANNEX 10)

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

- General summary in a tabular format for all chapters, listing the number of audited requirements per scoring for each chapter and the result (in percentage) per chapter.
- Overall summary: table of compulsory fields for specific IFS PACsecure Audit 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 audited site almost fulfils all IFS PACsecure Requirements, and adds value for every user/reader. The overall summary table, which includes compulsory information, shall be translated in English.
- List of all identified deviations and non-conformities for each requirement per chapter.
- List (including explanations) of all requirements evaluated as N/A (not applicable).
- Detailed audit report (checklist).
- Annex of the audit report, including:
  - Audit participants' list: list of key personnel present during the audit.
  - Reminder of IFS rules: tables on product scopes, IFS Scoring System and conditions for issuing of certificate.

1.3 The action plan (ANNEX 7)

For each audit 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 Audit 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:

- name and/or logo and address of the certification body
- name and/or logo of the accreditation body (used in conformity with accreditation body's rules) and registration number
- name and address of the audited site
- COID (IFS identification number) as defined in the IFS Database
- legal authorization number, if applicable

- GS1 GLN(s) related to the site(s) that has/have been covered during the audit (including off-site warehouse(s)), if applicable
- in case of multi-location production sites: name and address of the site's head office/central management, if applicable
- description of the audit 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/other GFSI recognised standard certified" (for further information, see chapter 2.2.1, Part 1 and Annex 1)
- level achieved
- audit score in percentage
- last unannounced audit date (last day of the audit). If an unannounced IFS PACsecure Audit has not yet been conducted for the respective COID, the certificate shall indicate the following: "Last audit conducted unannounced: N/A"
- star status indication in case the audit was conducted unannounced (star symbol to be added close to the IFS PACsecure Logo)
- audit date(s)
- follow-up audit date, if relevant
- next audit time period (recertification audit), 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 a verification link to the IFS Website.

Note: The IFS 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 IFS Software
The QR-code is implemented automatically when creating the certificate via IFS Software. The QR-code embodies a public link to a IFS Website which verifies the authenticity of the certificate.

QR-code for creating a certificate without the use of the IFS Software
For certification bodies that do not use the IFS Software to generate certificates, there is an area in the IFS Database where a QR-code for the respective COID can be downloaded.

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.

2 The IFS Software

In order to increase the standardisation of reporting information after the IFS Audit, an IFS Software has been developed and shall be used to generate the IFS Report.

Additional information about its use is provided separately in a manual.

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

Every IFS Audit 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:

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

In general, only the certified companies and the respective certification body who performed the audit have access to the full report.

All other user groups can only see the certification status of certified companies and use the following functions:

- Search for certified companies
- Manage their certified companies using a "favourites" option via "Supplier management"
- See the upcoming audit date of a company
- Receive important notifications and relevant lists that can be set individually.

The full report is only available if the certified company gives the permission to the respective user.

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 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 certified companies 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 e-mail notifications.

IFS
PACsecure

ANNEXES

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

IFS Food

Standard for auditing 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 packing.

IFS Broker

Standard for auditing persons and/or companies 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 auditing 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 risk for product contamination during the primary packing.

IFS Logistics

Standard for auditing 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 audit for IFS Food, IFS HPC or IFS PACsecure in combination with IFS Logistics.

IFS PACsecure

Standard for auditing 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 auditing 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.

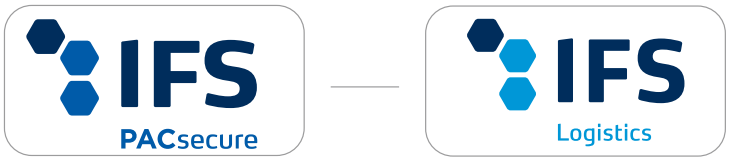
Scope determination between IFS PACsecure and other IFS Standards

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 Audit 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 audit IFS PACsecure/IFS Broker shall be performed. In the case of a combined audit, the company shall obtain two (2) reports and two (2) certificates.



IFS PACsecure and IFS Logistics

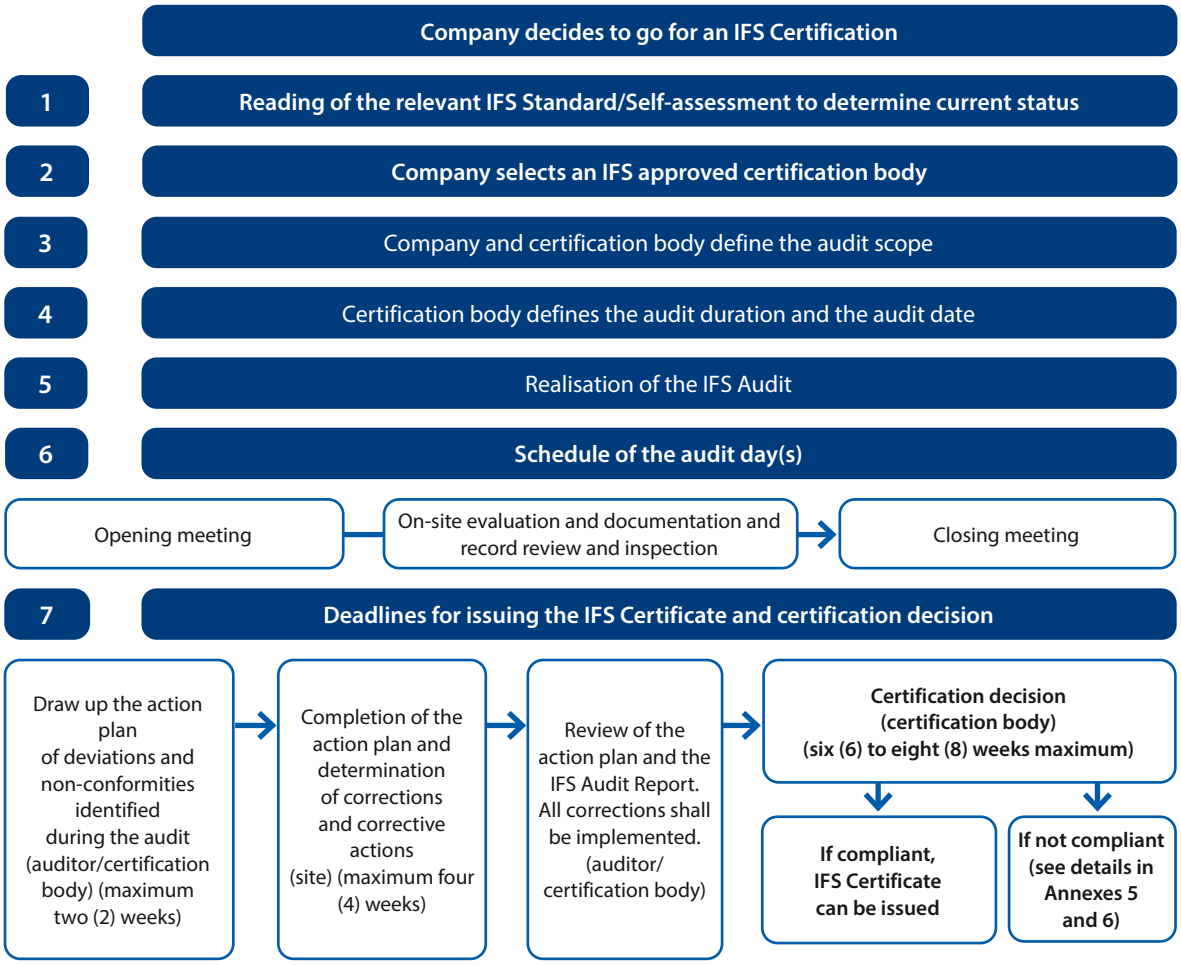
Clarifications/examples of scope application between IFS PACsecure and IFS Logistics:

- IFS Logistics only concerns logistics activities where companies have a physical contact with already primary packed products (transport, packaging of pre-packed products, storage and/or distribution, transport and storage of pallets, bags in box). It also applies for specific unpacked goods, such as bulk/tanker transport.
- For any kind of logistic processing services, meaning that the characteristics of the products are modified (or primary packaging is carried out), IFS Logistics is not applicable, except for specific logistic processing services.
- 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.

Notes:

- If the logistics activities owned by the packaging manufacturer are situated at the same physical location as the company, and if the company or the customer wishes to have this operation certified under IFS Logistics, then an IFS Logistics audit can be performed. In this case, the following requirements shall be fulfilled:
  - the logistics activities are only carried out for pre-packed products,
  - in case of two (2) certificates (IFS PACsecure and IFS Logistics), the respective scope of each audit and certificate shall be clearly defined,
  - the requirements of IFS PACsecure concerning transport and storage shall be evaluated during the IFS PACsecure Audit in any case,
  - an IFS PACsecure Audit of the packaging manufacturer shall be performed; IFS Logistics is an additional audit (but can be combined).
- If the logistics activities owned by the packaging manufacturer are situated off-site, then the company has the following three possibilities:
  - include it under the scope of IFS PACsecure and clearly stating its decentralised structure in the company profile of the IFS PACsecure Audit Report,
  - not to audit it but to state clearly in the company profile that this site is not IFS Logistics certified,
  - conduct an IFS Logistics Audit.

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 audit 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 production/conversion processes that are managed under the responsibility of the legal entity, on the same location, shall be included in the scope of an IFS PACsecure Audit.

All processes shall be audited as the exclusion is related to the final processed/converted product. The key concept is the evaluation of the product risk analysis that is exceptionally possible to exclude and that doesn't have any impact on product safety and quality.

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

Only in those exceptional situations where the IFS PACsecure Audited Company would like to exclude product(s) from the IFS PACsecure Audit Scope, shall the following questionnaire be filled in by the certification body.

Exclusions, when defined and validated by the certification body (after submission of this questionnaire), shall always be explained in the company profile of the audit report and shall be clearly specified in the audit scope of the audit report and certificate.

If product exclusions are defined (under exceptional circumstances and application of this questionnaire), they shall always have to be re-defined and reviewed each year by the certification body to ensure that the product exclusion is still valid and that the audit scope is still up-to-date.

Moreover, 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.

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

In any case (if some exclusions are defined or not), the number of employees to be taken into consideration to determine audit duration shall always be the total number of employees (and not only the number of employees involved in the activity which is not excluded).

Any exclusion which would not have been justified and noticed by the auditor during the audit, shall be audited either directly during the audit (with a necessary review of audit scope and maybe audit duration) or later through an extension audit.

Note 1: The only exception to this rule is seasonal process(es), which can be excluded, as long as the scope of the certification is unambiguous and only takes into account the process assessed in functioning.

Note 2: By definition, all products which are not specified in the Annex 3 are excluded from the scope of the IFS PACsecure Audit. Those products shall not be specified on the IFS Certificate as exclusions and shall only be described in the company profile of the audit report.

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

If, under exceptional circumstances, the company decides to exclude specific product ranges from the scope of the IFS PACsecure Audit, the following questionnaire has to be filled in by the certification body to check if any exclusions are allowed. The filled in questionnaire shall then be part of the audit plan.

Company name: _____ COID: _____

Planned audit scope: _____ Planned audit date: _____

Date of questionnaire validation: _____

Product/group of products excluded: _____

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

Name of the company employee who requested the 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 the hazard and risk management system identical for seasonal/sporadic products and regular products?

- ☐ No
- ☐ Yes → **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 audit 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 audit scope?

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

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

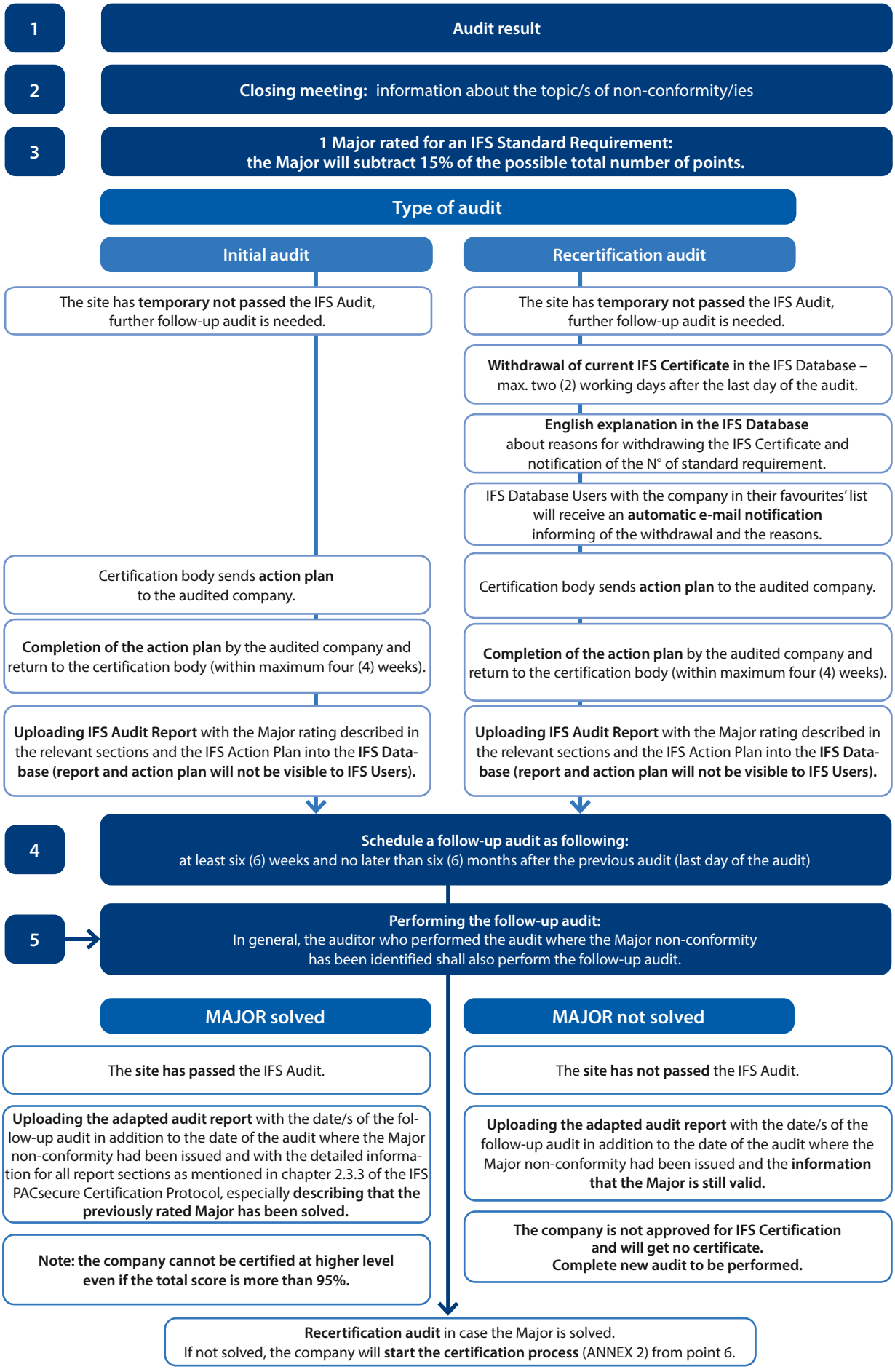
The manufacturer shall demonstrate the control of contamination risks between excluded and included products (allergens, chemical, physical, microbiological hazards, also at the level of storage and warehouse). Process flow chart related to the product to be excluded shall be sent to the certification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

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

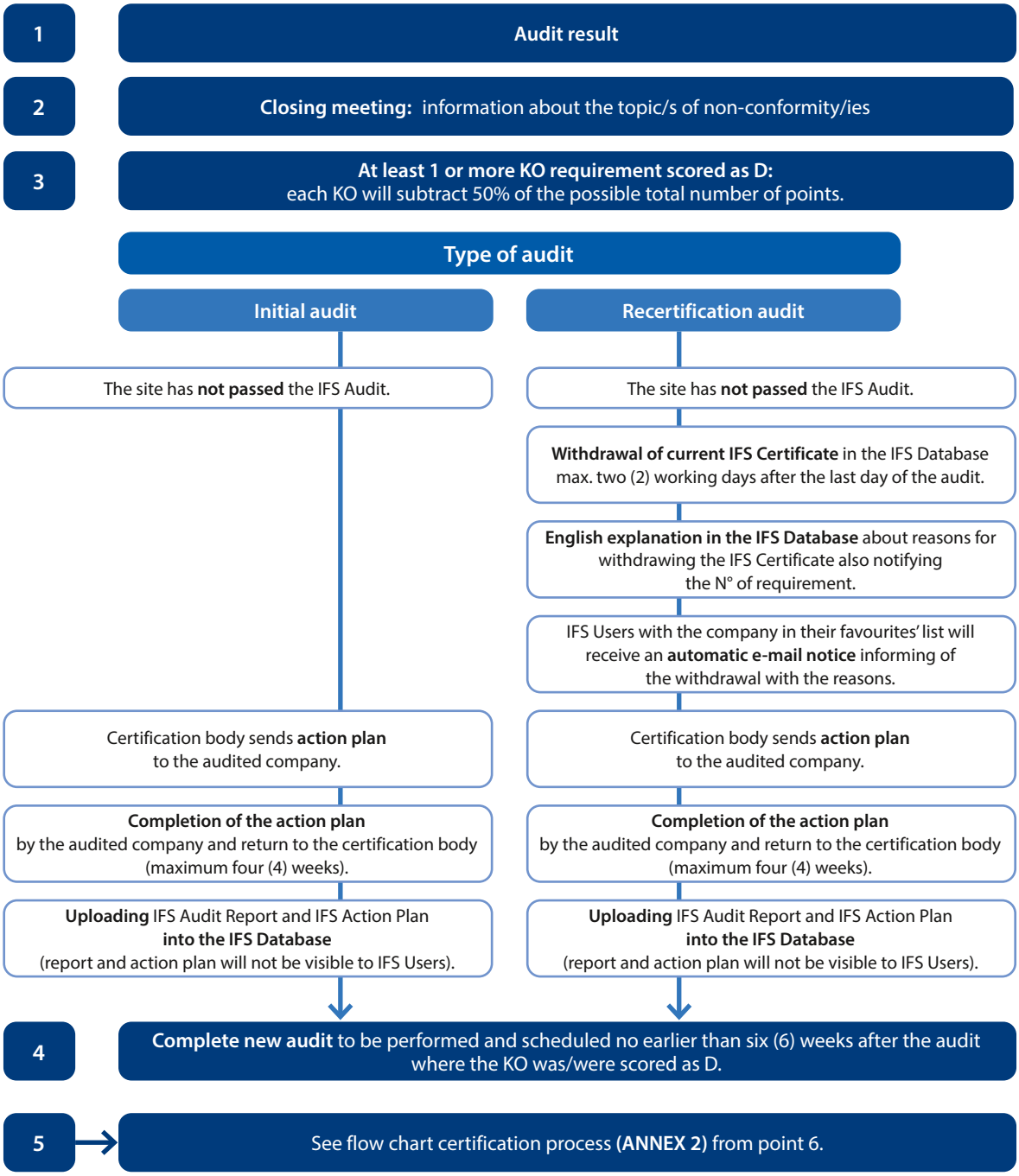
Exclusion is NOT possible

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%



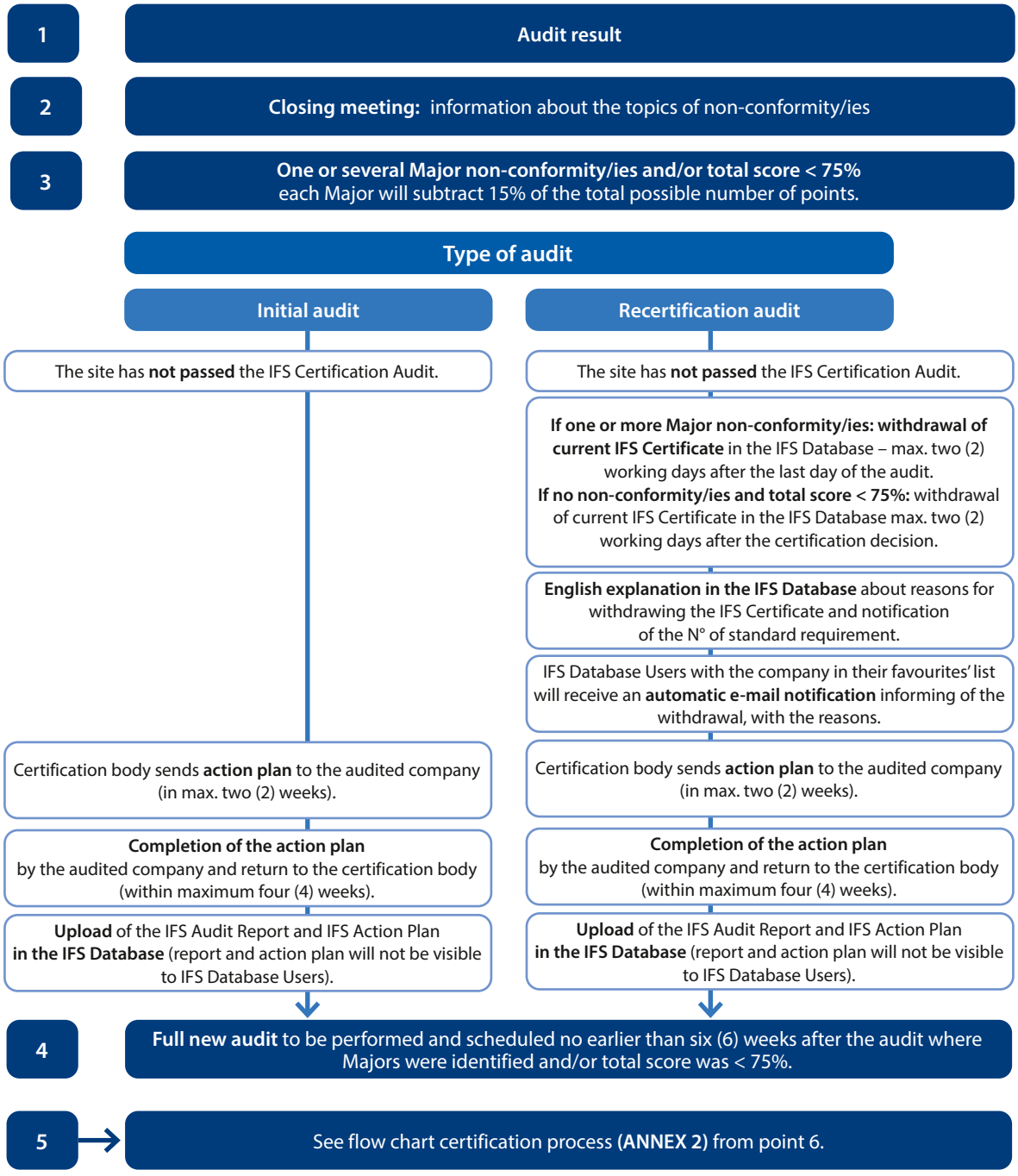
ANNEX 6: Flow chart for management of KO requirement scored with "D"



ANNEX 7: Action plan

N° of the requirement	IFS Requirement	Evaluation	Explanation (by the auditor)	Correction (by the company)	Responsibility (by the company)	Date (by the company)	Status of implementation	Corrective action (by the company)	Responsibility (by the company)	Date (by the company)	Release (by the auditor)	Validation date (by the auditor)
1.1.2	The corporate policy shall be broken down into specific …	C										
1.2.1	KO No 1: The senior management shall ensure that employees…	KO/B										
1.2.5	The senior management shall have implemented a system…	B										
1.3.1	The senior management shall ensure that the product safety…	**D**										
2.3.6.1	A hazard analysis and risk assessment shall be conducted for all possible…	**Major**										
2.3.9.1	KO No 2: Specific monitoring procedures in terms of method…	**KO/D**										

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



ANNEX 9: IFS Audit Report: audit overview

Cover page

Logo of the certification body

IFS PACsecure Version 3
February, 2024

Final IFS Audit Report
Announced/Unannounced

Audited company: "Paperboard Solutions Ltd"
[GS1 GLN(s) and legal authorisation number, where applicable]

Date of audit: 02.09./03.09.2024

Name and address of certification body

Accreditation number of the certification body

Audit Overview
IFS PACsecure Version 3, February 2024

Audit details

Lead auditor: Max Mustermann date/time: ***Co-auditor:*** date/time: ***Trainee:*** ***Witness auditor:*** ***Reviewer:*** ***Interpreter:*** ***Technical expert:***	***Date/time of current audit:*** 02.09.2024 (09:00–11:00) 02.09.2024 (13:00–18:00) 03.09.2024 (08:30–13:30)	***Date/time of previous audit:*** 09.03.2023 (09:00–18:00) 10.03.2023 (08:30–12:30) ***Certification body and auditor of previous audit:*** 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 audited 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 audit

Sheeting, printing, laminating, die-cutting, windowing and glueing of laminated/coated paperboard packaging intended as primary packaging for food 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]
Decentralised structure(s): [yes/no] and [description]
Multi-location production sites: [yes/no] and [description]

Final result of the audit

As a result of the audit performed on 02. 09. and 03. 09. 2024, "xyz" found that the processing activities of **Paperboard Solutions Ltd** for the above-mentioned scope of audit comply with the requirements set out in the IFS PACsecure Standard, Version 3, at **Foundation level**, with a score of XX %.	Recertification audit between XX. XX and XX. XX in case of announced audit and between XX.XX and XX.XX in case of unannounced audit.

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

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

Company profile
Company data
Year of construction of the audited 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 audited 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 audited 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 audited 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", provide 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):
Additional information:
Audit data
Language in which the IFS PACsecure Audit was conducted:
Audit duration (only for IFS PACsecure Audit):
In case of reduction/extension of audit duration, justify:
Which products were produced, and which processes have been running during the on-site evaluation?
Additional information:

ANNEX 10: IFS Audit Report: main content

IFS PACsecure
Version 3, FEBRUARY 2024

IFS Audit Report

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

	Chapter 1	Chapter 2	Chapter 3	Chapter 4	Chapter 5
	Governance and commitment	Product safety and quality management system	Resource management	Operational processes	Measurements, analyses, improvements
KO Non-con-formities	0	0	0	0	0
Major non-con-formities	0	0	0	0	0
A	0	0	0	0	0
B	0	0	0	0	0
C	0	0	0	0	0
D	0	0	0	0	0
N/A	0	0	0	0	0
Result per chapter (%)					

Overall summary: Table of compulsory fields for specific defined IFS PACsecure Audit Requirements and Key Elements

Part of the IFS Audit Report	N° of IFS PACsecure V3 Require-ment	Compulsory information to be added
Policy	1.1.1	Summary*
Corporate structure	1.2.1 KO 1	Summary*
	1.2.3	Summary*
	1.2.5	Summary*
	1.2.6	• Name of the competent authorities: [name] • Last visit of the competent authorities (even if it occurred more than 12 months ago): [date] • Have there been any mandatory actions connected to product safety, product fraud and/or legality of the product(s) ? [yes/no]
Management review	1.3.1	Summary*
Document Management	2.1.1.3	Summary*
Records and documented information	2.1.2.2	Summary*
Hazard and risk management system	2.2.1.1	Summary*
	2.2.1.2	Summary*
	2.3.8.1	Summary*

	2.3.9.1
	KO 2
		• CCP [number]:
		  ◦ process step: [information]
		  ◦ control method: [information]
		  ◦ critical limit(s): [information]
		  ◦ control frequency: [information]
		In case of N/A evaluation, provide explanations.

	2.3.11.2	Summary*
Personal hygiene	3.2.1	Summary*
	3.2.2 KO 3	Summary*
Training and instruction	3.3.1	Summary*
	3.3.2	Summary*

Part of the IFS Audit Report	N° of IFS PACsecure V3 Require-ment	Compulsory information to be added
Staff facilities	3.4.1	Summary*
	3.4.5	Summary*
Customer focus and contract agreement	4.1.3 KO 4	Which of the following 6 types does the customer agreements relate to [tickbox]: • product formula/configuration (including raw material characteristics) • process • technological requirements • testing and monitoring plan • wrapping • labelling **Note:** In case no customer agreements have been defined, N/A evaluation is possible.
Specifications/ finished products	4.2.1.2	• The following finished product specifications (minimum 2) have been reviewed during the evaluation: [product/last date of update] • The finished product specification(s) for retail brands which have been reviewed during the evaluation have been agreed with the customers: [yes/no]
Specifications/ raw materials	4.2.1.3 KO 5	• The following raw material specifications (minimum 5, based on the identified risks, more might be necessary) have been reviewed during the evaluation: [add material and last date of update] • Summary*
Special claims/ statements	4.2.1.5	• There are specific requirements from clients for claims: [yes/no]/ [list] • There are specific requirements from clients that certain treatment or manufacturing methods are excluded: [yes/no]/[list]
Product development	4.3.2	Summary*
	4.3.3	Summary*
Purchasing	4.4.1	Summary*
	4.4.3	Summary*
	4.4.4	Summary*
Product wrapping	4.5.1	• List the kind of wrapping materials in contact with products, used for finished products. [list]
Factory location	4.6.1	Summary*
Constructional requirements	4.9.1.1	• General summary of the conditions of the infrastructure: general condition, control measures, monitoring, what is the risk for product contamination, etc. [Description]

Part of the IFS Audit Report	N° of IFS PACsecure V3 Require-ment	Compulsory information to be added

Water	4.9.9.1	• Origin of the potable water/used water:
		• Own source: [yes/no]
		• Local water supplier: [yes/no]
		• Internal laboratory: [yes/no]
		• External laboratory: [yes/no]
		• Frequency of water analyses: [information]
		• Performed analyses:
		  ◦ Microbiological (parameters): [list]
		  ◦ Chemical (parameters): [list]

Compressed air and gases	4.9.10.1	Summary*
Cleaning and disinfection	4.10.1	Summary*
	4.10.4	Summary*
	4.10.5	Summary*
Waste management	4.11.1	Summary*
	4.11.6	Summary*

Foreign material risk mitigation	4.12.1 KO 6	• To control and mitigate the risk of foreign material contamination, the company uses the following equipment and methods: [list of equipment and location]
		• For foreign material detectors which are not defined as CCP, the following test pieces and sizes are used:
		  ◦ Iron: [size or range of sizes]
		  ◦ Non-iron: [size or range of sizes]
		  ◦ Stainless steel: [size or range of sizes]
		  ◦ Others: [material/size or range of sizes]
		• If no foreign material detection equipment is available, the following measures to mitigate the risk of foreign material contamination have been implemented: [list]

Pest monitoring and control	4.13.2	• External service provider: [yes/no] • Pest monitoring activities are carried out internally by own employees: [yes/no] • Frequency: [daily, weekly, monthly] • Inspections include: [target organisms] • Last inspection: [date] • The inspection reports show no particular pest activities inside facilities since the last IFS Audit. [or] The inspection reports show pest activities inside facilities since the last IFS Audit with the following actions: [kind of action(s)]

Part of the IFS Audit Report	N° of IFS PACsecure V3 Require-ment	Compulsory information to be added
Receipt and storage of goods	4.14.1	Summary*
	4.14.2	Summary*
Transport	4.15.1	Summary*
Maintenance and repair	4.16.1	Summary*
Equipment	4.17.1	Summary*
Traceability	4.18.1 KO 7	• During the evaluation, the following traceability test was conducted as initiated by the auditor. • Origin of the product sample: • Selected on-site by auditor: [yes/no] • Finished product: [article n°/product/batch (or lot) n°/production date] • Based on the traceability sample that was used to verify upstream and downstream traceability (from delivered products to raw materials, and vice versa) the given time could be proven; including wrapping materials and mass balance: [time] • The following raw materials and wrapping material specifications have been checked within the framework of the traceability test: ◦ [material/date or version of specification] • The result of the traceability test during the evaluation has been found to be compliant.
	4.18.2	Summary*
Allergen risk mitigation	4.19.2	• Allergens present at the site: [list] • Mitigation measures in place: [list]
Product fraud	4.20.2	• Raw material groups/product groups that were identified as risky in the vulnerability assessment: [list] • Criteria that were selected in the vulnerability assessment: [description] • Details of the vulneability assessment (dates, responsibilities, points of discussion, etc.):
	4.20.4	Summary*
Product defence	4.21.2	Summary*
Internal audits	5.1.1 KO 8	Summary*
Site factory inspections	5.2.1	Summary*
Process valida-tion and control	5.3.3	Summary*

Part of the IFS Audit Report	N° of IFS PACsecure V3 Require-ment	Compulsory information to be added
Measuring and monitoring devices and inspection equipment	5.4.1	Summary*
	5.4.2	Summary*
Quantity control monitoring	5.5.1	• Frequency and methodology of quantity checking: [description].
Product, testing and environmental monitoring	5.6.1	• Internally: the following analyses are performed: [analytic parameter or group of parameters] • Externally: the following analyses are performed: [analytic parameter or group of parameters]
	5.6.2	• List of parameters of environmental monitoring program: [list]
	5.6.3	Summary*
Product release	5.7.1	Summary*
Management of complaints	5.8.1	Summary*
	5.8.2	• Product complaints (within 12 months): • Total: [number] • From consumers: [number] • From retailers/customers: [number] • From authorities: [number incl. complaint reasons] • Main reasons for complaints from consumers/retailers: [list top 3] • Foreign body complaints (within 12 months): [number] [type of foreign body] • Foreign materials with most frequent complaints: [list top 3]
Withdrawal, recall, incidents	5.9.1 KO 9	• Number of withdrawals performed since the last audit: [number] • Number of recalls performed since the last audit: [number] • Cause of withdrawals: [description] • Type of product safety issue in case of recalls: [description]
	5.9.2	Summary*
Management of non-conforming products	5.10.1	Summary*
Management of deviations, non-conformities, corrections and corrective actions	5.11.1	Summary*
	5.11.3 KO 10	Summary*

Part of the IFS Audit Report	N° of IFS PACsecure V3 Require-ment	Compulsory information to be added
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 *: no free text but a summary that needs to be checked and validated by the auditor.

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 all requirements considered as not-applicable (N/A):

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

Detailed IFS Audit Report:

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

ANNEX to the IFS Audit Report

List of key participants:

Audit 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 3, Part 1)

Scoring and issue of certificate (based on chart 6, Part 1)

ANNEX 11: IFS Certificate

Certificate

(Unannounced Audit)

PACsecure(★)
(if star status)

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 processing activities of

Name of the audited company

Address

(GS1 GLN(s) and legal authorisation number, where applicable)
COID, (head office name and address, if applicable)
for the audit 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 activities, provide the certification status by writing the sentence: "The company has own broker activities which are/are not IFS Broker/other GFSI recognised standard certified".

Number and name of the product scope(s)
meet the requirements set out in the

IFS PACsecure Version 3, February 2024

and other associated normative documents
at Foundation level/Higher level
with a score of XX %
IFS Star Status due to unannounced audit, if applicable
(+ star symbol to be added close to the IFS PACsecure Logo)

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

Audit date(s) (if relevant: plus date of the follow-up audit):

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

Date and place:

Name and signature of the responsible person at the certification body:

Address of the certification body:

Logo and/or name of the accreditation body and its registration number
Logo and/or name of the certification body

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)	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 9 major allergens recognised in the United States according to the 2009 U.S. Food and Drug Administration (FDA) Model Food Code, Definitions section, page 12 and the FASTER Act, 2023. (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, sesame 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).
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 Standards, conformity assessment body is named certification body.

Terms	Related definitions
Audit	Process for obtaining relevant information about an object of conformity assessment and evaluating it objectively to determine the extent to which specified requirements are fulfilled. It includes any applicable evaluation activity, such as inspection, testing and management system audit.
Audit time window (unannounced audit)	Time period during which the unannounced audit may be performed. The date of reference for this time window is the audit due date (the date of first certification audit) in an audit cycle. Within the IFS PACsecure Certification Protocol (Part 1), the time window is [– 16 weeks; + 2 weeks] of the audit due date.
Batch (or lot) number	A unique combination of numbers, letters, and/or symbols given to products manufactured in the same batch/production unit and allows the history of production to be traced. **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.
Blackout period	Period of time that can be notified by the company to its certification body in which the unannounced audit cannot take place. This includes a maximum of ten (10) operational days when the production site is not available for audit (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 audit. The certification body will decide if the unannounced character of the audit is fulfilled.
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.
CCP (Critical Control Point)	A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in the hazard and risk management system.

Terms	Related definitions
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 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 microorganisms, 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 accuracy, honesty, fairness and legal compliance • they 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 claims and information to be added in the scope of the IFS PACsecure certificate, see chapter 2.2, Part 1.
Cleaning	The removal of soil, residue, dirt, grease or other objectionable matter.
Company	Any establishment which can be constituted by one or several production sites in which any stage of production and distribution of product is carried out. The company can have one or several legal entities registered and/or approved by the relevant authority on behalf of the business operator.
Composition	Quantified list of raw materials/components used to define the semi-finished or the finished product and how these are brought together (e.g. batch formulation, configuration, etc.).
Contamination	Introduction or occurrence of a contaminant in product or product environment. A contaminant can be any biological, chemical or physical agent, foreign material, or any other substances not intentionally added to product that may compromise product safety or suitability. Contamination can also mean correlation of wrapping among themselves.
Contractor	A company or person who is contracted by the company to carry out work for the site.

Terms	Related definitions
Control measure	Any action or activity that can be used to prevent or eliminate a hazard and/or risk or reduce it to an acceptable level.
Converter	A manufacturer that takes raw materials and converts them into a usable packaging article or packaging material (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. For the action plan of the IFS Certification Audit, the correction shall be implemented, at latest, before the certificate is issued.
Corrective action	Action to eliminate the cause of a detected deviation and/or non-conformity. For the action plan of the IFS Certification Audit, the corrective action shall be implemented, at latest, before the recertification audit.
Critical Limit	A criterion, observable or measurable, relating to a control measure at a CCP which separates acceptability from unacceptability of the product.
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.
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	Off-site facility (for example a workshop) owned by the company where part(s) of the processes and operations of the production site take place.
Deviation	In the IFS PACsecure Standard: Non-compliance with a requirement, without any impact on product safety related to products and processes. Deviations are requirements scored with a B, C, D and KO B requirements.
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 used in the production or manufacture of product(s).

Terms	Related definitions
Food contact packaging materials	Materials that: • are intended to be brought into contact with food or • are already in contact with food and were intended for that purpose or • can be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.
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 brand or customer brand by a different production site than the one being audited.
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.
HACCP plan	Documentation or set of documents, prepared in accordance with the principles of HACCP, to ensure control of significant hazards in the food business.
Hazard	A biological, chemical or physical agent in the product, 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 identified in raw materials, the environment, in the processing of or in the product and conditions leading to their presence, to decide whether or not they are significant hazards.
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 safety, product quality, legality and authenticity; or any force majeure event (e.g. critical resources/services disruption, natural disasters, loss, emergency situations, crisis, etc.) with a direct impact on delivering of trusted products.

Terms	Related definitions
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 audited 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 audit is an independent and objective assurance activity that is designed to add value and improve the operations of any organisation. It helps an organisation 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 safety, product quality, legality and authenticity.
Legal entity	A legal entity is the registered office of the packaging business where, according to agreement, the business operator has its administrative center. It generally identifies the place where the administrative organisation of the company is located.
Location	One physical address where the production site(s) is/are situated.
Mass balance	Test performed to measure the input quantity of raw materials (which remains in the finished product, even in the modified form) and outputs of finished products during a traceability test.
Monitoring	Determining the status of a system, a process, a product, a service or an activity. For control measures defined for a CCP and other control measures: the act of conducting a planned sequence of observations or measurements of control parameters to assess whether control measures defined for a CCP and other control measures are under control.

Terms	Related definitions
Non-conformity	In the IFS Standard, defined non-conformities are Major non-conformities and D evaluations of a KO requirement. Non-conformity can be given in case of: • non-respect of legislation, • product safety issues, • internal dysfunctions, and • customer issues.
Non-operating periods	Periods when the production lines are not operating at all, e.g. planned maintenance work, bank holiday, planned production site shutdown for holidays, etc.
On-site evaluation	Inspection and audit of the production area of the production site, which includes the following areas and/or activities: • Production/conversion processes, • Receipt, storage and dispatch areas, • Good Manufacturing Practices (GMP), including maintenance, hygiene, pest control and cleaning and disinfection activities, • Product development, • On-site laboratory, • Maintenance facilities, • Staff and sanitary facilities, • External areas.
Packaging materials	Any material, including printed material, used to: • Contain goods, which depends on their physical form and nature • Protect and prevent goods from mechanical damage due to the hazards of distribution • Preserve the goods, to prevent or inhibit chemical changes, biochemical changes and/or microbiological spoilage • Inform and communicate about the goods (e.g. legal requirements, product ingredients, usage, brand communication, etc.) • Extend the shelf life or to maintain or improve the condition of goods (e.g. active food contact materials) • Monitor the condition of the packaged goods or the environment surrounding them (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 materials and labelling are also considered as production steps: if carried out outsourced, these shall be considered as partly outsourced processes.
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.

Terms	Related definitions
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 conceived so as to constitute a sales unit to the customer or consumer.
Product	Result of a process or activities transforming inputs into outputs. It comprises wrapping materials used in product. In the IFS PACsecure Standard: "Product" is the term used to refer to the packaging components and/or packaging materials covered by the scope of application of the IFS PACsecure Standard (see Part 1, chapter 2.2, and Annex 3).
Product defence	Procedures implemented to ensure the protection of products and their supply chain from malicious and ideologically motivated threats.
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 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/ conversion processes.
Product fraud	The intentional substitution, mislabelling, adulteration or counterfeiting of product, raw materials or wrapping materials placed upon the market for economic gain. This definition also applies to outsourced processes.
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 materialsand wrapping materials.

Terms	Related definitions
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 materials, 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 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, legality and authenticity.
Product safety culture	Shared values, beliefs and norms that affect mindset and behavior toward product safety in, across and throughout an organisation. 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, at 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.

Terms	Related definitions
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 and disinfection activities, • Product development, • On-site laboratory, • Maintenance facilities, • Staff and sanitary facilities, • External areas.
Production site or site	An establishment in a specific physical location where the IFS PACsecure Audit is conducted in which any stage of production and distribution of products 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 defined by the company (including footwear and gloves) to protect the products from contamination, which is worn by employees, contractors and visitors.
Raw material	Any base material or semi-finished material used for the manufacture of a product. Raw materials include 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.
Resources	A stock or supply of money, materials, staff, and other assets that can be drawn on by the company in order to function effectively and continuously achieve objectives
Reviewer	Person of the certification body in charge of assessing the IFS Audit Reports before a certification decision is made. An IFS Reviewer is either an IFS PACsecure Auditor, or an IFS Auditor for any IFS Product Standard having taken part at the "IFS PACsecure Standard for Auditors" eLearning course, or an IFS PACsecure Pure Reviewer (if not an IFS PACsecure Auditor). The tasks of the IFS Reviewer are, at a minimum, to check: • The overall consistency of the IFS Audit Reports. • If the IFS Audit Reports are properly completed (e.g. compulsory fields, etc.). • If the findings are well described and in agreement with the evaluation. • If the corrections and corrective actions as well as the deadlines for implementation proposed by the audited production site have been validated by the auditor (or by a representative of the certification body) and are relevant. The review shall be documented.
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.

Terms	Related definitions
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, in order to identify the proper corrective action 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 sales units whether the latter is sold as such to the customer 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.
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 provider	Organisation that provides services to another company, for example, transport, storage, order picking control, cleaning and disinfection, etc.
Sign-off audit	First witness audit of an auditor after having passed the IFS Examination 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 Audit.
Significant hazard	A hazard identified by a hazard analysis, as reasonably likely to occur at an unacceptable level in the absence of control, and for which control is essential given the intended use of the product.
Staff facilities	Areas within a site, other than product handling areas, that are used by personnel, e.g. cloakrooms, toilets, canteens and restrooms.

Terms	Related definitions
Suspension (of IFS PACsecure Certificate)	Applies when the intention is to reinstate the exact same certificate (with same issue number, same validity, etc.) in case the suspension is lifted. Examples: • In case of pending investigations by the certification body, following a product safety incident or other event • For the certificates of all companies linked to a head office/central management, when a non-conformity is issued during the audit of the head office/central management • In case of non-payment of the current audit by the audited company.
System	Set of interrelated or interacting elements. A system is a planned, sustainable structured course of action. Depending on the complexity, documentation is recommended. A 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, semi-finished product, wrapping material) intended to be, or expected to be incorporated into a product, through all stages of production and distribution.
Traded products	Products manufactured, wrapped and labelled by and under a different company name to the production site being IFS PACsecure certified and which are not customer branded products.
Validation	Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Validation of control measures defined for CCPs and other control measures is obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome. **Note:** For pre-existing hazard and risk management systems, continuously conducted and documented verification procedures may act as a part of evidence of validation.
Verification	Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. The verification of control measures defined for CCPs and other control measures is 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.

Terms	Related definitions
Withdrawal (of IFS PACsecure Certificate)	Applies when it is neither intended nor possible to reinstate the exact same certificate (with same issue number, same validity, etc.). Examples: • When any information indicates that the products/processes may no longer comply with the requirements of the certification system especially in case of non-conformity(ies) identified during the audit (main or follow-up audit) or when access is denied (apart from force majeure). • In case the production stopped and moved to a new location. • In case of cancellation of certification contract (between the certification body and the company).
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.
Witness audit, to be performed every two (2) years, for approved IFS PACsecure Auditors (monitoring witness audit)	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 their 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 audit (as a team member). • shall be an experienced IFS Auditor (see requirements under chapter 3.4, Part 3). It is not mandatory for the auditor to be qualified for all product scopes of the audit. The certification body shall specify the name of the witness auditor in the participants' list of the IFS Audit 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 IFS Standard Audit or GFSI recognised certification standard audit in related scope accredited to ISO/IEC 17065:2012 norm. **Note 1:** In case of an audit team in which the team can split during the audit (as both auditors have company's product scope(s)), it is not possible to perform a witness audit, as the auditor who is witnessed doesn't perform a full IFS Audit. But if the team does not split, it is possible to perform a witness audit for the lead auditor, as it will be possible to witness the auditor during a full IFS Audit. **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 Audits can also be accepted.
Wrapping materials	In the IFS PACsecure Standard: "Wrapping materials" is the term used for the material which is utilised to package the product sold by the audited company. If they are removed, the quality, safety and/or legality of the products are affected.

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