IFS HPC

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Standard for auditing personal care and household products and processes compliance in relation to product safety and quality

VERSION 3

DECEMBER 2022

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 assessment of food suppliers. The audit provided a uniform approach towards food suppliers. This was the first version 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 sectors. 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 HPC Standard covering household and personal care products was first introduced in 2009 to complement the IFS Standards Portfolio.

0.2 IFS Objectives, Mission and Vision

The aim of IFS Certification is to assess whether the processes of a manufacturer are able to produce products that are safe, legal and in compliance with customer specifications. That is why both, product safety and quality, are essential components of all IFS Standards. The IFS Audit is product and process focused and ensures that the development of high-quality products is ensured 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 globalization, in addition to the constantly growing significance of the private labels the retailers are responsible for. An IFS Certification enables the reduction of costs of long repetitive audits and additionally supports company management by means of uniform reports and a modern, user-friendly database.

The mission of IFS clearly states that IFS Standards go beyond product safety with the aim to "deliver trusted products", which fulfil the expectations of the buying company.

With the objective that an IFS Certificate demonstrates that the production site has implemented a functional product safety and quality management system, IFS together with its large network is continuously increasing and optimizing its portfolio of standards, 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.

0.3 History of the IFS Household and Personal Care Standard (IFS HPC)

Customer expectations have increased in terms of product safety and quality of the household and personal care products. As these products have a direct impact on consumer health and safety, buyers and retail quality managers decided that more transparency was needed in the way these products are produced and give more confidence to the market.

IFS along with international stakeholders (industries, retailers, auditors, etc.) from Germany, France, Spain, Switzerland and Italy have developed this third version of the IFS Household and Personal Care Products Standard (IFS HPC).

This standard covers key aspects of the product safety and quality management system of companies manufacturing household and personal care products (e.g. risk assessment, good manufacturing practices, traceability, customer specifications, corrective actions, etc.).

The aim of this standard is to assess the safety and quality of household and personal care products and the compliance with the law and customer specifications. It is also intended to be used as a tool to support businesses to meet new requirements on quality, transparency and efficiency, and to improve product integrity along the entire supply chain.

It is possible to perform IFS HPC V3 Audits from 1st of June 2023.
From 1st of September 2023, the IFS HPC V3 is mandatory.

0.4 Coverage of the IFS HPC Standard

The HPC Standard is applicable to producers of household and personal care products (HPC products) and can only be used for processing companies and/or companies that pack loose HPC products. For more details on the IFS Audit Scope, see chapter 2.2, Part 1.

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

0.5 Content of the IFS HPC Standard

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

- Part 1: IFS HPC Certification protocol
- Part 2: IFS HPC Audit Checklist (list of IFS HPC Requirements)
- Part 3: Requirements for accreditation bodies, certification bodies and auditors
- Part 4: Reporting, IFS Software and the IFS Database.

The IFS HPC Standard is linked to the IFS HPC Doctrine which is another normative document. The IFS HPC Doctrine provides additional rules and clarifications on the interpretation of some requirements of the IFS HPC Standard. Both normative documents shall be implemented following the defined date of implementation after publication.

0.6 Review of the IFS HPC Standard

The IFS Technical Team and its working groups need to demonstrate control over the content and quality of the IFS HPC Standard. That includes review to ensure compliance with all relevant requirements. The working groups members represent all stakeholders involved in the audit process: retailers, HPC industries, certification bodies and experts.

Besides the review, the main objective for the working groups is to share practical experiences, review changes or alignments of the IFS HPC Standard and clarification needs for the IFS HPC Doctrine, discuss the requirements of the audit report and decide on training needs.

PART 1

PART 1
IFS HPC Certification Protocol

0 Purpose and content

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

1 The IFS HPC Certification process

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

The companies shall prepare in advance for the IFS HPC 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 HPC Audit Checklist (Part 2) to assess compliance with the product 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 list of audit requirements to determine the level of compliance of processes and products. An audit is always focused on the following fundamental elements:

1) **Product and process-based 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 HPC 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 HPC Audit.
   During the IFS HPC Audit, the auditor shall collect objective evidence to evaluate compliance with the IFS HPC Audit Checklist (Part 2).
   One of the key elements to ensure high uniformity between the application of the PPA is to follow an **audit trial**. This audit trail consists of the following main steps:

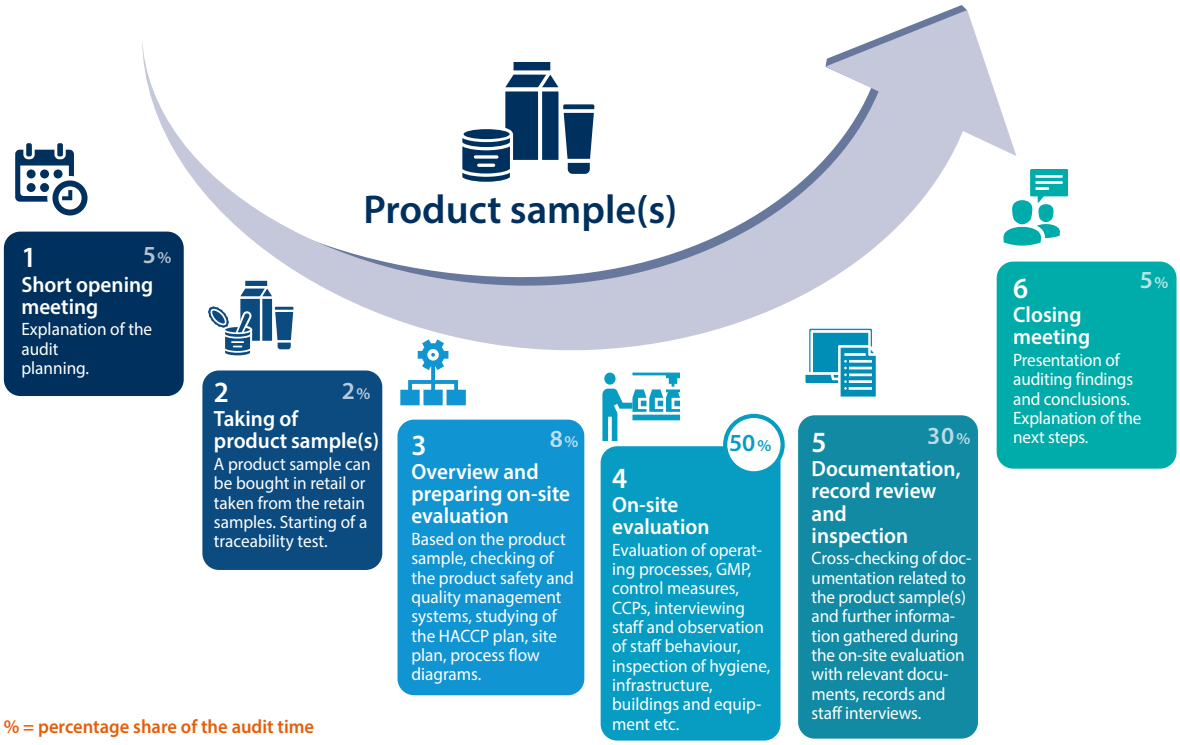
- **Product sampling:**
  The selection of samples shall be risk based but can also follow other criteria. The aim is to make a representative selection of all products and processes included in the certification scope to gain maximum information about the production site and its products.
  The use of relevant product samples (sampled by the auditor on-site in advance or at the beginning of the audit) is essential and allows the IFS Auditor to follow a uniform path to obtain all necessary evidence. In addition, auditors shall perform a traceability test on the sampled product(s) during the audit.

Note: IFS has published guidelines (IFS Auditor Guideline and IFS Good Auditing Practices (GAP) Guideline), which provide further information on topics to be checked and/or requested from the audited company during the IFS HPC 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 processes. It can be decreased to 1/3 if a site has simple processes and the total audit duration was reduced to a maximum of 1,5 days (see chapter 3.1, Part 1).
  The on-site evaluation of the production site shall include (but may not be limited to) the following areas:
  - Production 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:
  - Critical control points (CCPs) and other control measures as well as the corresponding monitoring records to cross-check them with the hazard analysis and risk assessment information
  - Observe and interview employees
  - Inspect product and technology characteristics
  - Take further samples for cross-checking, when necessary
  - Review recipes 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, 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".

Chart 1



% = percentage share of the audit time

2) IFS Auditor qualification

The specific expertise of the IFS Auditor 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.

3) Annual certification cycle

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

4) Certification by certification bodies accredited to the ISO/IEC 17065:2012 norm contracted with IFS Management GmbH

Reliability of the certification is guaranteed through accredited, internationally recognized, 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.

5) Surveillance and harmonised rules by the IFS Standard Owner

As part of the 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 ensures the quality and integrity of the implementation of IFS Standards. The different measures are undertaken following a risk-based approach as well as the management of complaints which have been raised by stakeholders. **The company shall be informed by its certification body about the procedures and rules of the IFS Integrity Program.** More information on the integrity program can be found in chapter 5, Part 1.

2 Before the IFS HPC Audit

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 IFS Requirements 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

To undertake an IFS HPC Audit, the company shall appoint an IFS approved certification body accredited to the ISO/IEC 17065:2012 norm for the IFS HPC Standard. The list of all IFS international 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 certification details.
- 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, see Part 4.

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

To ensure the high quality expected of an IFS HPC Audit, it is obligatory that at least one auditor is on-site who holds an active approval for the corresponding IFS Standard.
To assist the IFS HPC Auditor in preparing 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 HPC Audit including decentralised structures.
- Cases where parts of the production activities or products are outsourced to a third-party on behalf of the IFS HPC certified production site.
- Overview of the exported products, including the different destination countries where the products are sold to.
- Any request for exclusion of products from the scope of the IFS HPC Standard shall be carefully reviewed by the certification body to determine whether the exclusion is possible.
- History of the certification status, for example type of certification/scope, last unannounced audit, date of the last certification audit (even if performed by another certification body), if a certificate has been withdrawn in the past, etc.

More information on outsourced processes and exclusions can be found in chapter 2.2.2, Part 1 and Annex 4.
If the IFS HPC 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 about any changes that may affect their ability to conform to the certification requirements (e.g., recall, alert on products, organisation and management, modification to the products or the production method, contact address and production sites, new address of the production site etc.). The details shall be defined and agreed between both parties. As required in the IFS HPC Checklist (Part 2), requirement 1.2.5, some specific situations require a notification to the certification body within three (3) working days.

After receiving such information from the sites (limited to three (3) specific situations mentioned in the requirement 1.2.5 of the IFS HPC Checklist), the certification body shall:

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

The IFS HPC 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 the IFS HPC Doctrine.

2.2 Scope of the IFS HPC Audit

IFS HPC can only be applied when a product is "processed" or where there is a hazard of product contamination coming from primary packing.
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).

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. 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 2.2.3, Part 1**.

The selection of the product scope(s) depends on the final products manufactured by the production site. IFS HPC Standard relies on four product scopes. All applicable scopes shall be mentioned on the IFS HPC Certificate and Report.

Scopes of the IFS HPC Standard:
Scope 1: Personal care products
Examples: shampoos, toothpastes, cosmetics wipes, eau de cologne, perfumes, nail polishes, coverage creams, tanning products, eye liners, concealers, lipsticks, lubrication strip of shavers, shaving products, etc.

Scope 2: Household chemical products
Examples: pet care hygiene products, detergents, softeners, cleaning and polishing agents, pre-charged foam sponges, air fresheners, toilet rim blocks, aroma sticks, shoe polish, softeners, candles/scented candles, matches, household insecticides, etc.

Scope 3: Daily use household products
Examples: disposable table ware (cutlery, cups, etc.) or made of stainless steel, trash bags, toothpicks, napkins, kitchen roll papers, coffee filters, aluminium foil, baking paper, plastic food storage containers, household gloves, household sponges, scourers, brooms, mops, buckets, etc.

Scope 4: Personal hygiene products
Examples: menstrual cup, toilet paper, toothbrushes, diapers, combs, razors, hairbrushes, feminine hygiene products (tampons, sanitary pads, panty liners etc.), cotton pads, bath sponges, tweezers, manicure set tools, tissue papers, medical devices class I (like gauze/bandages, classic plasters, compresses—without the sterile condition, cotton wool, incontinence products) etc.

Note: For products out of the scope of the IFS HPC Standard, see Annex 3.

2.2.1 Details of the audit scope

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 rule:

- The different types of products shall be described in sufficient detail including description of the type of packaging materials (e.g. aerosol cans, PET bottles, folding cartons, etc.). General explanations like production of "cosmetic products" are not allowed, as this does not sufficiently describe information of the detailed company´s range of products.

The following elements shall not be mentioned in the scope:

- Certain activities of a production site are always part of the IFS HPC 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 a partly outsourced product.
- Brand information is not allowed as it does not provide any information to the products and processes of the production site.
- Reference to product certifications or labels/claims that are under specific regulations (e.g. organic, BPA free, FSC etc.) shall not appear in the scope on the certificate to avoid confusion on the scope of application of the IFS HPC Certification. Information on claims can only be provided in the report.
- Exclusion of production process(es) including storage and transport is not allowed.
- Exclusion of product(s) may be accepted under the following specific conditions which are listed in Annex 4.

2.2.2 Outsourced processes and IFS HPC Audit Scope

a) Partly outsourced processes:
A partly outsourced process is defined in the IFS HPC Standard as a production step or part(s) of a production process (including primary packing and labelling) that is carried out off-site by a third-party on behalf of the IFS HPC certified site. This includes processes which are partly outsourced by a sister company within the same company group and applies to both, customer branded products and the company´s own branded products.

- **Note:** 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 HPC Checklist (4.12 and 4.13), especially to the requirements 4.12.7 and 4.13.5.

The requirements applicable for the management of partly outsourced process (es) are described in Part 2 (requirements in section 4.4). In addition, the following rules apply:

- In the audit report of the audited site (audit overview): a description of the partly outsourced processes and certification status of the appointed third-party shall be provided.
- If the appointed third-party is IFS HPC certified, its COID (IFS Identification Code Number) can also be mentioned.
- On the certificate of the audited 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 Annex 11.

b) Fully outsourced products and traded products:
Fully outsourced products are products manufactured, packed and labelled (under the own company brand or customer brand) by a different production site to the one being audited.
Traded products are products manufactured, packed and labelled by and under a different company name to the production site being IFS HPC certified.

Fully outsourced products and traded products are not covered by the IFS HPC Certification.

It is recommended that these activities are certified under IFS Broker or any equivalent standard based on the ISO 17065:2012 norm (e.g. a combined IFS HPC / IFS Broker 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 equivalent standard certified"**.

2.2.3 Realisation of the IFS HPC 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:

- Single production site.
- Multi-location production sites.
- Multi-legal entity production site.
- Production site with decentralised structure(s).

1. **Single production site**
   A single production site is a site which is not centrally managed by a head office / central management, has only one legal entity and no decentralised structure(s).
   Such site shall have one audit, one COID, one report and one certificate.

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

   a) Company with head office / central management

   i. When the head office / central management has additional processing activities, the site shall be audited and subjected to an own IFS HPC Certificate and Audit Report.
   If there are no processing activities, the head office / central management cannot be subject to an IFS HPC Certificate. The company can decide 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 audit is performed at the head office, the company shall ensure that all necessary information and responsible personnel are available from the head office / central management (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 an audit is performed at the head office / central management, the following rules apply:
   - The audit of the head office / central management shall always take place before the audit of each production site.
   - The maximum period of time between the audit of the head office and the ones 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 site shall get an individual report and certificate.
   - 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 not fixed or 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 shall be linked to the head office / central management.

b) Company without head office / central management

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

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

3. Multi-legal entities production site

a) If a production site has multiple legal entities at one location with same scope, the following rules apply:

- One audit shall be performed.
- The report and the certificate 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 location, with different scopes, the following rules apply:

- Each legal entity shall have its own COID, report and certificate.
- The audit duration shall be calculated separately for each COID. A head office / central management can be appointed which may allow a reduction of audit duration by a maximum of 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 be suspended/withdrawn, unless the certification body can demonstrate that these are not impacted.

4. Production site with decentralised structure

A decentralised structure is a facility (e.g. 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 IFS Audit Report.

2.3 Type of HPC Audits

Different types of audits shall be conducted depending on the certification status and cycle of the production site. IFS HPC Audit (full on-site):
An IFS HPC Audit shall always be performed on-site (fully remote audits are not permitted) and during **consecutive working days**, for announced and unannounced audit options. For initial audits and/or first 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 certification audit. This also includes requirements where a yearly review is requested.

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). To perform such IFS Split Audit, the normative document "IFS Split Audit Protocol" shall be used and a justification shall be mentioned 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 HPC Certification Audit of a production site during which all the requirements of the IFS HPC Audit Checklist shall be audited by an IFS HPC approved Auditor. This type of audit is only applicable when there is no previous certification history available.

b) "New" initial audit
The audit which is performed:

- After an interruption of the certification cycle (see chapter 4.3, Part 1) or
- After a failed certification audit due to one or several non-conformity(ies) or a total score below 75%, or
- After a follow-up audit is failed
- After a failed extension audit

In this case, the following applies:

- The certification history (for IFS HPC) shall be checked.
- The audit report and action plan from the previous IFS HPC 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 HPC Audit is failed, the IFS HPC Report shall be uploaded in the IFS Database and this audit cannot be considered as pre-audit.

Audit option:
Initial audits can be performed on an announced or unannounced basis. For more information on audit options, see chapter 2.4.

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 and thorough audit of a production site, during which all the requirements of the IFS HPC Audit Checklist shall be audited by the auditor and lead to a renewal of the existing IFS HPC Certification. The period during which a recertification audit shall be performed is shown on the certificate and the audit shall be performed during this period to maintain the certification cycle.

It is the responsibility of the production site to renew their certification in due time. Therefore, all IFS HPC certified companies shall receive a reminder from the IFS Database, three (3) months before certification expiration.
If the audit is not performed in due time, all stakeholders with access to the IFS Database and with the respective company in their favourites list will receive an email notification.

The auditor shall review the action plan from the previous IFS HPC 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 from the previous audit 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 audit checklist, Part 2. The link between two (2) consecutive audits ensures a continuous improvement process.

Audit option:
Recertification audits can be performed on an announced or unannounced basis. For more information on audit options, see chapter 2.4

2.3.3 Follow-up audit

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

During the follow-up audit, the auditor shall focus 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 be generally performed by the same auditor who performed the main audit (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 full new initial audit shall be performed.

Audit outcomes:

- Successful follow-up:
  - The positive outcome 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
- Failed follow-up:
  - The report of the failed follow-up 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 6.

Note: The upload of a follow-up audit report is free of charge.

Audit options:
Only announced is possible.

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 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 hazard analysis / risk assessment (especially CCP's if existing) different than the ones audited by the auditor 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 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 differ 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 and safety risks and shall be documented.

Audit outcomes:
Conditions for passing an 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. It shall keep the same expiry date as the certificate of the main audit.

The extension audit is failed in the following situation: in the event of one (1) or more non-conformity(ies).

The updated certificate and extension audit report shall be uploaded in the IFS Database.
In addition, the following consequences shall be enforced:

- The full audit (including the initial/recertification 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 uploading of an extension audit report is free of charge.

2.4 IFS HPC Audit options

Before scheduling and performing the IFS HPC Audit, the production site shall decide whether the audit shall be conducted on an announced or unannounced basis.

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 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 company to ensure the unannounced character of the audit. **The production site shall inform its certification body about the unannounced registration 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). 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 (a notification will be sent to the favourites list when this status is obtained).
The status will be withdrawn once an announced audit takes place.

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

These are the rules that apply in case of unannounced audit:

- The production site shall provide the certification body with the name(s) of the on-site person(s) to be contacted at the production site.
- The production site can provide a 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) 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 at latest four (4) weeks before the start of the unannounced audit time window and cannot be changed at a later stage.
- If a production site produces seasonal products and has registered for the unannounced audit option, the expected seasonal production dates shall be notified to the certification body and the time window [– 16 weeks, + two (2) weeks] does not apply. These companies are not permitted to provide a blackout period (see chapter 2.5, Part 1) to the certification body. 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 having access to the IFS Database and with the respective production site in their favourites list will receive a 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 shall be invoiced by the certification body for the total cost of the audit.

2.4.2.1 Registration unannounced audits for multi-location production sites with a head office / central management:

- 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 is audited through 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 is audited through 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 table below:

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**
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 (1) 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 HPC 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 shall be notified by the company at latest four (4) weeks before the start of the audit time window. All audit days shall be in the time window to validate 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.
The audit time schedule shall:

- Include the audit duration,
- Include appropriate details on the audit scope,
- 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 IFS 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 an 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 the type of ICT (Information and Communication Technologies) used to evaluate the checklist requirements.
- If the IFS HPC Standard 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.

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

3 IFS HPC Audit realisation

The realisation of the IFS HPC 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 (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 the hazard analysis / risk assessment (especially CCPs, if existing) 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 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 total possible maximum number of employees over a year
- Number of deviations and/or non-conformities found in the previous audit
- Etc.

In all cases, the minimum IFS HPC Audit duration 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.

At least 50% of the total IFS Audit duration shall be allocated to the on-site evaluation (within the production areas of the physical site) to allow the auditor auditing comprehensively the products and the processes. This time on-site can be decreased to 1/3 if a site has simple processes. In any case, the certification body / auditor shall justify the decision for a reduction in the IFS Audit Report.

Factors that may reduce audit duration:
Under specific situations, **and only in one of the limited following cases**, the certification body **may decide to reduce the minimum calculated audit duration** by 0,5 day:

a) IFS combined Audits (e.g. IFS HPC / IFS Broker or IFS HPC / IFS Logistics) under the condition that some parts are already audited for one of the standards.

b) Multi-location companies: in the case requirements have already been audited at the head office / central managing site.

c) Multi-legal entity production site in case the legal entities have different scopes at one physical location, a head office / central management can be appointed which may allow a reduction of audit duration by maximum 0,5 days (as for the multi-location approach).

d) For a site having simple processes (e.g. companies only assembling packaging and introducing the product within the packaging, or having only one specification, one client….).

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

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

- Two (2) hours for audit preparation.
- Six (6) hours for audit report writing.

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

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 thirty (30) minutes after entering the site).

- **Evaluation of existing product safety and quality management system:** achieved by checking documentation (hazard analysis / risk assessment, quality management documentation, etc.).
- **On-site evaluation**: detailed observation of all on-site production area, production lines and production processes, which includes interviews with the working personnel and the gathering of information on key process parameters, such as the monitoring of critical control points (if existing) and control measures to be cross checked with the hazard analysis / risk assessment information.
- **Documentation and record review and inspection**: evaluation of documents and procedures, cross checking of documents and records based on investigations and findings from the on-site evaluation.
- Final conclusions drawn from the audit.
- **Closing meeting**: end of the audit, the auditor (or lead auditor for an audit team) shall present all findings and discuss all deviations and non-conformity (ies) 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. At the opening and closing meetings the most senior manager shall be present 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 HPC Standard which will be used as the basis for the audit report.

IFS requires certification bodies / auditors to provide a mandatory document which 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 date.
- be signed by a representative of the company, auditor(s) and if applicable from trainee(s), auditor in progress, auditor under observation, witness auditor 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

To determine whether compliance with a requirement of IFS HPC Checklist has been met, the auditor shall evaluate all requirements of the checklist (Part 2), which are classified either as regular requirements or as KO requirements.
The IFS Scoring System covers a scoring range based on the level of compliance of the requirement, from full compliance to a deviation and/or non-conformity.

In the IFS HPC Standard, there are six (6) scoring possibilities and the option of not-applicable (N/A). Points are awarded for each requirement according to the following chart:

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 given to any regular requirement (which is not defined as a KO requirement) Reasons for Major rating are: • There is a substantial failure to meet the requirements of the standard, which includes but is not limited to product safety and/or the legal requirements of the production and/or destination countries • A process is out of control which might have an impact on product safety	Major non-conformity will subtract 15% of the possible total amount; the certificate cannot be issued
KO requirement scored with a D (non-conformity)	The requirement is not implemented	KO non-conformity will subtract 50% of the possible total amount; the certificate cannot be issued

KO requirements
There are specific requirements in the IFS HPC Standard which are named KO requirements. These requirements are essential and address key topics to be ensured by the production site to reach compliance.

In the IFS HPC Standard the following six (6) requirements are defined as KO requirements:

1.2.1 Governance & Commitment

2.2.3.8 Monitoring system of each CCP

4.2.2.2 Finished product specifications

4.16.1 Traceability

5.9.1 Procedure for product recall, withdrawal and incidents

5.11.2 Corrective actions

Scoring of KO requirements is explained in the following chart:

Chart 4: Scoring of a KO requirement

Scoring	Explanation	Points
A	Full compliance	20 points
B (deviation)	Small part of the requirement is not implemented, with no impact on product safety, legality and customer requirements.	0 points
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 a KO non-conformity(ies) certification cannot be granted. 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 number of the requirement(s) involved in 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 company in their favourite list will receive an email notification (with the explanations about the identified non-conformity (ies) from the IFS Database, informing them that the current certificate has been withdrawn.

Not applicable requirements (N/A)
When the auditor decides that a requirement is not applicable in the production site, the auditor has to evaluate it as N/A (not applicable) and shall provide an explanation in the audit report.

It is not possible to evaluate a KO requirement as N/A, except for KO requirement on monitoring system of each CCP (KO N°2).
N/A is also not possible for requirement 2.2.3.6 about determination of CCP (as even if a company does not have any CCP's, the company shall document a logical approach which needs to be assessed by the auditor).

If there are a significant number of requirements which are deemed as not applicable, using a total point score 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 status of the production site i.e., certification on foundation or higher level.

The total score is calculated as follows:
Total number of points = (total number of IFS HPC Requirements (points) – requirements evaluated as N/A (points)) × twenty (20)

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

Explanations by the auditor in the IFS Report:

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 non-conformity/ies,
- KO requirements even if the requirements are scored with A,
- Requirements audited as not applicable.

4 Post IFS HPC Audit actions

4.1 Action plan

The auditor and/or certification body shall issue the action plan (with the list of findings) within two (2) weeks. A provisional 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. For more information, see Annex 8.

4.1.1 Company´s completion of the action plan

The company shall provide the following information 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 N°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 are:

- Training records
- Updated procedures with traceable modifications
- Before and after pictures
- Evidence (e.g. email) 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 production site 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.
More information on chapter 1.5, Part 4.

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 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 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 of the IFS Audit and the IFS Reviewer. The technical review shall include as a minimum all tasks of an IFS Reviewer chapter 3.5 ,Part 3.

Based on the result of the technical review, the nominated reviewer will recommend the issuance of an IFS HPC 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 HPC 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 action	Report form	Certificate
Total score is ≥ 95%	Passed at IFS HPC 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 HPC 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 (1) Major and total score is ≥75%	Not passed, unless further actions taken and validated in a 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
Total score is below 75%	Not passed	Actions and new initial audit to be agreed upon (no earlier than six (6) weeks after the audit where the final score was < 75%).	Report including action plan provides status	No
More than one (1) Major and/or total score is below 75%	Not passed	Actions and new initial audit to be agreed upon (no earlier than six (6) weeks after the audit where the final score was < 75%).	Report including action plan provides status	No

Audit Result	Status	Company action	Report form	Certificate
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)

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 follow-up audit can be found in chapter 2.3.3.

If more than 1 Major, or 1 or more KO with D non-conformity/ies and/or total score is <75%: the IFS HPC 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 two (2) working days if the audit is failed due to one or several non-conformity(ies) or two (2) 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 is recommended to be completed and all requirements shall be evaluated to give the company a full overview of its situation.
- The action plan should be completed for improvement purposes.
- A full new audit shall be performed no earlier than six (6) weeks after the audit where the non-conformity(ies) was/were issued.

Any failed IFS HPC Audit shall not be considered as a pre-audit.

For more information on failed audits and certificate withdrawal process see chapter 3.2.1 and Annexes 5, 6 and 7.

4.2.1.2 Deadlines for issuing the IFS Certificate

If the auditor and the nominated reviewer recommend the IFS HPC Certification after positive validation of the evidence of implementation of corrections, the certification body can make the decision to issue the certificate. The audit report, the action plan and the certificate shall 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 the action plan to the company: maximum two (2) weeks.
- 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 uploading them to the IFS Database: maximum (2) weeks.

More information can be found in Annex 2.

4.3 Certification cycle

The validity of the IFS HPC 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 date of issue of the certificate. This allows the certificate validity to remain the same, even if the recertification audit date changes every year and does not exactly correspond 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, this will lead to a break in certification and a new initial certification cycle will be initiated.

If the recertification audit takes place later than the above-mentioned time window, the certification of the company will not be visible anymore and the COID will be automatically set to an inactive status in the IFS Database.

The previous audit report and certificate remains visible in the IFS Database for a further three (3) months (after the end of certificate validity).

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 following 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) 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 the 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 following situations such as:

- In case of pending investigations by the certification body following a product safety incident or other event.
- In case of non-payment for the current audit by the audited production site.
- 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

If the suspension is lifted, the certification body shall make all necessary modifications to public information, authorisations for use of brands, etc. 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., 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 authorities, accreditation bodies, etc.). The consent for distribution of the IFS HPC 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 HPC Audit Report. The audit report and associated documentation including the auditor's notes shall be stored safely and securely for a period of five (5) years. Detailed access conditions in regard to information from the audit report are described 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 are allowed to accompany the checks. However, prior contact with the selected sites is prohibited.
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 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 withdrawal of the current IFS Certificate.
For each integrity on-site check, a report is prepared and is only made available to 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

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. If special topics have to be clarified during these integrity certification body office audits, this could also lead to integrity witness audits of IFS Auditors or to integrity on-site checks at companies certified by the respective certification body.

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 the 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

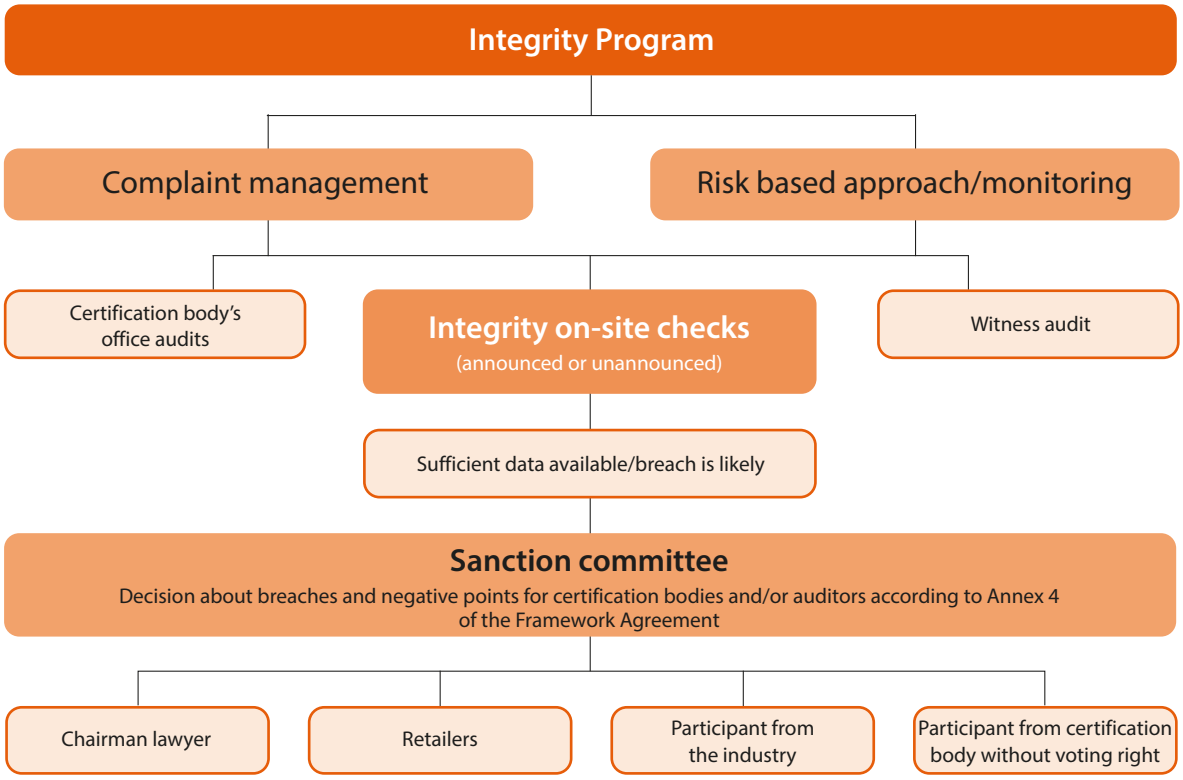
If the cause of a deficiency has been found to be the fault of a certification body and/or an auditor, following a complaint or following the risk-based approach / monitoring quality assurance actions, IFS will forward all necessary information anonymously to an independent sanction committee. The sanction 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 determine 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 accumulating, but the period is limited to 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 N°7).

Chart 7: Summary of IFS Integrity Program Activities



6 IFS Logos

The copyright of IFS HPC and the registered trademark is fully owned by IFS Management GmbH. The IFS Logos shall be downloaded via the secured section of the IFS Database.

Furthermore, the terms and conditions below shall be communicated to the 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 (Annex 9) 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 HPC 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 HPC 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 HPC certified production site, an IFS HPC supporting company or an IFS HPC 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 HPC Logo in promotional material
The IFS HPC Logo shall not be displayed on the product itself, 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 HPC 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 HPC Logo
The IFS HPC Logo shall not be used in any way that may imply that IFS Management GmbH is responsible for the certification decision. In case of exclusion regarding the audit scope, the IFS Logo can be used, but the following claim shall be written at the bottom: "Some products are excluded from the scope of the IFS HPC Audit and 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 HPC Certification
All the above-mentioned rules apply to any communication regarding IFS HPC. This also means that the use of the wordmarks "IFS", "International Featured Standards", or "IFS HPC" or similar is not allowed to be communicated on finished products which are available to the end-consumer.

PART 2

PART 2
List of IFS HPC Audit Requirements

About the requirements:
- Requirements with a "*" require compulsory information for the IFS HPC Audit Report.

1 Governance & 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.

This corporate policy shall be communicated to all employees and shall be broken down into specific objectives for the relevant departments.

1.1.2 All relevant information related to product requirements shall be communicated effectively and in a timely manner to the relevant personnel.

1.2 Corporate structure

1.2.1* KO N° 1: The senior management shall ensure that employees are aware of their responsibilities related to product requirements and that mechanisms are implemented to monitor the effectiveness of their operation. Such mechanisms shall be clearly identified and documented.

1.2.2 The senior management shall provide sufficient and appropriate resources to meet the product and process requirements.

1.2.3 The department responsible for product safety and quality management shall have a direct reporting relationship to the senior management. An organizational chart shall be documented and maintained showing the structure of the company.

1.2.4 The company shall ensure that all processes (documented and undocumented) are known by the relevant personnel and are applied consistently.

1.2.5* The senior management shall ensure that the certification body is informed of changes that may affect its ability to conform with the certification requirements .
This includes at a minimum:

- any legal entity name change,
- any production site location change.

In addition, for the following specific situations:
product recall(s) by official order and/or any visit from the authorities which results in notification and/or penalties related to product safety and/or legality, the certification body shall be informed within three (3) working days.

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 it is execution shall not exceed 15 months. Such reviews shall contain at least:

- a review of policy(ies) and objectives,
- review of the product safety culture,
- results of audits and site inspections,
- positive and negative customer feedback,
- process compliance and product conformity,
- status of corrections and corrective actions,
- notifications from authorities.

1.3.2 Actions from the management review shall be clearly aimed at supporting improvement. The management review shall assess follow-up actions from previous management reviews and any change that could affect the product safety and quality management system. The management review shall be fully documented.

1.3.3 The senior management shall identify and review at least once within a 12-month period, or whenever significant changes occur (e.g. by internal audits or site inspection) the infrastructure and work environment needed to achieve conformity to product requirements. This shall include at a minimum the following:

- buildings (including external conditions of the premises),
- supply systems,
- 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.

2 Product safety and quality management system

2.1 Quality management

2.1.1 Document management

2.1.1.1 The product safety and quality management system shall be documented, implemented and maintained and shall be kept in one secure location. This applies to both physical and/or digital documented systems.

2.1.1.2 All documents shall be clearly legible, unambiguous and comprehensive. They shall be available to relevant personnel at all times.

2.1.1.3 A procedure shall be documented, implemented and maintained to control of documents and their amendments. All documents which are necessary for compliance with the product requirements shall be available in their latest version. The reason for any amendments to documents critical for those requirements shall be recorded.

2.1.2 Records and documented information

2.1.2.1 All relevant records and documented information necessary for the product requirements shall be completed, detailed and securely maintained and shall be available on request.

2.1.2.2 Records and documented information shall be legible and genuine. They shall be maintained in a way that subsequent revision or amendment is prohibited unless amendments are done by authorized personnel. If records are documented electronically, a system shall be in place to ensure only authorized personnel have access to create or amend those records (e.g. password protection).

2.1.2.3* All records 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 shelf life. For products which have no shelf life, the duration of record and documented information keeping shall be justified and this justification shall be documented.

2.2 Product safety management

2.2.1 Risk assessment framework

2.2.1.1 Before developing the hazard analysis and risk assessment, the company shall have implemented all necessary good manufacturing practices / best practices which are commonly used in its scope of activity.

2.2.1.2 The basis of the company's product safety management system shall be a fully implemented, systematic and comprehensive risk management system. It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The hazard analysis and risk assessment shall be adequate and implemented at each production site.

2.2.1.3 The hazard analysis and risk assessment shall cover all raw material groups, products or product groups, as well as every process (included outsourced processes) from incoming goods until the dispatch of final products, including product packaging material management.

2.2.1.4 The company shall ensure that the hazard analysis and risk assessment shall be based upon scientific literature or technical verified specifications relating to the manufactured products and procedures.
This information shall be maintained in line with any new technical and scientific process development.

2.2.1.5 In the event of changes to raw materials, packaging materials, processing methods, infrastructure and equipment, the hazard analysis and risk assessment shall be reviewed in order to ensure that product safety requirements are complied with.

2.2.2 Risk assessment team

2.2.2.1 The risk assessment team shall be multidisciplinary and include operational staff. Personnel appointed as risk assessment team members shall have specific knowledge of hazards and risks associated to products and processes. Where competent knowledge is not available external expert advice shall be obtained.

2.2.2.2 Those responsible for the development and maintenance of product safety management system shall have received adequate training in the application of the risk management principles based on the risk assessment tool (Risk matrix, FMEA, HACCP, RPN, etc.) which the company uses.

2.2.2.3 The risk assessment team shall have senior management support and shall be well known and established within the company.

2.2.3 Hazard analysis and risk assessment

2.2.3.1 **Describe the product**
A full description of the product shall be documented and maintained and shall contain all applicable relevant information on product requirements, at a minimum:

- composition (including rework when applicable),
- physical, chemical and microbiological parameters,
- methods of treatment,
- packaging,
- durability (shelf life),
- conditions for storage, methods of transport and distribution.

2.2.3.2 **Identify intended use and foreseeable use**
The intended use and foreseeable use of the product shall be described in relation to the expected use of the product by the consumer taking into account vulnerable groups of consumers.

2.2.3.3 **Construct flow diagram**
A flow diagram shall be documented and maintained for each product or product groups, raw material groups and for all variations of the processes and sub-processes (including rework, outsourcing and reprocessing). The flow diagram shall determine every step and clearly identify each critical control point and other control measures. It shall be dated and in the event of any changes the flow diagram shall be updated.

2.2.3.4 **On-site confirmation of the flow diagram**
The risk assessment team shall verify the flow diagram by on-site checks at all operation stages. Amendments to the diagram shall be made, where appropriate.

2.2.3.5 Conduct a hazard analysis and risk assessment for each step

2.2.3.5.1 A hazard analysis shall be conducted covering all possible and reasonably expected physical, chemical (including allergens) and biological hazards. A hazard analysis and a risk assessment shall be conducted for each step of the process from raw materials to the finished products. The analysis shall include also hazards linked to materials in direct contact with the product.

2.2.3.5.2 The hazard analysis shall consider the likely occurrence of hazards and severity of their adverse health effects. Consideration shall be given to the specific control measures that shall be applied to control each hazard. The methodology for assessing the risk shall be documented.

2.2.3.6* **Determine critical control points and other control measures**
The determination of relevant CCP's and other control measures shall be facilitated by the application of a decision tree or other tool(s), which demonstrates a logical reasoned approach.

2.2.3.7 **Establish validated critical limits for each critical control point**
For each critical control point critical limits shall be defined and validated to identify when a process is out of control.

2.2.3.8* **KO N° 2: Establish a monitoring system for each critical control point**
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.

2.2.3.9 Records of CCP's monitoring shall be verified by a responsible person of the company and maintained for a relevant period.

2.2.3.10 The operative personnel in charge of the monitoring of CCP's and other control measures shall have received specific training/instruction.

2.2.3.11 The control measures other than CCPs, shall be monitored, recorded and controlled by measurable or observable criteria.

2.2.3.12 **Establish corrective actions**
In the event that the monitoring indicates that a particular CCP or control measure other than CCPs is not under control, corrective actions shall be documented and implemented. Such corrective actions shall also take into account any action taken relating to non-conforming products and identify the root cause for the loss of control of CCPs.

2.2.3.13* **Establish verification procedures**

Procedures of verification shall be documented, implemented and maintained to confirm that the hazard analysis and risk assessment are effective. Verification activities of the hazard analysis and risk assessment include for example:

- internal audits,
- testing,
- sampling,
- evaluations,
- deviations and non-conformities,
- complaints.

The results of this verification shall be performed at least once within 12-month period or whenever significant changes occur and shall be incorporated into the hazard analysis and risk assessment.

3 Resource management

3.1 Human resources

3.1.1 All personnel performing work that affects product safety, legality and/or quality shall have the required competence by education, work experience and/or training, commensurate with their role.

3.1.2 The responsibilities, competence and job descriptions for all job titles having an impact on product safety and product quality, shall be documented, implemented and maintained. Assignment for key roles shall be defined.

3.2 Personal hygiene

3.2.1* Risk based requirements relating to personnel hygiene shall be documented, implemented and maintained. These include at a minimum the following fields:

- hair and beards,
- protective clothing (including use in staff facilities),
- hand washing, disinfection and hand hygiene,
- eating, drinking and smoking/vaping or other use of tobacco,
- actions to be taken in case of cuts or skin abrasions,
- fingernails, jewellery and personal belongings (including personal medication),
- notification of infectious diseases / health issues.

3.2.2 The requirements for personal hygiene shall be understood and applied by all relevant personnel, contractors and visitors. Compliance with the requirements shall be checked regularly.

3.2.3 Visible jewellery (incl. piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated based on risks.

3.2.4 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 different from the product colour. Where appropriate:

- plasters/bandages shall contain a metal strip,
- single use gloves shall be worn.

3.3 Protective clothing for personnel, contractors and visitors

3.3.1 Company procedures shall exist to ensure that all personnel, contractors and visitors are aware of the rules regarding the management of wearing and changing protective clothing in specified areas in accordance with product requirements.

3.3.2 In work areas where wearing headgear and/or beard snood (covering) is required, the hair shall be covered completely so that product contamination is prevented.

3.3.3 Usage rules shall be implemented for work areas/activities where it is required to wear gloves (coloured differently from the product colour).

3.3.4 When required, suitable protective clothing to ensure personnel safety shall be available in sufficient quantity for each employee.

3.3.5 All protective clothing shall be thoroughly and regularly laundered. Based on risks, the company shall determine if clothing shall be washed by a contract laundry, on-site laundry or by the employee according to a documented guidelines which shall include the checking of its cleanliness.

3.4 Procedure applicable to health and infectious diseases

3.4.1 There shall be written and communicated measures for personnel, contractors and visitors in case of any health issue or infectious disease which may have an impact on product safety. In case of declaration of any, actions shall be taken to minimize risk of contamination of products (if applicable to product or activity).

3.5 Training and instruction

3.5.1 Documented training and/or instruction programs shall be implemented with respect to the product and process requirements and the training needs of the employees based on their job and shall include:

- training contents,
- training frequency,
- employee's task,
- languages,
- qualified trainer/tutor,
- training effectiveness.

3.5.2 The documented training and/or instruction programs shall apply to all personnel, including temporary workers and employees from external companies, employed in the respective work area. Upon employment, and before commencing work, they shall be trained in accordance with the documented training/instruction programs.

3.5.3 Records shall be available of all training/instruction events stating:

- list of participants (this shall include their signature),
- date,
- duration,
- contents of training,
- name of trainer/tutor.

3.5.4 The contents of training and/or instruction shall be reviewed and updated when necessary. Special considerations shall be given at a minimum to these specific issues:

- product safety and quality (e.g. GMPs, risk assessment, etc.).
- product safety culture,
- product defence,
- product related legal requirements,
- product/process modifications,
- feedback from the previous documented training/instruction program.

3.6 Staff facilities

3.6.1 Adequate staff facilities shall be provided and shall be proportional in size, equipped for the number of personnel, designed and controlled so as to minimize product safety risks. Such facilities shall be maintained in a way to prevent contamination.

3.6.2 Product contamination risks by food and drink and/or foreign materials shall be minimized. Consideration shall be given to food and drink from vending machines, canteen and/or brought to work by personnel.

3.6.3 The company shall provide suitable changing rooms for personnel, contractors and visitors. Where necessary, outdoor clothing and protective clothing shall be stored separately.

3.6.4 Changing rooms shall be located so that they allow direct access to the areas where products are handled. Any exceptions shall have been comprehensively evaluated based on risks.

3.6.5 Toilets shall not have direct access to an area where products are handled. Any exception shall be comprehensively evaluated based on risks. The sanitary facilities shall be equipped with adequate hand washing facilities. The sanitary facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.

3.6.6 Hand hygiene facilities shall be provided near points of entry to, and within production areas, as well as at staff facilities. Based on risks further areas shall be similarly equipped.

3.6.7 Hand hygiene facilities shall provide:

- running potable water at an adequate temperature,
- adequate cleaning and/or disinfection equipment,
- adequate means for hand drying.

3.6.8 Based on risks following additional requirements regarding hand hygiene shall also be provided:

- hand contact-free fittings,
- hand disinfection,
- adequate hygiene equipment,
- signage highlighting hand hygiene requirements,
- waste container with hand contact free opening.

3.6.9 A risk based program shall be implemented and maintained to control effectiveness of hand hygiene.

4 Operational processes

4.1 Customer focus and contract agreement

4.1.1 A process shall be implemented and maintained to identify fundamental needs and expectations of customers. The feedback from this process shall be taken as input for company's continuous improvement.

4.1.2 All requirements related to product safety and quality within customer agreement, and any revision of these clauses between the contract partners, shall be documented, communicated and implemented by each relevant department.

4.1.3 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-conformity/ies identified by competent authorities.

4.2 Specifications and formulas

4.2.1 Raw materials (including packaging materials), semi-finished products and rework specifications

4.2.1.1 Specifications shall be documented and implemented for all raw materials (raw materials/ingredients, additives, packaging materials, rework) and where relevant, for semi-finished products. The specifications shall be up to date, unambiguous, available and always in conformance with legal requirements.

4.2.1.2 Identification of raw materials including packaging materials shall contain the following information:

- name of the product,
- unique identification code,
- date or number of receipt (if relevant),
- supplier´s name,
- expiry date, if existing,
- batch reference given by the supplier and the one given at receipt, if different.

4.2.1.3 A re-evaluation of the suitability of raw materials and semi-finished products shall be in place in cases where they are close to the best before date/expiry date or when they are returned to storage or other relevant parameters given by the supplier.

4.2.1.4 For all packaging materials which could have an impact on products, relevant documents (e.g. DoC, etc.) shall exist which attest compliance with legal requirements. In the event that no specific legal requirements are applicable, evidence shall be available to demonstrate that packaging materials are suitable for use. This applies for packaging materials which could have an influence on semi-finished and finished products.

4.2.1.5 The company shall define the key parameters for the packaging materials in detailed specifications complying with the current relevant legislation and other relevant hazards or risks.

4.2.2 Finished product specifications

4.2.2.1 Specifications shall be documented and implemented for all finished products. They shall be up to date, traceable, unambiguous, relevant to all personnel and in compliance with legal and customer requirements. Where required by customers, product specifications shall be formally agreed.

4.2.2.2* KO N° 3: Current and approved finished product specifications shall be the basis for the composition of products. They shall also be the basis for the control of the production process and to monitor the finished products' compliance.

4.2.2.3 Where products are requested to be labelled and/or promoted with "free from" certain substances or ingredients, or where certain methods of treatment or production are excluded, measures shall be implemented to demonstrate compliance with such statement.

4.2.2.4 A procedure to control the creation, approval and amendment of specifications shall be documented, implemented and maintained and shall include where required, the acceptance of the customer(s).
This procedure shall include the update of finished product specifications in case of any modification related to:

- raw materials,
- formulas/recipes,
- processes which impact the finished products,
- packaging materials which impact the finished products.

4.3 Legislative framework and product development

4.3.1 Legislative framework

4.3.1.1 The company shall comply with the current applicable legislation and where relevant, register its activity of production to the local authorities. The company shall be able to demonstrate its own role in the supply chain.

4.3.1.2 The company shall have a system in place to ensure:

- it is kept informed of all relevant legislation on product safety and quality issues,
- scientific and technical developments,
- industry codes of practice.

Legislation shall be understood and applied.

4.3.1.3 For all relevant raw materials, safety data sheets shall be available in the format required by the destination country and kept up to date.

4.3.1.4 Where relevant, the safety data sheet and/or composition for final products shall be provided and communicated to the appropriate organizations (e.g. national safety centers, public website, etc.), taking into consideration the current legislation of the destination country.

4.3.1.5 If applicable, the company shall mandate a qualified safety assessor in accordance with the current legislation to consider the general toxicological profile of the ingredients, their chemical structure and exposure level, and finally provide the company with a safety assessment of the finished product regarding human health.

4.3.1.6 A procedure shall ensure that labelling complies with current legislation of destination country and customer requirements.

4.3.1.7 The company shall ensure that in the event of changes to

- process characteristics,
- product formulation including rework,
- packaging material,
- legal requirements,
- product quality requirements,
- customer requirements,

labelling shall be reviewed and adapted when necessary.

4.3.2 Product development / product modification / modification of production process

4.3.2.1 The company shall have an implemented procedure for product development/modification that takes into account risks and patents and that demonstrates that all existing and new products are designed to meet legal requirements. Legal changes, e.g. ingredients, etc. which make it necessary to change products and/or subjected to deadlines, shall be coordinated with customers as soon as possible.

4.3.2.2 The product development/modification process shall result in specifications about formulation, packaging requirements, manufacturing processes, process parameters related to the fulfilment of product requirements.
The progress and results of product development shall be properly recorded and have to be ensured by checks such as:

- factory trials,
- performance tests,
- stability tests,

- organoleptic tests,
- product testing,
- compatibility tests.

4.3.2.3 Without the authorization from the patent holder, the company shall not use raw materials, composition or production processes or other intellectual properties which are already patented.

4.3.2.4 Where relevant, shelf life tests / stability tests shall be carried out taking into account product formulation, packaging, manufacturing and storage conditions. The shelf life (e.g. expiry date, best before, PAO) of the labelled goods shall be calculated accordingly, from the original production date. Where relevant for products with shelf lives, tests shall be done at the end of the product shelf life on retained samples.

4.3.2.5 Where specific tests are needed, equipment shall be available and pertinent (such as dosages for regulated ingredients, preservatives, biocides etc.). In case tests are not performed on-site, results of these external tests shall be available.

4.3.2.6 Claims shall be supported by scientific evidence (e.g. sun screen formulations, detergents, etc.) to ensure that the product meets the stated claim.

4.3.2.7 Where relevant, pilot equipment(s) shall be available and used in order to guarantee the possible scale-up.

4.3.2.8 Recommendations/instructions for application and/or use of the products shall be validated and documented, where appropriate.

4.3.2.9 The finished product shall be designed and labelled to prevent non intended use to protect the safety of the potential user. The risk assessment shall address this topic.

4.3.2.10 Based on risks, the company shall check and verify the suitability and interaction between the product and packaging in direct contact and intended or expected to be in direct contact, and it shall take into account:

- physical and functional characteristics,
- organoleptic characteristics (if applicable),
- microbiology and chemical parameters (e.g. migration test results).

4.4 Purchasing

4.4.1 The purchased materials shall be evaluated based on risks, and supplier´s status for product safety, legality and quality. The results shall be the basis for the testing and monitoring plans.

4.4.2 The purchasing services, which have, based on risks, an impact on product safety and product quality, shall be evaluated to ensure they comply with defined requirements.
This shall take into account at a minimum:

- the service requirements,
- the supplier's status (according to its assessment),
- the impact of the service on the finished products.

4.4.3 A procedure for the sourcing of raw materials, semi-finished products and packaging material, and the approval and monitoring of suppliers (internal and external) shall be documented, implemented and maintained. This procedure shall contain at a minimum:

- raw materials and/or supplier´s risks,
- required performance standards (e.g. certification, origin, etc.),
- exceptional situations (e.g. emergency purchase),

and based on risks, additional criteria, for instance:

- audits performed by an experienced and competent person,
- testing results,
- supplier reliability,
- complaints,
- supplier questionnaire.

4.4.4 Where a company outsources a part of the product processing and/or primary packing and/or labelling, it shall have it documented in the product safety and quality management system and ensure control over such processes to guarantee that product safety and product quality are not compromised.

4.4.5 When required by the customer, there shall be evidence that the customer has been informed and has agreed to such outsourced process.

4.4.6 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.

4.4.7 Suppliers of outsourced processes shall be approved through:

- certification against IFS HPC or equivalent,

or

- documented supplier audit performed by an experienced and competent person, which shall include at a minimum, requirements for product safety, quality and legality,

or

- in case of a private label (e.g. retailer brand), the customer is expressively accepting other conditions.

4.4.8 The company shall check the products on receipt from its subcontractor based on a documented sampling plan.

4.4.9 The sourcing of materials and supplier audits 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 audit shall be documented.

4.5 Factory exterior

4.5.1* Potential adverse impact on product safety and quality from the factory environment (e.g. ground, air) shall be investigated. Where risks have been identified, measures shall be documented, implemented and reviewed for effectiveness (e.g. extremely dusty air, strong smells) at least once within a 12 month period or whenever significant changes occur.

4.5.2 The factory exterior shall be clean, tidy and maintained in good condition.

4.5.3 All grounds within the site shall be clean, tidy and maintained in a way to prevent contamination. Where natural drainage is inadequate, a suitable drainage equipment shall be installed.

4.6 Plant layout and process flows

4.6.1 Site plan(s) covering all buildings shall be documented and shall describe, maintained at a minimum the process flow of:

- finished products,
- packaging materials,
- raw materials,
- semi finished products including rework,
- waste,
- personnel,
- water.

4.6.2 The process flow from receipt of goods to dispatch, shall be implemented and maintained, reviewed and where necessary, modified to ensure that the microbiological, chemical and physical contamination risks of raw materials, packaging materials, semi-finished, rework and finished products are avoided. The cross-contamination risks shall be minimized through effective measures.

4.6.3 Where relevant, products shall not be produced, stored and filled on the same equipment as products with another intended use unless validated results are available that there is no negative effect on the products.

4.6.4 Based on risks, areas sensitive to microbiological, chemical and physical hazard(s) shall be designed and operated to ensure product safety is not compromised.

4.6.5* Where relevant for laboratories:

- location of laboratories at the factory shall not affect product safety,
- microbiological laboratory shall be physically separated from chemical laboratory.

4.7 Production and storage premises

4.7.1 Constructional requirements

4.7.1.1 All premises used in the manufacture and storage of products shall be designed, constructed and maintained to allow unobstructed installation, ease of maintenance, efficient pest control and easy cleaning of the equipment, as well as compliance with all relevant legislation.

4.7.1.2 Premises where the products are prepared, treated, processed and stored shall be designed and constructed so that product safety and quality is ensured.

4.7.2 Walls

4.7.2.1 Walls shall be constructed to meet production requirements in a way to prevent contamination to reduce condensation and mold growth, and to facilitate cleaning.

4.7.2.2 The surfaces of walls shall be maintained in a way to prevent contamination and easy to clean. Based on risks they shall be impervious and wear-resistant to minimize product contamination risks.

4.7.3 Floors

4.7.3.1 Floors shall be easy to clean and designed and constructed to meet production requirements (e.g. mechanical loads, cleaning materials, etc.).

4.7.4 Ceilings/overheads

4.7.4.1 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 minimize the accumulation of dirt and condensation and shall not pose any physical and/or microbiological contamination risks.

4.7.4.2 Where false ceilings are used, access to the vacant area shall be provided to facilitate cleaning, maintenance and inspection for pest control.

4.7.5 Windows and other openings

4.7.5.1 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.

4.7.5.2 Where there are contamination risks, windows and roof glazing shall remain closed and fixed during production.

4.7.5.3 Where windows and roof glazing are designed to be opened for ventilation purposes, they shall be fitted with easily to clean pest screens or other measures to prevent any contamination.

4.7.6 Doors and gates

4.7.6.1 Doors and gates shall be maintained in a way to prevent contamination and easy to clean. Based on risks, they shall be constructed to avoid:

- splintering parts,
- flaking paint,
- corrosion.

4.7.6.2 Plastic strip curtains separating areas shall be maintained in a way to prevent contamination and easy to clean.

4.7.7 Drainage system

4.7.7.1 Drainage systems shall be easy to clean and designed to minimize product contamination risks (e.g. entry of pests, transmission of odour or contaminants). The hygienic disposal of waste water shall be ensured.

4.7.7.2 Water or other liquids shall reach drainage using appropriate measures without difficulties. Puddles shall be avoided.

4.7.8 Lighting

4.7.8.1 All working areas shall have the levels of light according to the activities carried out.

4.7.8.2 Based on risks, all lighting equipment and electric fly killer units shall be protected.
The factory areas where this clause shall apply:

- handling of unpackaged products and raw materials,
- storage of raw materials including packaging materials,
- changing rooms.

This does not preclude that other areas shall not have protected lighting equipment or electric fly killer units.

4.7.9 Air conditioning/ventilation

4.7.9.1 Natural and/or artificial ventilation covering process/product needs shall exist in all areas.

4.7.9.2 If ventilation equipment is installed, filters and other components shall be easily accessible and monitored, cleaned or replaced as necessary.

4.7.9.3 Air conditioning equipment and artificially generated airflow shall not compromise product safety and quality.

4.7.9.4 Dust extraction equipment shall be designed, constructed and maintained in areas where considerable amounts of dust are generated.

4.7.10 Water

4.7.10.1* A water monitoring program shall exist covering all process waters (e.g. water used in the facilities, for cleaning activities, used as an ingredient, etc.). The testing of all process waters shall incorporate at a minimum:

- chemical, physical and microbiological specifications,
- frequency,
- method of water treatment depending on product requirement (e.g. deionization, distillation, etc.).

Special consideration shall be given after periods of no water consumption (e.g. after a weekend or holiday period) and when the stagnation of water cannot be avoided.
The risk assessment shall address this topic.

4.7.10.2 A water monitoring program shall verify that the water treatment is adequate and effective on a risk-based sampling plan.

4.7.10.3 Recycled water which is used in the process shall not pose a contamination risk. Records of compliance testing shall be available.

4.7.10.4 If applicable, different process water quality shall be clearly distinguished throughout the site and shall not pose a risk of contamination.

4.7.11 Compressed air

4.7.11.1 The quality of compressed air that comes in direct contact with the product or packaging intended to be in contact with the product shall be monitored based on risks. Compressed air shall not pose contamination risks.

4.8 Cleaning and disinfection

4.8.1 Risk based cleaning and disinfection schedules shall be validated, documented and implemented. These shall specify:

- objectives,
- responsibilities,
- the products used and their instructions for use,
- methods of cleaning (including dosage of cleaning and disinfection chemicals),
- the areas and timeslots for cleaning and disinfection,
- documentation requirements,
- cleaning in place (CIP) criteria, if applicable,
- hazard symbols (if necessary).

4.8.2 Defined methods for monitoring shall be adequately documented and implemented. Monitoring records for cleaning and disinfection shall be available.

4.8.3 Cleaning and disinfection activities shall be documented and implemented and shall result in effectively cleaned premises, facilities and equipment.

4.8.4 Only competent personnel shall perform cleaning and disinfection activities. The personnel shall be trained and retrained to carry out the cleaning schedules.

4.8.5 The effectiveness of the cleaning and disinfection measures shall be verified. The verification shall rely on a risk-based sampling schedule and shall consider one or several actions like for example:

- visual inspection,
- rapid testing,
- analytical testing methods.

Resultant actions shall be documented.

4.8.6 Cleaning and disinfection activities shall be reviewed and modified according to any changing circumstances (e.g. construction work, new products, new machines, changes of climate etc.). Where necessary, the cleaning and disinfection schedules shall be adapted.

4.8.7 Current safety data sheets (SDS) and instructions for use shall be always available on-site for chemicals and cleaning agents. Personnel responsible for cleaning and disinfection activities shall be able to demonstrate their knowledge of such instructions.

4.8.8 Cleaning utensils and chemicals shall be clearly identified, used and stored appropriately to avoid contamination or unintended use.

4.8.9 If relevant, the cleaning of production tools shall be carried out at specific locations or specific time periods separated from the production process. If this is not possible, these operations shall be controlled as to not affect the product safety and quality.

4.8.10 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.

4.9 Waste management

4.9.1 A waste management procedure shall be documented, implemented and maintained to prevent cross contamination.

4.9.2 All local legal requirements for waste disposal shall be met.

4.9.3 Product waste and other waste shall be removed from areas where product is handled. The accumulation of waste shall be avoided.

4.9.4 Waste collection areas and waste containers (incl. compactors) shall be maintained tidy, clean to minimize pest attraction, and where necessary disinfected. Waste containers shall be clearly marked, suitably designed and in a good state of repair.

4.9.5 Waste shall be collected in separate containers in accordance with the intended means of disposal. Such waste shall be disposed by authorized third-parties only. Records of waste disposal shall be kept by the company. Whenever possible, destruction of waste shall be intended to avoid re-use of non-compliant products.

4.10 Foreign material risk mitigation

4.10.1 The products being processed shall be protected against physical contamination, which includes but is not limited to:

- environmental contaminants,
- oils or dripping liquids from machinery,
- dust spills.

Special consideration shall also be given to product contamination risks caused by:

- equipment and utensils,
- pipes,
- walkways,
- platforms,
- ladders.

If for technological characteristics and/or needs, the products cannot be protected, control measures shall be implemented.

4.10.2* Based on risks, procedure(s) shall be documented, implemented and maintained to prevent contamination with foreign material.

4.10.3 In areas where raw materials, semi-finished and finished products are handled the use of wood shall be avoided. Where the presence of wood cannot be avoided the risks shall be controlled and the wood shall be clean and pose no risks to product safety.

4.10.4 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.

4.10.5 The accuracy of all equipment and methods designed to detect and/or eliminate foreign materials shall be specified. Functionality tests of such equipment and methods shall be carried out at least at the start and end of production as well as at every product changeover. In case of malfunction or failure, the impact on products and processes shall be assessed.

4.10.6 Potentially contaminated products shall be isolated. Access and actions for further handling or testing for these isolated products shall be carried out only by authorized personnel.

4.10.7 A glass and brittle material procedure shall be implemented taking into account preventive and corrective measures; the procedure shall include reference to procedures in the event of glass or brittle material breakage. Where a risk assessment has identified a potential for product contamination, the presence of brittle material (including glass) shall be excluded or if this is not possible, the risk shall be managed.

4.11 Pest monitoring and control

4.11.1* Risk based pest control measures shall be documented, implemented and maintained. They shall comply with local legal requirements and shall take into account 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.

4.11.2 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 taken.

4.11.3 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.

4.11.4 Incoming deliveries shall be inspected on arrival for the presence of pests. Any findings shall be recorded.

4.11.5 Based on risks, external doors and gates shall be designed to prevent the ingress of pests; if possible, they shall be self-closing.

4.11.6 The effectiveness of the pest control measures shall be verified, including trend analysis to allow timely appropriate actions. Records of this verification shall be available.

4.11.7 Where a company hires a third-party service provider for pest control, all above mentioned requirements shall be documented in the service contract. A person at the company shall be appointed and competent to monitor the pest control activities. Even if the pest control service is outsourced, responsibilities for the necessary actions (including ongoing supervision of pest control activities) shall remain within the company.

4.12 Receipt and storage of goods

4.12.1 All incoming goods including packaging materials and labels, shall be checked for compliance against specifications and a determined risk-based monitoring plan. The inspection plan shall be justified by risk assessment. Records of those inspections shall be available.

4.12.2 A system shall be implemented and maintained to ensure storage conditions and locations of raw materials including packaging materials, semi-finished and finished products correspond to product specifications and shall not have any negative impact on other products.

4.12.3 Outdoor storage shall be kept to a minimum. Where products are stored outside it shall be ensured that there is no risk of contamination or adverse effect on product safety and quality.

4.12.4 When raw materials including packaging materials are repacked the new label shall contain the relevant information as on the original label.

4.12.5 All products shall be identified. Use of products shall be undertaken in accordance with the principles of First In / First Out and/or First Expired / First Out, and in accordance with relevant industry best practices.

4.12.6 Periodic inventory shall be performed to ensure stock reliability. Any significant discrepancy shall be investigated and corrective action taken.

4.12.7 Where a company hires a third-party storage service provider, the service provider shall be subject to IFS Logistics Requirements. If the third-party service provider is not certified to IFS Logistics, all relevant requirements equivalent to the company's own warehousing practices shall be fulfilled and this shall be defined in the respective contract.

4.13 Transport

4.13.1 The transport vehicles used to transport goods shall be in good condition and shall protect the products from adverse weather conditions and external influences. The conditions inside the vehicle for example:

- absence of strange smells,
- high dust load,
- adverse humidity,
- pests,
- mould,
- vehicle integrity,

shall be checked and documented before loading and unloading to ensure compliance with the defined conditions.

4.13.2 Procedures to prevent contamination during transport (as well as internal transport) including loading and unloading shall be documented, implemented and maintained.

4.13.3 Risk-based hygienic requirements for all transport vehicles including tank trucks and equipment used for loading/unloading (e.g. hoses of silo installations) shall be implemented. There shall be records of the measures taken.

4.13.4 Loading and unloading areas shall have equipment in place to protect transported products from external influences.

4.13.5 Where a company hires a third-party transport service provider all the requirements specified within section 4.13 shall be defined in the respective contract or the service provider shall be subjected to IFS Logistics Requirements or equivalent standard.

4.14 Maintenance and repair

4.14.1 A maintenance plan shall be documented, implemented and maintained that covers all critical equipment (including transport) for compliance with product requirements. This applies both to internal maintenance activities and service providers. The plan shall include responsibilities, priorities and due dates.

4.14.2 Product requirements and prevention of contamination shall be ensured during and after maintenance and repair work. Records of maintenance and repair work and of corrective actions taken shall be kept.

4.14.3 All materials used for maintenance and repair shall be fit for the intended use and not pose contamination risks.

4.14.4 Failures and malfunctions of premises and equipment (incl. transport) essential for product safety and quality shall be identified, documented and reviewed to enable prompt actions and to improve the maintenance plan.

4.14.5 Temporary repairs shall be carried out so that product requirements are not affected. Such work shall be documented, and a short-term deadline set for eliminating the fault.

4.14.6 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, to prevent any product contamination.

4.15 Equipment

4.15.1 Equipment shall be suitably designed and defined for the intended use. Before commissioning, it shall be validated that the product and customer requirements are complied with. Consumables used for equipment should not affect the product safety and quality of the product.

4.15.2 Where relevant for product safety, evidence for conformity shall be in place to demonstrate that equipment, utensils and other materials in contact with the product are suitable for the intended use.

4.15.3 Equipment shall be located to allow effective cleaning, disinfection and maintenance operations.

4.16 Traceability

4.16.1* KO N° 4: 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 packaging in direct contact with product and intended or expected to be in direct contact with product. The traceability system shall incorporate all relevant records of:

- **receipt,**
- **processing at all steps,**
- **use of rework,**
- **distribution.**

Traceability shall be ensured at all stages and documented until delivery to the customer.

4.16.2 The company shall ensure that the used packaging and labelling correspond to the product being packaged and comply with agreed customer product specifications. This shall be regularly checked and documented.

4.16.3 The traceability system shall be tested at least once within a 12-month period or whenever significant changes occur. The test samples shall verify 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). The traceability of the finished products shall be performed within four (4) hours maximum.

4.16.4 It shall be possible to identify at all times all major equipment used for the production of finished product (containers of raw materials and of semi-finished products, mixers, filling lines, etc.).

4.16.5 If required by customer and/or law, identified samples representative of the manufacturing batch shall be stored appropriately and kept until expiration date of the finished product, and if necessary, for a determined period beyond this date.
For products which have no shelf life, the storing duration shall be justified, and this justification shall be documented.

4.17 Allergen risk mitigation

4.17.1 Information about allergens requiring declaration shall be available. The company shall have a continuously maintained system to demonstrate all raw materials containing allergens used at its premises are known and identifies all blends and formulas to which such raw materials containing allergens are added.

4.17.2* Risk based measures shall be implemented and maintained from receipt to dispatch, to ensure that potential cross contamination of products by allergens is minimized. The potential cross contamination risks shall consider at a minimum:

- environment,
- transport and storage,
- raw materials,
- allergen precursors,
- production process.

Implemented measures shall be monitored.

4.17.3 Finished products containing allergens requiring declarations, shall be declared in accordance with legal requirements and/or customer requirements.

4.18 Product defence

4.18.1 A product defence procedure and plan shall be implemented in relation to assessed threats. This shall encompass at a minimum:

- identification of critical areas and/or practices and policy of access by employees, visitors and contractors,
- transport vehicles,
- IT,

- legal requirements, if applicable,
- any other appropriate control measure.

The product defence plan shall be well known and established within the company and shall be reviewed annually and upon changes.

4.18.2 The responsibilities for the product defence shall be defined. The responsible person(s) shall have full commitment from the senior management.

5 Measurements, analyses and improvements

5.1 Internal audits

5.1.1 An effective internal audit program shall be documented, implemented and maintained and shall ensure that all the requirements of the IFS Standard are assessed within a 12-month period and its execution shall not exceed 15 months. The company shall have a risk assessment in place where activities 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.

5.1.2 The auditors shall be competent and independent from the audited department.

5.1.3 Internal audits shall be documented and results communicated to the senior management and to the persons responsible for the concerned activities. Compliances, deviations and non-conformities shall be documented and communicated to the relevant persons.

5.2 Site inspections

5.2.1 Site inspections shall be planned and carried out for topics, for example:

- constructional status of production and storage premises,
- external areas,
- product control during processing,
- hygiene during processing and within the infrastructure,
- foreign material hazards,
- personal hygiene.

The frequency of inspections shall be based on risks and on the history of previous results.

5.3 Process validation and control

5.3.1 The criteria for process validation and control shall be defined. Process parameters (temperature, time, pressure, chemical properties, etc.) which are essential to ensure the product safety and quality shall be monitored, recorded continuously and/or at defined intervals and secured against unauthorized access and/or change.

5.3.2 Processing operations shall be carried out in accordance with processing control documentation and shall include:

- suitable equipment,
- composition of the product,
- list of all raw materials identified according to relevant documents indicating batch numbers and quantities,
- detailed processing operations for each stage, such as addition of raw materials, temperatures, mixing times, sampling and semi-finished product transfer.

Where applicable, a batch number shall be assigned.

5.3.3 The company shall ensure that in the event of changes to processing methods, equipment, and product formulation (including rework and packaging material), process characteristics are reviewed to assure that product requirements are complied with. If relevant, customers shall be informed accordingly.

5.3.4 All rework operations shall be validated, monitored and documented. These operations shall not affect the product safety and quality.

5.3.5 Procedures shall be documented, implemented and maintained for prompt notification, recording and monitoring of equipment malfunction and process deviations.

5.3.6 If substantial process modifications occur a revalidation shall be carried out.

5.4 Calibration, adjustment and checking of measuring and monitoring devices

5.4.1 Measuring and monitoring devices required to ensure compliance with product safety and product quality shall be identified and recorded. Their calibration status shall be recorded. Measuring and monitoring devices shall be legally approved if required by current relevant legislation.

5.4.2 All measuring devices shall be checked, monitored, adjusted and calibrated at defined, recognized standard/methods and within relevant limits of the process parameter values. The results shall be documented.

5.4.3 All measuring devices shall be used exclusively for their defined purpose. Where the results of measurements or the status of the device indicate a malfunction, the device in question shall be immediately repaired or replaced. Where malfunction has been identified, the impact on processes and products shall be assessed to identify whether non-conforming products have been processed.

5.5 Quantity control monitoring

5.5.1* The frequency and methodology of quantity checking shall be implemented and maintained to meet legal requirements (including destination country/ies) and customer specifications.

5.5.2 Compliance criteria to control lot quantity shall be defined.

5.5.3 Monitoring shall be implemented and recorded according to a sampling plan which ensures a proper representation of the manufacturing lot. Results of these checks shall be compliant with defined criteria for all products ready to be delivered.

5.6 Product testing and environmental monitoring

5.6.1 There shall be procedures ensuring that all specified product requirements are met, including legal requirements, performance and specifications. Results of microbiological, physical and chemical analysis required for that purpose shall be available.

5.6.2 Suitable equipment and environment shall be available for all tests performed.

5.6.3 Analyses which are relevant for product safety, quality and legality 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 the appropriate accredited programs/methods, the results shall be cross-checked by laboratories accredited to these programs/methods (ISO/IEC 17025) at least once within a 12-month period, or whenever significant changes occur. The company shall be able to demonstrate that the results are reliable.

5.6.4 Documented evidence shall exist which ensure the reliability of the internal analysis results, on the basis of official and non-official recognized analytical methods.

5.6.5* Testing and monitoring plans for internal and external analyses shall be riskbased to ensure that product safety, quality, legal and specific customer requirements are met. The plan shall cover at a minimum:

- raw materials,
- semi-finished products (if applicable),
- finished products,
- packaging materials,
- contact surfaces of processing equipment (if appropriate),
- relevant parameters for environmental monitoring.

The testing plan shall include the frequency of the tests and the tolerance associated to the specification limits.

5.6.6 The results shall be reviewed regularly and trends identified. Immediate corrections shall be implemented for any unsatisfactory results, or where such trends indicate unsatisfactory results. When unsatisfactory trends are identified, the impact on processes and products as well as the need for actions shall be assessed.

5.6.7 When relevant, sampling of raw materials and of bulk product shall be performed in an appropriate manner and by authorized personnel.

5.6.8 Where internal analyses or controls are undertaken, these shall be carried out in accordance with defined procedures by competent and approved personnel.

5.6.9 Results of checks on finished products including rework material shall be reviewed by authorized personnel to verify the conformity of the finished and semi-finished products with the acceptance criteria. Appropriate corrective actions shall be undertaken for any unsatisfactory results.

5.6.10 For monitoring of the quality of the finished product, organoleptic 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.

5.6.11 The testing and monitoring plans shall be regularly reviewed and updated, based on results, changes to legislation or issues that may have an impact on product requirements.

5.6.12 In-process controls shall not compromise product requirements.

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 including packaging materials, semi-finished and finished products, and packaging materials complying with product and customer requirements, are processed and dispatched.

5.8 Management of complaints from authorities and customers

5.8.1* A procedure shall be documented, implemented and maintained for the management of product complaints (including any written notification from the competent authorities, if relevant), and shall take into account specific procedures (e.g. undesirable effects).

5.8.2 All complaints shall be recorded, readily available and assessed by competent staff. Where it is justified, actions shall be taken immediately.

5.8.3 Complaints shall be analysed with a view to implementing actions to avoid the recurrence of deviations and non-conformity.

5.8.4 The results of complaint data analysis shall be made available to the relevant responsible persons including the senior management.

5.9 Management of product recall, product withdrawal and incidents

5.9.1* KO N° 5: 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 safety, quality, and legality. 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 authorized 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 (if necessary), and contacts availability,**
- **a communication plan including customers, authorities, and where applicable consumers.**

5.9.2 The procedure shall be subject to internal testing for recall/withdrawal, by covering the end-to-end process, at least once within a 12-month period and its execution shall not exceed 15 months. The outcome of the test shall be reviewed for continuous improvement.

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 packaging 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.

5.10.2 The procedure for the management of non-conforming products shall be understood and applied by all relevant employees.

5.10.3 Where non-conforming products are identified, immediate actions shall be taken to ensure that product safety and product quality requirements are complied with.

5.10.4 Finished products (including packaging) that are out of specification shall not be placed on the market under the corresponding label unless a written approval of the brand owner is available.

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 and non-conformities and non-conforming products, with the objective to close the non-compliances and avoid recurrences by corrections and/or corrective actions. This shall include a root cause analysis at least for deviations and non-conformities related to safety, legality and/or recurrence of deviations and non-conformities.

5.11.2* KO N° 6: Corrective actions shall be formulated, documented and implemented as soon as possible to avoid further occurrence of deviations and non-conformity. The responsibilities and the timescales for corrective actions shall be defined. The documentation shall be securely stored and easily accessible.

5.11.3 The effectiveness of the implemented corrections and corrective actions shall be assessed, and the results of the assessment documented.

PART 3

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).

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

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 HPC Standard, the related normative document and the household and/or personal care industry.

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

The person in charge or at least one member of the accreditation committee shall have taken part in the "IFS HPC Awareness" eLearning course (organized 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 HPC Awareness" eLearning course with the main emphasis on the IFS Certification Protocol, list of requirements, Part 3 and Part 4.

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

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

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

In general, the assessor(s) shall have working knowledge of the ISO/IEC 17065:2012 norm and the IFS normative documents (IFS HPC Standard and Doctrine). The person at the accreditation body responsible for IFS Standards can participate in official IFS Training courses / 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 HPC Awareness e-Learning course, or by being trained internally by an accreditation body leader who has taken part in the IFS training(s) / certification body conference)
- taken part in a risk assessment training course
- have a minimum of two (2) years' experience in the household and/or personal care industry.

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 HPC Certification Process) and at least one accreditation witness assessment shall be performed during an initial assessment.

The certification body is allowed to operate for a maximum of two (2) years before achieving the accreditation for IFS HPC. In this case, at least one of the IFS HPC 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 recertification audit, 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 (1) head office assessment per year.
- A minimum of one (1) accreditation witness assessments 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 at a minimum:

- at least 10% or two (2) IFS HPC Auditors files whichever is greater, and
- at least 2% of delivered assessments or two (2) site files whichever is greater.

The use of non-exclusive auditors shall be adequately addressed in the sample of auditor files.

For consecutive accreditation witness assessments, the accreditation body shall wherever possible select two (2) different IFS HPC Auditors of the certification body 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 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.

2 Requirements for the certification bodies

Certification bodies intending to perform IFS HPC 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 authorized 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 HPC.

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 representative, 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 HPC

The certification body shall be accredited to the ISO/IEC 17065:2012 norm for IFS HPC by an IAF recognised accreditation body. Certification bodies in the process of IFS accreditation to ISO/IEC 17065 may organize the witness assessment(s) before having achieved accreditation status.

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 twenty (20) working days of receiving information from the assessed site.

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

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

- If the complaint relates to the quality of IFS 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 N°7). 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 HPC Auditor or IFS HPC 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 related 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, and there will be 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, 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 Auditors, Reviewers, In-house Trainers and 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, reviewers, and in-house trainers, as it is required by the IFS Standard. Therefore, certification bodies have the following responsibilities:

- To manage witness audits (by accreditation bodies, IFS 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 chapter 3.4, 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 HPC Auditors but new to the certification body when starting to perform IFS HPC 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 assessed during the previous two (2) years).
- To ensure that no auditor shall perform more than three (3) consecutive IFS HPC 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, and audits that have been observed as a trainee, including IFS Auditor in progress (AIP) audits 1 to 5).
- To ensure that all auditors and reviewers have a valid contract with them.
- To obtain a 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
  - absence of conflict of interest, including a declaration in case of any association to the company being assessed, currently or within the last two (2) years.

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 Training. This approved IFS In-house Trainer shall have taken part in the "IFS HPC Awareness" eLearning course organized by IFS.
- To organize eight (8) hours of an in-house training for IFS HPC Auditors and Reviewers, for the purpose of sharing experience, calibration and updating knowledge of relevant legal requirements among other relevant aspects related to the standard, doctrine and IFS Audits. The IFS In-house Trainer is responsible for the content of the training and shall lead at least part of the training. The content of the yearly IFS In-house Training can include among other topics the following contents:
  - Household and/or personal care products-related legislation.
  - Risk assessment.
  - Relevant elements of the IFS HPC Standard and IFS HPC Doctrine.
  - Auditing practices.
  - Failures in reports and findings.
  - Etc.
- The yearly IFS In-house Training shall be solely dedicated to IFS and it can either take place via face-to-face meeting or via online session(s). The signature list and the agenda of the training shall be available upon request.
- To be fully cognisant of the examination regulations provided by IFS and available on the IFS Website.
- To ensure the IFS Audit Report and associated documentation including auditor's notes are stored safely and surely for a period of five (5) years and shall be available on request.

The certification body is responsible for appointing an auditor or an 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 IFS HPC Auditor.
- One contracted reviewer.
- One approved IFS In-house Trainer.
- One contact person for IFS.

In case of any change related to IFS Trainers and IFS responsible person, the certification body shall inform the IFS Offices.

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

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

3.1 Requirements for IFS HPC 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.

Exclusives 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 a new exclusive auditors in the IFS Database.

Non-exclusive auditors are fully responsible for their own application as IFS HPC Auditor and shall register themselves as a new non-exclusive auditor in the IFS Database. The competencies of a new non-exclusive auditor are assessed directly by IFS Auditor Management department 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. IFS HPC Auditors can work on an exclusive basis with only one certification body or on a non-exclusive basis for one or more certification bodies.

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

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

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

3.1.2 Initial application

Candidates applying to qualify as IFS HPC Auditor 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:

Science or bioscience degree (e.g. engineering, chemistry, pharmacy, biology, etc.)

or

at least a successfully completed household and/or personal care related professional higher education,

or

if the candidate has a different education background: five years (5) professional experience in the HPC industry related to production activities.

b) Working experience:

A minimum of two (2) years full-time professional experience related to the household and/or personal care industry including the following functions: functions related to production activities (e.g. quality assurance, product safety, R&D) in the household and/or personal care industry or in retail;

or

two (2) years of professional experience auditing in the HPC industry and/or product safety inspection or enforcement.

Experience from consultancy in relation to household or personal care production activities may be recognised as a maximum of one (1) year towards the work experience, if it can be proven by customer contracts, invoices, orders or confirmations.

c) General audit experience:

A minimum of five (5) complete audits shall be performed by the auditor (conducted as a lead or co- auditor) in the processing industry during the previous two (2) years. The audits shall have been carried out at different production sites.

d) Additional qualification:

The candidate shall have participated and successfully completed a:

- Lead auditor course (e.g. recognised lead auditor course like IFS, IRCA, etc.) with a duration of at least 40 hours.
- Risk assessment / HACCP course with a duration of approximately 16 hours.

e) Specific and practical knowledge per product scope

Two (2) years professional experience in the household and/or personal care industry in relation to processing activities for each applied product scope.

Experience from consultancy related to product processing activities may be recognised as a maximum of one (1) year towards work experience, if it can be proven by customer contracts, invoices, orders or confirmations.

Or

Five (5) audits per scope (conducted as a lead or co-auditor) belonging to the following categories:

- IFS Progress HPC Assessments (intermediate level or at least eight (8) hours duration).
- Second party audits including product safety and quality with confirmed evidence.

- Product safety oriented audits (including regulation, traceability, risk assessment, product safety and GMPs) against accredited or managed schemes.

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

f) Language

Additionally to their mother tongue, IFS HPC Auditors shall be fluent in English.
If the auditor wishes to perform audits in other language(s), they shall be able to provide evidence of fluency in this/these other language(s) 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 HPC 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 includes writing reports in this language without an interpreter.

g) eLearning provided by IFS ("IFS Product and process approach")

The candidate shall have taken part at the IFS Training on product and process approach.

3.1.3 IFS HPC Training courses and written examination process

Auditors who comply with the requirements specified in chapter 3.1.2, shall participate in two (2) different type of courses and an examination process.

3.1.3.1 IFS HPC Awareness e-Learning and course and scope specific course(s)

The auditor shall participate at:

- "IFS HPC Awareness" eLearning course, and this shall not have taken place more than one year prior to the date of initial application for the written IFS HPC Examination.
- Product scope(s) course the auditor is confirmed for.

3.1.3.2 Written IFS HPC Examination process

The final step shall be the written examination process comprised of:

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

Detailed rules for the online written IFS HPC Examination are provided by IFS Office.

3.1.4 Sign-off audit

Upon successful completion of the written IFS HPC Examination, auditors shall be signed off during their first IFS HPC Audit acting as a lead auditor under supervision of a fully qualified witness auditor. The sign-off audit is the first witness audit of an auditor after having passed the written IFS HPC Examination for the purpose of confirmation of competencies for final approval as an IFS HPC Auditor. The sign-off audit shall be performed during a full IFS HPC Certification Audit where the audit scope matches the product scope (s) the auditor is going to be approved for.

The witness auditor shall be an approved IFS HPC Auditor for the relevant audit scope(s) of the audited company.

Once the IFS Witness Audit Report of the performed sign-off audit has been approved by IFS, the auditor will be activated as an IFS HPC Auditor in the IFS Database and a personal IFS HPC Auditor Certificate will be issued for the activated auditor. The IFS HPC 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 HPC 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 of passing the oral IFS Examination. The validity stops at the end of the second calendar year, irrespective of the date of activation as an IFS HPC Auditor.

Example: if an auditor passes the written IFS HPC Examination on 20.04.2023, the auditor certificate will be valid until 31.12.2025.

3.2 Conversion of auditors to get the IFS HPC Auditor approval

IFS has implemented specific rules for auditors already qualified for specific other schemes to recognize already gained experience. Therefore, for specific auditor approvals, requirements stated below shall apply to an auditor who wishes to become IFS HPC Auditor.

Chart 9

Auditor approval	Further requirements	Approval for specific IFS HPC Scope
IFS PACsecure	Participation at IFS HPC Product Scope Training for scope 3 (including written exams)	Scope 3
	For other product scope(s) approval, the candidate shall have a minimum of one (1) year experience in the household and/or personal care industry through demonstrated working or a minimum of five (5) audit experiences in the relevant IFS HPC Product Scope or product scope, and participation at the relevant IFS HPC Product Scope Training (including written exams).	Relevant product scope(s)

Auditor approval	Further requirements	Approval for specific IFS HPC Scope
IFS Food	Minimum of one (1) year experience in the household and/or personal care industry through demonstrated working or a minimum of five (5) audit experiences in the relevant HPC product scope, and participation at the IFS HPC Awareness e-Learning course plus relevant IFS HPC Product Scope Training (including written exams).	Relevant product scope(s)
Other product safety certification schemes recognized under ISO 17065 (in the relevant HPC product scope)	Participation at the eLearning IFS Product and process approach. Participation at the "IFS HPC Awareness" eLearning course and relevant IFS HPC Product Scope Training (including written exams).	Relevant product scope(s)

3.3 Specific training program for "auditor in progress" (AIP)

If a candidate has no auditing experience yet but fulfils all other requirements of 3.1.2 except "d) General audit experience", she/he can take part in the IFS training program for "Auditors in Progress". All other rules for auditors in the standard are not affected and shall be fulfilled.
In the framework of the AIP program, the candidate shall pass the written IFS HPC Examination before participating in an adjusted program for gaining audit experience.

This program is only possible for exclusive auditors. However, auditors can initially apply as a non-exclusive auditor, but after having passed the written IFS HPC Examination, they have to switch to the exclusive status to be able to gain audit experience and complete the AIP program under the responsibility of one certification body.

The steps for an IFS Auditor in progress (AIP) are the following:

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

II. Pass the written IFS HPC Examination. Once the written IFS HPC Examination is passed, the candidate becomes an IFS "auditor in progress" (AIP).

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

Chart 10: Auditor in progress auditing / assessing experience 1–5

N° of audit/Audit	Tasks	Possible audit / Audit types
1	Trainee without participating in the audit	• Audit covering traceability, risk assessment, legal compliance of destination countries, GMPs in the relevant HPC manufacturing industry **or** • IFS Progress – HPC Assessments (intermediate level or at least eight (8) hours duration).
2–3	Trainee Active participation in the IFS HPC Audits under supervision and responsibility of a lead auditor	• Audit covering traceability, risk assessment, legal compliance of destination countries, GMPs in the relevant HPC manufacturing industry **or** • IFS Progress – HPC Assessments (intermediate level or at least eight (8) hours duration).
4–5	Trainee Active participation in the IFS HPC Audits under the supervision and responsibility of an approved IFS HPC Auditor	• IFS HPC Audit (not necessarily for the related product scope).
6 (sign-off audit)	Under own responsibility as a lead auditor	• IFS HPC Audit The audit scope matches with the product scope(s) the IFS Auditor in progress is applying for. Witnessed by an IFS HPC Witness Auditor who is approved for all product scope(s) of the audit.

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

- performed in a company where the audit scope matches the product scope(s) the IFS Auditor in progress is applying for,
- witnessed by an IFS HPC Auditor who is approved for product scope(s) of the audit.

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

The auditing/assessing experience, including the sign-off audit, shall be completed within a period of two (2) years after passing the written IFS HPC Examination.

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

Additional information on the auditor in progress (AIP):

- The audit team shall never separate during the audits/assessments.
- Audits 1–5 are accepted for scope extensions in future and can be performed in any product scope.
- Only one "auditor in progress" shall take part in these training audits/assessments.

3.4 Maintenance of auditor's approval

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

- Every year:
  - to have taken part in a one (1) day / 8 hours yearly in-house training by the certification body (see details in chapter 2.6, Part 3).
- Every two (2) years:
  - to have performed a minimum of ten (10) accredited product safety audits including as a minimum five (5) IFS HPC Audits as a lead or co-auditor. This is applicable from the first full year following the approval as an IFS HPC Auditor.
  - to be assessed by the certification body during a full IFS HPC Audit (on-site monitoring witness audit), 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 product safety certification standard 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 HPC Audit, the witness auditor shall be an approved IFS Auditor (for any IFS Product Standard) and shall fulfil the requirements to act as an IFS Witness Auditor, as defined in chapter 3.5.

    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.

    Note 1: Successfully completed witness assessments from accreditation bodies or witness audits from the IFS Integrity Program during IFS HPC Audits can replace the witness audits from the certification body.
    Note 2: For an audit team, the lead auditor can only be witnessed if the audit team did not split during the audit.

  - to have attended and successfully completed a two (2) days IFS Calibration Training organized by IFS. The first mandatory IFS Calibration Training shall be completed in the second calendar year following the date when the written IFS HPC Examination was passed.

The non-exclusive auditors are responsible for maintaining their own IFS Approval.
In case of non-exclusive auditors, the conditions mentioned above are applicable (including every year to have taken part in a one (1) day in-house training with each certification body the non-exclusive auditor is linked to in the IFS Database.) In addition, they have to be assessed by each certification body they work with during a full IFS HPC Audit (on-site monitoring witness audit).

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

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

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

Example of duration of validity of the IFS HPC Auditor's Certificate:

- Date of passing the initial written IFS HPC Examination: 25th of May 2023
- Date of end of validity for IFS HPC Auditor Certificate (initial approval): 31st of December 2025
- The auditor shall participate in the IFS HPC Calibration Training between 1st January and 31st of December 2025.

If the auditor has fulfilled all the above mentioned requirements, the new end of validity of the IFS HPC Auditor Certificate (re-approval) is: 31st December 2027.

3.4.1 Temporarily inactive auditor

If an auditor needs to take a timeout (i.e., a break from her/his activity as an IFS HPC 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 department of both the start and end date of the timeout period as soon as possible. Non-exclusive auditors shall provide to the IFS Auditor Management department with the above requested information.

If, due to this timeout, the requirements mentioned in 3.4 to maintain auditor approval are not fulfilled, the auditor shall fulfil the following these mentioned conditions within a one (1) year period following the timeout and before they can resume their activity as an IFS HPC Auditor. If not, the auditor will lose their IFS HPC approval and shall participate in the IFS Examination and sign-off audit to be approved as an IFS HPC Auditor again.

In case of a standard version change during this temporary timeout, the auditor conversion process shall be applied.

3.4.2 Scope extension for approved IFS HPC 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 HPC Auditor.

For extension of product scope(s), the auditor shall provide the same evidence as for the initial approval process (see chapter 3.1.2 e)). The auditor shall have participated at all the steps of the audit.

In addition to this evidence, the auditor shall take part to the related IFS HPC Scope Training and take the relevant exam.

Note: IFS HPC Audits which were performed under the supervision of a witness auditor can count for the witness auditor to apply for a product extension (if IFS HPC Auditor).

Participation in an IFS HPC Audit as technical expert or interpreter can also count to apply for a scope extension.

3.4.3 Further rules and explanations concerning the non-exclusive approach

Each auditor can switch their status between exclusive/non-exclusive (and vice versa). The concerned certification bodies will be notified automatically by IFS for every switch between the two 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 nor a contact person for IFS).

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

3.4.4 General rules about audit teams

All members of the audit team shall be approved IFS HPC Auditors.
In case of assessing in teams the following requirements apply:

- An IFS Audit Team consists of IFS HPC 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 of the product scope of the audit scope. This means that if the lead or (co) auditor(s) do not have individually, all product scopes which are necessary for the audit, they have to assess all parts of the audit related to product scope knowledge, together.
- A minimum of two (2) hours shall be added to the calculated 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 competencies for product scope are always covered during the audit. No crossing over is allowed: if the lead or co-auditor(s) do not have individually have all product scopes necessary for the audit, they have to remain together during all parts of the auditor where the approval of both auditors are necessary. Only an auditor with all relevant product scope(s) 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.

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

The different responsibilities of each role and requirements they shall fulfil will be shown in chapter 3.6 to gain a clear overview.

a) IFS Reviewer:

The role of the IFS Reviewer comprises the following tasks:

- review the IFS HPC Audit Reports according to the IFS HPC Standard and the IFS HPC Doctrine. Including:
  - the overall consistency of the IFS Audit Reports,
  - completion of IFS Audit Reports (e.g., compulsory fields, etc.),
  - the proper description of the findings and justifications if relevant,
  - check if the correction and corrective actions as well as the deadlines for implementation proposed by the assessed company have been validated by the auditor (or by a representative of the certification body) and are relevant,
  - assurance that the relevant fields are translated in English where necessary.

The review shall be documented.

The IFS HPC Auditors cannot review IFS Audit Reports where they have been involved in the execution of the audit (e.g., as IFS Witness Auditor, trainee).

The requirements to be an IFS Reviewer shall be:

- IFS HPC Auditor
  or
- IFS Auditor for any IFS Product Standard having taken part at the "IFS HPC Awareness" eLearning course
  or
- fulfil the following requisites (pure IFS Reviewer):
  - science or bioscience degree (e.g. engineering, chemistry, pharmacy, biology, etc.) (as a minimum a bachelor's degree or equivalent),
  - to have attended (as auditor or observer) at five (5) complete audits (related to product safety and/or quality of HPC products) in the last five (5) years,
  - to participate at the "IFS HPC Awareness" eLearning course.
  - Risk assessment / HACCP course with a duration of approximately 16 hours.

In addition, the IFS Reviewer shall have taken part in a one (1) day / 8 hours at the yearly in-house training organized by the certification body.

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.

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 / 8 hours in-house training with **each certification body** the non-exclusive auditor is linked to in the IFS Database.

Note: if not IFS Auditor, the IFS Reviewer shall participate at one (1) day online IFS Calibration Training for reviewers/trainers organized by IFS. The IFS Calibration Training shall be completed in the second calendar year following the date of the initial approval.

b) IFS In-house Trainer:

The role of an IFS In-house Trainer comprises the following tasks:

- train IFS HPC Auditors and reviewers,
- inform when a new IFS HPC Doctrine is published and to train auditors and reviewers in case the published information has an impact on the performance of the IFS HPC Audit (this training can be done face-to-face, online or by webinar),
- organize and create the content for the yearly in-house training for IFS HPC Auditors and reviewers.

The requirements to be an IFS In-house Trainer are:

- IFS HPC Auditor
  or
- IFS Auditor for any IFS Product Standard having taken part at the "IFS HPC Awareness" eLearning course
  or
- fulfil the following requisites (pure IFS In-house Trainer):
  - science or bioscience degree (e.g. engineering, chemistry, pharmacy, biology, etc.) (as a minimum a bachelor's degree or equivalent)
  - to have attended (as auditor or observer) at five (5) complete audits (related to product safety and/or quality of HPC products) in the last five (5) years
  - to participate at the "IFS HPC Awareness" eLearning course.

In addition, the IFS In-house Trainer shall:

- carry out or have taken part in a one (1) day / 8 hours at the yearly in-house training,
- be continuously staying informed about any new information on the IFS HPC Standard and Doctrine (provided by IFS to the certification body),
- have taken part at the new "IFS HPC Awareness" eLearning course provided by IFS and afterwards to carry out an in-house course for all approved IFS HPC Auditors and reviewers before they perform audits and technical reviews in case of a new version of the IFS HPC Standard is published. The duration of this specific IFS in-house training based on the new version of the IFS HPC Standard shall be two (2) days / 16 hours.

Note: if not IFS Auditor, the IFS In-house Trainer shall participate at one (1) day online IFS Calibration Training for reviewers/trainers organized by IFS. The IFS Calibration Training shall be completed in the second calendar year following the date of the initial approval.

c) IFS Witness Auditor:

The role of an IFS Witness Auditor comprises the following tasks:

- monitor the audit performance of IFS HPC Auditors by an on-site witness audit for the maintenance of auditor's approval,
- witness the sign-off audit (only done by already IFS HPC Auditors with the approved relevant scope(s)),
- supervise the audit activity of the auditor in progress (AIP) (only done by already IFS HPC Auditors),

- provide comprehensive witness audit reports, which shall be made available to IFS on request.

The requirements to be an IFS Witness Auditor are:

- IFS HPC Auditor
  or
- IFS Auditor for any IFS Product Standard having taken part at the "IFS HPC Awareness" eLearning course
  or
- fulfil the following requisites (pure IFS Witness Auditor):
  - science or bioscience degree (e.g. engineering, chemistry, pharmacy, biology, etc.) (as a minimum a bachelor's degree or equivalent),
  - to have attended (as auditor or observer) at five (5) complete audits (related to product safety and/or quality of HPC products) in the last five (5) years,
  - to participate at the "IFS HPC Awareness" eLearning course.

In addition, the IFS Witness Auditor shall:

- be appointed as IFS Witness Auditor in the IFS Database,
- participate at the certification body yearly in-house training course on IFS HPC
- have taken part in the IFS Witness Auditor eLearning course (only once). This eLearning course is organized by IFS,
- be approved for the language(s) in which the audit is performed.

The IFS Witness Auditor shall use the template for IFS Witness Audit Reports for all witness audits (sign-off and monitoring witness audits).

It is the responsibility of the certification body to ensure that the witness auditor has the required skills, both on interpersonal and professional levels, to be able to witness other auditors in a constructive manner.

3.6 Overview for initial and maintenance of approval and tasks of different IFS Roles

The following chart 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

Function/role in certification body	Profile/requirements for initial approval	Requirements for maintenance of approval	Tasks
IFS HPC Auditors (see chapter 3.1)	• Education • Work experience • Qualifications • General audit experience • Specific knowledge in product scope • "IFS HPC Awareness" eLearning course • eLearning ("IFS Product and process approach") • Passed written IFS HPC examination • Sign-off audit	• Every year: one (1) day (8 hours) in-house training by the certification body • Every two (2) years: minimum of ten (10) accredited product safety audits including as a minimum five (5) IFS HPC Audits as a lead or co-auditor. • Be assessed through a witness audit every two (2) calendar years. • Every two (2) calendar years: IFS HPC Calibration Training, organized by IFS	• Perform IFS HPC Audits • Review IFS HPC Audits Reports (if not performed by themselves • Option to be IFS In-house Trainer

Function/role in certification body	Profile/requirements for initial approval	Requirements for maintenance of approval	Tasks

IFS Reviewers (see chapter 3.5)	• IFS HPC Auditor
	or
	• IFS Auditor for any IFS Product Standard having taken part at the "IFS HPC Awareness" eLearning course
	or
	• Fulfil the following:
	  ◦ pure science or bioscience degree (e.g. engineering, chemistry, pharmacy, biology, etc.) (as a minimum a bachelor's degree or equivalent)
	  ◦ to have attended (as auditor or observer) at five (5) complete audits (related to product safety and/or quality of HPC products) in the last five (5) years
	• to participate at the "IFS HPC Awareness" eLearning course
	• Risk assessment / HACCP course with a duration of approximately 16 hours.
		• have taken part in a one (1) day / 8 hours at the yearly in-house training organized by the certification body
		• if not IFS Auditor, the IFS Reviewer shall participate at one (1) day online IFS Calibration Training for reviewers/ trainers organized by IFS.
		
		The IFS Calibration Training shall be completed in the second calendar year following the date of the initial approval.
			• To review the IFS HPC Audit Reports according to the IFS HPC Standard and the IFS HPC Doctrine

Function/role in certification body	Profile/requirements for initial approval	Requirements for maintenance of approval	Tasks

IFS In-house Trainers (see chapter 3.5)	• IFS HPC Auditor
	or
	• IFS Auditor for any IFS Product Standard having taken part at the "IFS HPC Awareness" eLearning course
	or
	• Fulfil the following:
	  ◦ pure science or bioscience degree (e.g. engineering, chemistry, pharmacy, biology, etc.) (as a minimum a bachelor's degree or equivalent)
	  ◦ to have attended (as auditor or observer) at five (5) complete audits (related to product safety and/or quality of HPC products) in the last five (5) years
	• to participate at the "IFS HPC Awareness" eLearning course
		• carry out or have taken part in a one (1) day / 8 hours at the yearly in-house training organized by the certification body,
		• staying informed about any new information on the IFS HPC Standard and Doctrine
		• have taken part at the new "IFS HPC Awareness" eLearning course organized by IFS and afterwards to carry out an in-house course for all approved IFS HPC Auditors and reviewers before they perform HPC Audits and reviews in case of a new version of the IFS HPC Standard is published.
		• if not IFS Auditor, the IFS In-house Trainer shall participate at one (1) day online IFS Calibration Training for reviewers/ trainers organized by IFS.
		
		The IFS Calibration Training shall be completed in the second calendar year following the date of the initial approval.
			• Train auditors and reviewers
			• Organize and generate the content for the yearly in-house training for IFS HPC Auditors and reviewers
			• When a new IFS HPC Doctrine is published, to train all approved IFS HPC Auditors and reviewers

Function/role in certification body	Profile/requirements for initial approval	Requirements for maintenance of approval	Tasks

IFS Witness Auditors (see chapter 3.5)	• IFS HPC Auditor
	or
	• IFS Auditor for any IFS Product Standard having taken part at the "IFS HPC Awareness" eLearning course
	or
	• Fulfil the following:
	  ◦ pure science or bioscience degree (e.g. engineering, chemistry, pharmacy, biology, etc.) (as a minimum a bachelor's degree or equivalent)
	  ◦ to have attended (as auditor or observer) at five (5) complete audits (related to product safety and/or quality of HPC products) in the last five (5) years
	  ◦ to participate at the "IFS HPC Awareness" eLearning course
	• Have taken part in the IFS Witness Auditor eLearning course. This online course is provided by IFS.
		• Every year: One (1) day (8 hours) in-house training by the certification body	• Monitor the audit performance of IFS HPC Auditors by an on-site witness audit for the maintenance of auditor's approval
			• Witness the sign-off audit (if HPC Auditors approved for the relevant scope(s))
			• Supervise the audit/audit activity of the AIP (if HPC Auditors)

PART 4

PART 4
Reporting, IFS Software and IFS Database

0 Introduction

After performance of an IFS HPC Audit a detailed and well-structured report shall be completed. In general, the language of the report shall be the working language of the company. In cases where the language of the report is not English, additional information detailed in section 1.5, shall be translated in English.

Depending on the case, an additional English version of the report could also be prepared.

Note: for any combined IFS Audit (IFS HPC / IFS Broker or IFS HPC / 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 HPC Audit Report shall be prepared according to the following format:

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

1 Reporting

1.1 IFS HPC Audit Report: audit overview (Annex 8)

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

- "Unannounced audit" if the audit was unannounced,
- certification body logo,
- IFS HPC Logo,
- name of the assessed site and legal authorisation number, if applicable,
- GLN (Global Location Number), if available,
- date(s) of the audit,
- name and address of the certification body,
- certification body's accreditation details.

Audit overview
The audit overview shall include the following mandatory information:

- **Audit option**
  If the audit was unannounced, "Unannounced audit" shall be mentioned on the audit overview of the report.

- **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.
- **Scope of the audit**
  - detailed description of processes and products,
  - numbers of the product scope(s).
- **Additional information**
  - description of exclusions, if applicable,
  - description of partly outsourced processes (explanations, number of subcontractors, description including name, address and certification status), if applicable,
  - description of decentralised structure(s), if applicable, and off-site warehouse(s) (name the location):
    - if IFS Logistics certified, provide the COID
    - if not, mention if it has been covered during the IFS HPC Audit,
    - if not, describe the company's control measures.
  - description of multi-location production sites, if applicable.
- **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 the outcome ("the Major non-conformity has been solved"),
  - 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)
- **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.

1.2 IFS HPC Audit Report: main content (Annex 10)

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

- General summary in a tabular format for all chapters, listing the number of assessed requirements per scoring for each chapter and the result (in percentage) per chapter.
- Overall summary of compulsory information for specific IFS HPC Requirements. For those specific requirements, the auditor shall provide additional justifications and/or further background information, even in case of an A scoring. This leads to a more significant and descriptive report, even if the assessed site almost fulfils all IFS HPC Requirements and adds value for every user/reader.
- List of all identified deviations and non-conformities for each requirement per chapter.
- 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 Action plan (Annex 8)

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 HPC Audit process, the certification body shall issue a certificate. For the purpose of international recognition and overall consistency, IFS HPC 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,
- if the audit was unannounced, "Unannounced audit" shall be mentioned,
- name and address of the audited site,
- COID (IFS identification number) as defined in the IFS Database
- legal authorisation number, if applicable,
- GS1 GLN(s) related to the site(s) that has/ve 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 be always translated in English,
- description of processes/products,
- number and name of the 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 equivalent standards 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). The certificate shall indicate the following: **"Last audit conducted unannounced: N/A"**,
- IFS Star Status indication in case the audit was conducted unannounced.
- audit date(s) and time,
- follow-up audit date, if relevant,
- next audit time period (recertification audit),
- 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 HPC 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 the IFS Website which verifies the authenticity of the certificate.

QR-code for creating a certificate for non IFS Software users
For certification bodies that generate certificates and do not use the IFS Software there is an area in the IFS Database where a QR-code for the respective COID can be downloaded.

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

1.5 Information to be translated into English

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

- Audit overview:
  - Scope of the audit
  - Additional information (if applicable):
    - Exclusions
    - Partly outsourced processes
    - Multi-location production sites
    - Decentralised structure(s)
  - Company profile:
    - Company data
    - Audit data
- Main content:
  - Overall summary of compulsory information (table of compulsory fields)
  - Detailed IFS Audit Report:
    - Deviations and non-conformities
- Action plan:
  - Corrections and corrective actions

2 IFS Software

To increase the standardisation of the IFS Reporting, IFS Software has been developed and shall be used to generate the IFS Report.

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:

- Auditors
- Certification bodies
- Certified companies/suppliers
- 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 supplier
- 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 suppliers to select their favourites from all certified companies that are listed in the IFS Database and to store them in a separate list.

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

IFS
HPC

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 packaging.

IFS Broker

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

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

IFS HPC

Standard for 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.

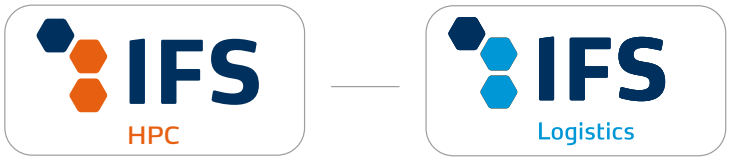
Scope determination between IFS PACsecure and other IFS Standards

IFS HPC and IFS PACsecure

If a manufacturer produces products which are intended to be used as daily use household products, the IFS HPC Standard applies.

IFS HPC and IFS Broker

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



IFS HPC and IFS Logistic

Clarification of scope application between IFS HPC and IFS Logistics:

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

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

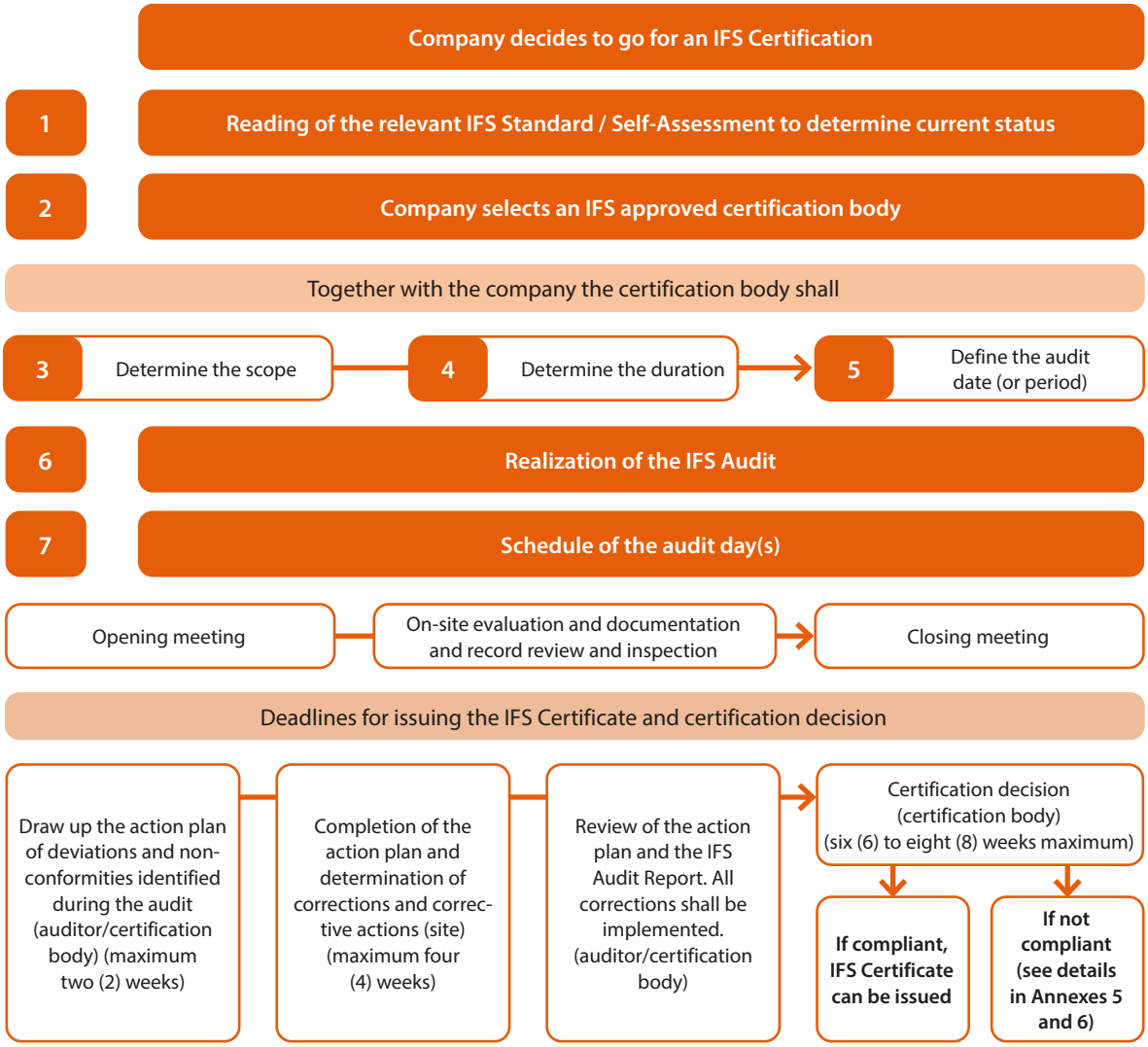
- the logistics activities are only carried out for pre-packed products,
- the respective scope of each audit (IFS HPC and IFS Logistics) shall be clearly defined in the two (2) certificates, and also in the audit report,
- considering the IFS Logistics is an additional certification, the requirements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

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

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

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

ANNEX 2: Certification process



ANNEX 3: Products out of the scope of the IFS HPC Standard

- Appliances and electronic/electric devices (e.g. electronic toothbrushes)
- OTC and medicines under medical prescription
- Toys (except make up for children dolls)
- Products to maintain car activities (e.g. motor lubricants, etc.)
- Medical devices (more than class I)
- Chemicals (as raw materials)
- Clothes and textiles
- Plant care products (e.g. fertilizers, etc.)
- All activities/processes covered by other IFS Standards (e.g. food processing, trade activities and logistics activities, etc.

ANNEX 4: Questionnaire for product exclusions

By definition, all processes and products which are managed by the company/legal entity, on the same site and which are under their responsibility, **shall be included in the IFS HPC Audit Scope.**

Regarding the exclusions, the key concept is the evaluation of the product risk analysis which may confirm whether an exceptional product exclusion is possible (with no impact on product safety and quality).

If exclusion of product(s) is required by the company, then the following rules shall be fulfilled:

a) Application

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

b) On-site verification by the auditor

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

c) Approval

- After the IFS Audit and with the inputs provided by the auditor into the IFS Audit Report, the certification body shall inform the company the exclusion has been approved.
- The exclusion shall always be specified on the certificate, in addition to the information included into the audit report.

d) Additional requirements for the companies and certification bodies

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

IFS HPC questionnaire for certification bodies, to define product exclusions in the audit scope

If, under exceptional circumstances, the company decides to exclude specific product(s) from the scope of the HPC 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 be part of the audit time schedule.

Name of the company: _____ COID: _____

Planned audit scope
(product scope and description): _____ 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: _____

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

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

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

2) Is the product seasonal/sporadic?

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

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

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

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

4) Is/are the initial step(s) of the production 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)**

5) 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**

6) 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**

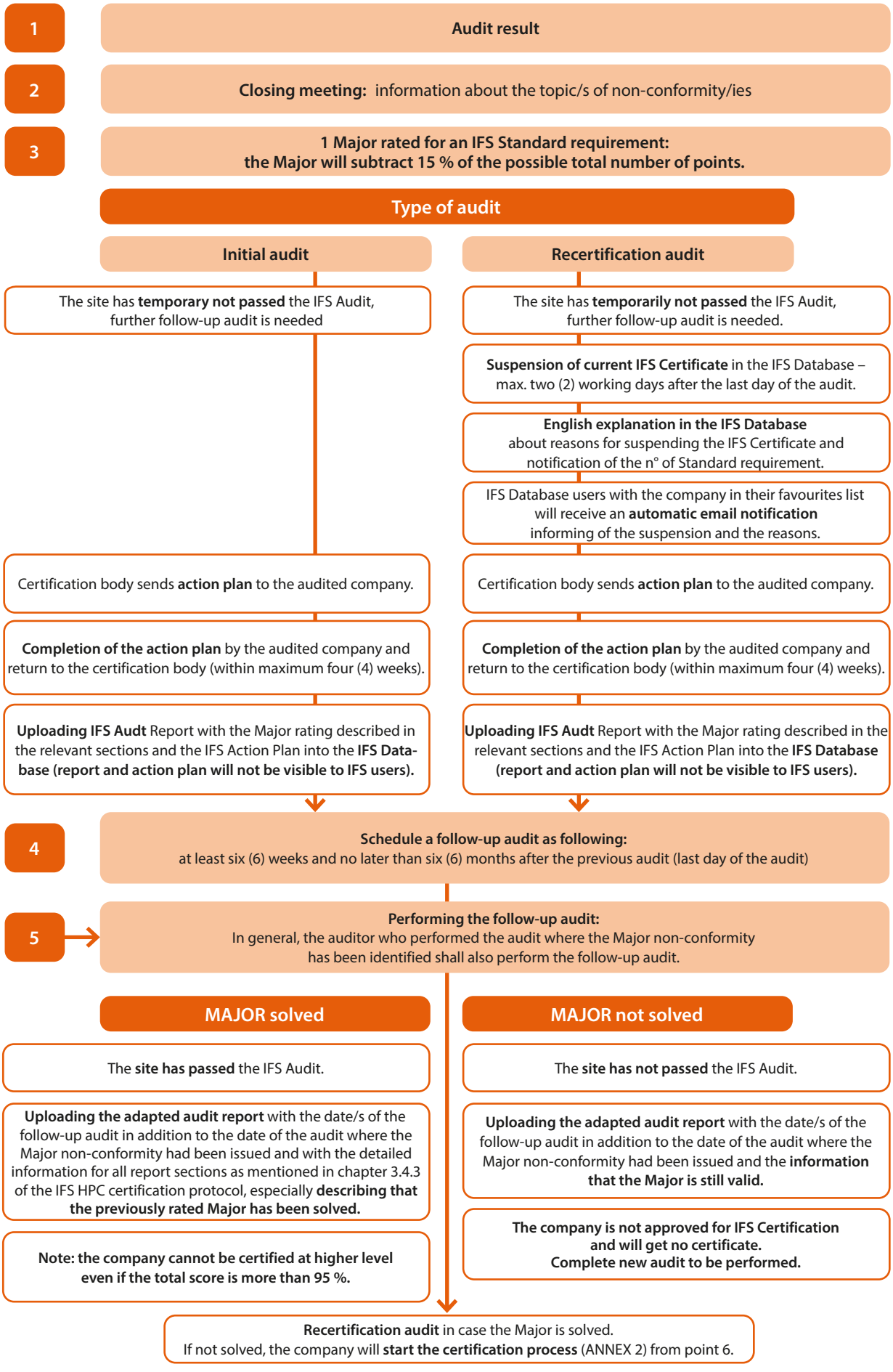
Exclusion is NOT possible

The auditor shall 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).

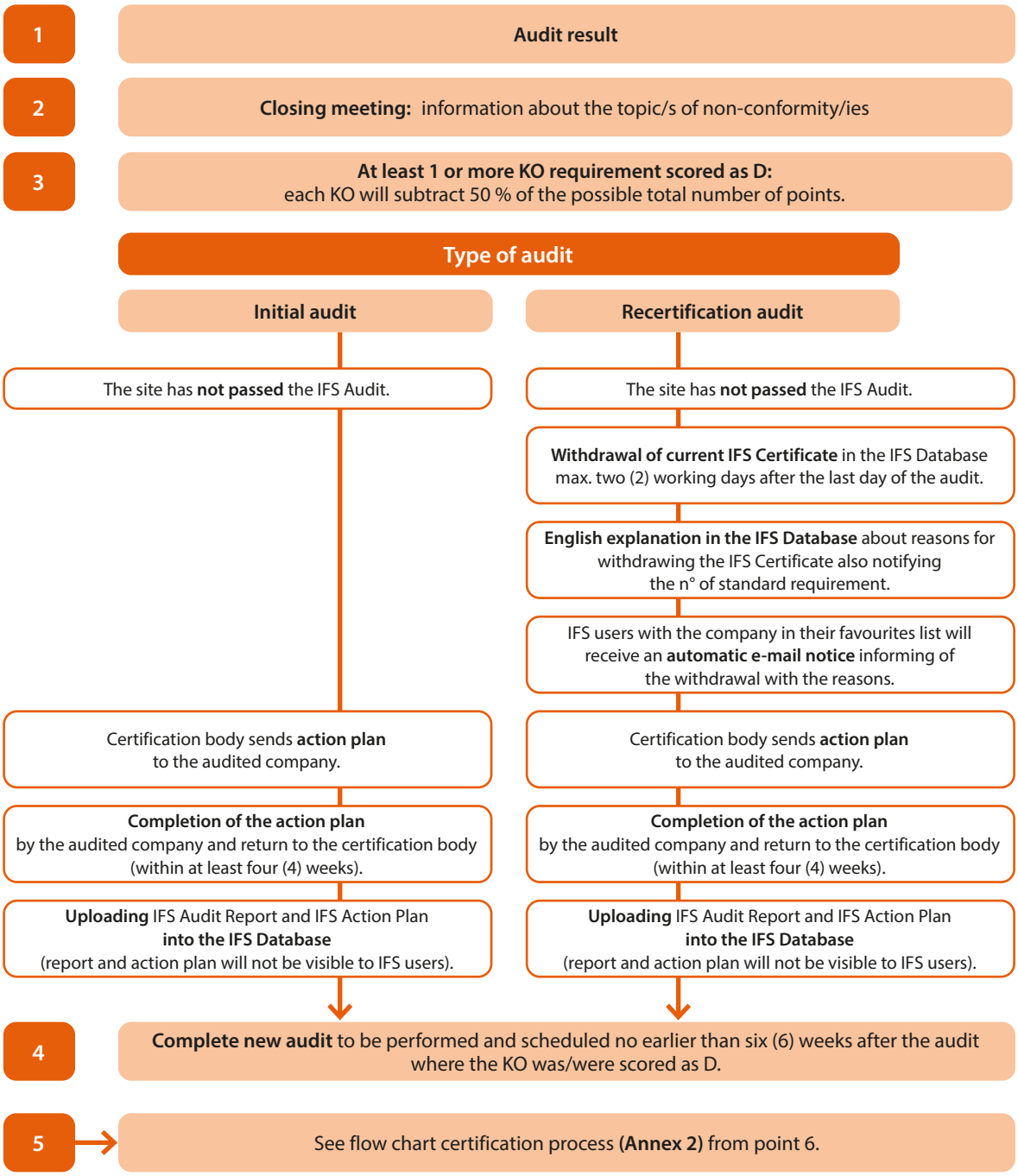
Glossary:

Terms	Related definitions
Different area	Different location or zone of the company with or without physical segregation.
Differentiable	Being subjected to different product characteristics, like e.g. different product kind/type, different name, different packaging material, etc. Products which are fully equivalent but only having – as different characteristics – a different label is not enough to differentiate a product.
Documentary on-site evaluation	Can only be performed if the product scopes and/or risk assessment / HACCP (incl. allergens, contaminants, etc.) are identical for seasonal/sporadic products and regular products. This evaluation shall address, at least, risk assessment / HACCP, production records, traceability test, customer specifications and complaints.
Common initial steps	Applies to upstream processing steps or same raw materials which are common between included and excluded products.
Regular product	Product which is processed all year long, in opposite to seasonal or sporadic product.
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.
Sporadic products	Products that are irregularly processed (on order / tailor made) and which process cannot be scheduled in advance.

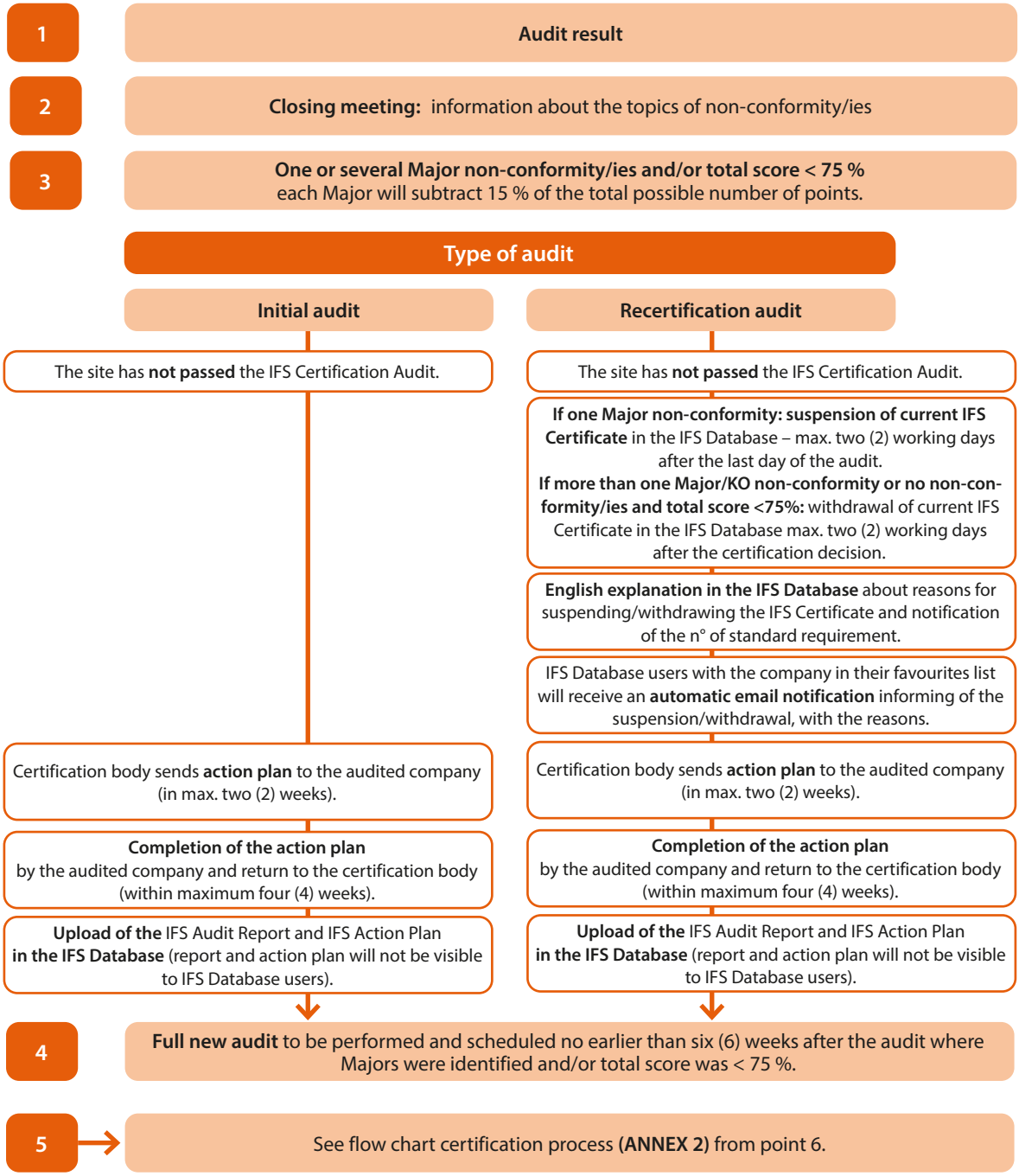
ANNEX 5: Management of one Major non-conformity and total score ≥ 75%



ANNEX 6: Management of a KO requirement scored with a D



ANNEX 7: Management of more than one or several Major non-conformity/ies and/or total score < 75%



ANNEX 8: 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 (by the company)	Type of evidence and name of the document(s)	Corrective action (by the company)	Responsibility (by the company)	Date (by the company)	Status of implementation (by the company)	Validation date (by the auditor)
1.2.2	**KO N°1: The senior management shall ensure that…**	KO / C											
1.2.3	**The department responsible for product safety…**	Major											
1.2.4	**The company shall ensure that all processes…**	C											

ANNEX 9: IFS Audit Report: audit overview

Cover page

Unannounced audit (if applicable)

Logo of the certification body

IFS HPC Version 3
DECEMBER 2022

Final IFS Audit Report

Audited company: "Pampering Pets Ltd"
[GS1 GLN(s) and where applicable legal authorisation number]

Date of audit: 07.06. / 08.06.2023

Name and address of certification body

(Unannounced, if applicable) Audit overview
IFS HPC Version 3, December 2022

Audit details

Lead auditor: Nadia Example date / time: ***Co-auditor:*** date / time: ***Trainee:*** ***Witness auditor:*** ***Reviewer:*** ***Interpreter:*** ***Technical expert:***	***Date / time of current audit:*** 07. 06.2023 (09:00–18:00) 08. 06.2023 (08:30–17:30)	***Date / time of previous audit:*** 15.05.2022 (09:00–18:00) 16.05.2022 (08:30–12:30) ***Certification body and auditor of previous audit:*** TEST GmbH/Frank Test

Name and address of the company (or head office): Pet Care Actions Elm Street 12345 Madrid Spain		***Name and address of the audited site:*** Pampering pets Ltd Evergreen Terrace 12346 Madrid Spain	
		COID:	
		Contact person in case of emergency (e.g. recall): [Name, e-mail and phone number at a minimum]:	
Phone: 0 1 2 3 4 5 6	Fax: 01 23 45 67 89	Phone: 0 1 2 3 4 5 6 8	Fax: 01 23 45 67 89
Website: www.petcareactions.com	E-mail: info@petcareactions.com	Website: www.petcareactions.com	E-mail: info@petcareactions.com

Scope of the audit

Mixing, filling, assembly and packing of pet care products, including shampoos and softeners packed into PET bottles and plastic tubes.

Product scope(s): 2 Household chemical products

Additional information

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 07. 06. and 08. 06. 2023, "xyz" found that the processing activities of Pampering Pets Ltd for the above-mentioned scope of audit comply with the requirements set out in the IFS HPC Standard, Version 3, at Foundation level, with a score of XX%.

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

Detailed description of follow-up on corrections and corrective actions from previous audit:

Company profile
Company data
Key investment related to the production and product safety and quality during the last 12 months (construction changes, machinery, etc.)
Year of construction of the assessed site(s):
Number of total employees (including part time and shifts):
Area of the production site (including storage area) in square meters/feet:
Number and description of buildings, floors and production lines (including decentralised structure(s), if applicable):
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:
Has the company been listed on any public notification portal of non-food dangerous products since the last IFS Audit? [yes/no] If yes, which one? Explanation of the cause:
Does the audited site have fully outsourced products and/or traded 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 partly outsourced processes? If "yes": specify these processes.
Does the site have own logistics activities (besides the activities covered by the IFS HPC Certification)
Does the company fulfil the requirements about the use of the IFS (HPC) Logo, as defined in the IFS HPC Certification Protocol (Part 1)? [yes/no] If "no": [explanation]
List if the production site is certified according to other schemes. Specify scheme's names:
Audit data
Language in which the IFS HPC Audit was conducted:
Audit duration:
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 HPC Version 3,
December 2022

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 & commitment	Product Safety and Quality Management System	Resource Management	Operational Processes	Measurements, Analyses, Improvements
KO Non-conformities	0	0	0	0	0
Major non-conformities	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 HPC Audit Requirements and key elements

Part of the IFS HPC Audit Report	N° of IFS HPC Require-ment	Compulsory information to be added
Corporate structure	**1.2.1 KO n° 1**	• Minimum description (e.g., how the senior management take accountability for the effectiveness of the safety and quality management system, how they ensure employees are aware, and how is monitored the effectiveness of the operation).
	1.2.5	• Date and time of last visit (when exists, even when more than 12 months ago) and name of the authorities. Status (open/closed).
Record keeping	2.1.2.3	• Duration of record keeping for product safety and legality related records.
Determine Critical Control Points (CCPs) and other control measures	2.2.3.6	• a) If existing, list CCPs • b) if not existing, justification why CCPs are not necessary.
Establish a monitoring system for each CCP	**2.2.3.8 KO n° 2**	• If applicable, description of the monitoring procedure for each CCP which includes at a minimum: process step, control method, critical limit, and control frequency. Also, the sample(s) checked during the IFS Audit shall be described. • In case of N/A, provide explanation
Establish verification procedures	2.2.3.13	• Date of last hazard analysis and risk assessment system verification.
Personal hygiene	3.2.1	• Description of how the hygiene requirements is communicated to personnel, contractors and visitors.
Specifications	**4.2.2.2 KO n° 3**	• Description of finished product specifications which were checked during the audit. • Indicate if the finished product specifications have been agreed upon with the customers.
Factory exterior	4.5.1	• Description of the location of the site and the conditions of the external areas.
Laboratories	4.6.5	• Which analyses are performed in the own laboratory? Which ones by an external one?
Water	4.7.10.1	• Description of how the process water is checked, stating particularly whether the water is checked by the company's own laboratory or via an external laboratory. • Which analyses are performed? (with parameters).

Part of the IFS HPC Audit Report	N° of IFS HPC Require-ment	Compulsory information to be added
Foreign material risk mitigation	4.10.2	• Description of the equipment and methods used to detect foreign materials (e.g. filters, sieves, X-ray, metal detection) and where they are placed in the process. • If foreign material detectors are not defined as CCP, description of the test pieces and sizes. • If no foreign material detection equipment is available, descrip-tions of the used preventive measures (e.g. visual detection methods).
Pest monitoring and control	4.11.1	• Are the pest control services managed by in-house staff or by an external provider used? • Frequency and kind of checks. • In case of identification of pest activity, what were the corrective actions?
Traceability	**4.16.1 KO n° 4**	• Description of the traceability system and documentation for traceability in the company. • Description of which product/s was/were used for the traceability test during the IFS Audit including details concerning used raw materials, ingredients, additives, rework, for the final product / mass balance / results of the traceability tests backwards and forward. **Note:** The traceability test(s) shall always be based on a sample chosen by the auditor.
Allergen risk mitigation	4.17.2	• What kind of preventive measures and control measures are in place to ensure that cross contamination is minimised?
Quantity control monitoring	5.5.1	• Description of the frequency and methodology of quantity checking.
Product analyses	5.6.5	• Indicate the analyses carried out by the company to ensure that product requirement and specifications are met, the frequency of these analyses and if are carried out in their own laboratory and/or in an external laboratory.
Management of complaints	5.8.1	• Range or indicator of complaints raised by consumers, customers and authorities separately since last audit. • Main root cause of complaints identified by the company.
Management of incidents, product with-drawal, product recall	**5.9.1 KO n° 5**	• Specify how many withdrawals and recalls have been performed since the last audit. • Specify the product(s) involved and the cause(s) of withdrawals and product recall.
Corrective actions	**5.11.2 KO n° 6**	• Description of samples chosen during the audit for the follow-up of the corrective actions originating from internal audits, customer audits, certification audits, complaints, lab analysis, etc., and or any other source except the previous IFS Audit.

Part of the IFS HPC Audit Report	N° of IFS HPC 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 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 scored with 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:

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

IFS Scoring System (based on charts 3 and 4, Part 1)

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

ANNEX 11: IFS Certificate

Certificate

IFS
HPC (★)
(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 processing activities of …

Name of the audited company

Address

(GS1 GLN(s) and where applicable, legal authorisation number),
COID, (head office, 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 equivalent standards certified".

Number and name of the product scope(s)

meet the requirements set out in the

IFS HPC Version 3, December 2022

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

Certificate-Register number:
Date of the last unannounced audit (last day of the audit):
"Last audit conducted unannounced: N/A"

Audit date (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 HPC 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
Audit (IFS)	Determination process which includes evaluation methods such as auditing and inspection, to determine to what extent a production site and its related processing activities comply with the specified requirements (laid down in Part 2). The IFS Audit is conducted by following an audit trail, including an on-site evaluation and a documentation and record review/inspection in which auditing and inspection technics are applied alternately.
Audit time window (unannounced audit)	Period of time 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). Within the IFS HPC Certification Protocol (Part 1), the time window is [– 16 weeks; + 2 weeks] of the audit due date.
Assessor (for accreditation bodies)	Person assigned by an accreditation body to perform, alone or as part of an audit team, an audit of a conformity audit body. **Note:** in the IFS Standards, conformity audit body is named certification body.
Audit	Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. In the IFS Audit, auditing is limited to the examination of management processes which are leading to a compliant process/product.
Auditor	An individual who is qualified to provide audits, such as certified auditor. Note: an employee who is qualified and independent of the audited function typically conducts first-party / internal audit within the organization. A totally independent certified auditor who is not involved in the customer-supplier relationship conducts third-party audits.
Auditor in progress (AIP)	Candidate in the process of gaining auditing/assessing experience and has to pass the written IFS Examination to become a qualified IFS HPC Auditor. For further information, see chapter 3.3, Part 3 of the Standard.
Batch (lot) number	A unique combination of numbers, letters, and/or symbols that identifies a batch (or lot) and from which the production and distribution history can be determined. **Note:** When a company uses the word "lot" and "batch" simultaneously; the company shall determine what is the definition and application of both words used.
Blackout period	Period of time the company may notify 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.

Terms	Related definitions
Calibration	Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure, or a reference material and the corresponding values realized by standards.
CCP (critical control point)	A step within the production process identified by the hazard analysis and risk assessment at which control shall be applied and which is essential to prevent, eliminate or reduce to an acceptable level a product safety hazard. Loss of control at this step may increase the likelihood of an adverse health effect of the consumer (e.g., illness, injury, etc.).
Claims	Any message or representation, including pictorial, graphic or symbolic representation, in any form (product label, packaging, advertisement, specifications, product inserts), which states, suggests or implies that the product has particular characteristic(s) or effect(s) that is/are not inherent to the product and/or is not generally present in similar products. The following list of examples of the particular characteristic(s) and/or effects doesn't claim to be exhaustive: • nature or composition (e.g. organic, "natural", "free from", "source of", "reduced", etc.), • standards of identity for products (e.g., meat products, specific labels, etc.), • origin or provenance (e.g., "made in…", "product of…", PDO/PGI etc.), • methods of production/processing (e.g. fair-trade, religious claims, etc.), • specific properties, structure and/or function related to a risk reduction for customers and/or consumers (e.g., related to prevent or reduce the risk of health diseases, prevent the contamination by spoilage or pathogen micro-organisms, etc.) • specific properties, benefits and/or effects for customers and/or consumers due to the usage of the product (e.g., anti-aging effect in cosmetics, extend shelf life of food in packaging, improving or modifying a physiological function or biological activity associated with health in food, etc.) Claims linked to the product can be declared only if: • Evidential support is available to demonstrate their truthfulness, honesty, fairness and the legal compliance. • Are approved to be used by the relevant authority, when applicable. • Clear and understandable information is provided to the users (customer, consumer and/or end-user, as applicable) about the particular characteristic(s) and/or effect(s) declared in regard to the intended use of the product. **Note:** in case of IFS Audits, claims shall not be used in the description of the audit scope on the IFS Certificate, to avoid confusion on the scope of the IFS Audit and certification.

Terms	Related definitions
Company	Any establishment in which any stage of production, conversion and/or distribution of products is carried out. The company can have one or several legal entities registered and/or approved by the relevant authority.
Composition	Quantified list of components/ingredients used to define the semi-finished or the finished product and how these are brought together. (e.g. batch formulation, recipe, etc.).
Consumables	Materials such as cleaning agents and lubricants that are used up during cleaning, sanitization or maintenance operations.
Contamination	Introduction or occurrence of a contaminant in product or product environment. A contaminant can be any biological, chemical agent, physical foreign material, or any other substances that may compromise product safety or suitability.
Consumer unit	The smallest unit of the product that can be sold to the final users and/or consumers, which is available on the market, at the point of purchase.
Contractor	A company or person who is contracted by the company to carry out work within the site.
Control measure	A step within the production process identified by the hazard analysis and risk assessment at which control can be applied and which is essential to prevent, eliminate or reduce a hazard/risk in the product and/or the environment to an acceptable level. The loss of control at this point may not lead to an adverse health effect of the consumer (e.g., illness, injury, etc.). Acceptable levels may be derived from legal and regulatory requirements, industry standards, scientific information, internal requirements, customer requirements, and specifications, among others.
Consumer	The ultimate consumer of a product who will not use it further as part of any business operation or activity.
Correction	Action to eliminate a detected deviation and/or non-conformity. It shall be implemented, at latest, before a certificate is issued.
Corrective action	Action to eliminate the cause of a detected deviation and/or non-conformity. It shall be implemented, at latest, before the recertification audit.
Customer	A customer is a business company or person (e.g. broker) to whom products are sold either as a finished product or as a semi-finished part of the finished product and further actions are expected.
Customer agreement	A negotiated and usually legally enforceable understanding between a customer and the company.
Customer branded product	A product which is manufactured by the production site and sold under the brand name of its customer (e.g. private label).
Decentralised structure	Facility (for example a workshop) owned by the company where part(s) of the processes and operations of the production site take place.
Deviation	Non-compliance with a requirement, without any impact on product safety related to products and processes. In the IFS Standards, deviations are requirements scored with a C, D and KO requirements scored with a C.

Terms	Related definitions
FEFO (first expired-first out)	Common process in which the first expiring products – relating to the shelf life – are removed from storage first.
FIFO (first in- first out)	Common process in which the first received products are removed from storage first.
Flow diagram	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular item.
Formula	Exhaustive description of quantity and quality of raw materials to be used to process the products as required in customer specifications. Formula can also include technological parameters and specific "know-how" on the process.
Good manufacturing practices	The good manufacturing practices constitute the practical development of the quality assurance concept through the description of the plant activities that are based on sound scientific and state of the art judgement and risk assessment. This allows a producer to define the activities that enable obtaining a safe product that meets defined characteristics e.g. appropriate equipment and environment as well as safety aspects in the whole process/area. In the IFS HPC Standard the good manufacturing practices are aimed to be implemented prior performing the hazard analysis and risk assessment. In the event of no specified good manufacturing practices in the scope of activity, the company shall develop its own GMP´s.
Hazard	A biological, chemical or physical agent with the potential to cause an adverse health effect.
Hazard analysis	The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for product safety and therefore shall be addressed in the risk assessment.
Head office audit (for accreditation bodies)	Audit of the Conformity Audit Body Head Office. **Note:** in the IFS Standards, conformity audit body is named certification body.
Hygiene	Conditions and measures that are required to ensure that packaging material and product is safe.
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 to: • monitor, as preventive actions performance of auditors and certification bodies as well as assessed companies, • manage, as corrective actions, any complaints addressed to IFS. These measures are aimed to ensure the quality of the IFS Standards.

Terms	Related definitions
Internal audit	General process of audit, for all the activity of the company. Conducted by or on behalf of the company for internal purposes. An internal auditing is an independent and objective assurance and consulting activity that is designed to add value and improve the operations of an organization. It helps an organization accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.
Key roles	Personnel who have significant responsibilities and accountability for the development and maintenance of product integrity.
Legal authorization number	Official authorization number of a manufacturing site to start a production activity.
Legal entity	A legal entity is the registered office of the HPC business where, according to agreement, the HPC business operator has its administrative center. It generally identifies the place where the administrative organization of the company is located.
Location	One physical address where the production site(s) is/are situated.
Monitoring	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether CCPs and other control measures are under control.
Non-conformity	Non-fulfilment of a specified requirement. Non-conformity can be given in case of: • non-respect of legislation, • product safety issues, • internal dysfunctions and • customer issues. In the IFS Standards, defined non-conformities are Majors and D evaluations of a KO requirement.
Non-operating periods	Periods when the production lines are not operating at all, e.g. planned maintenance work, bank holiday, planned company shutdown for holidays, etc.
On-site evaluation	Inspection and audit of the production area of the physical site, which includes the following areas: • production 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 and/or maintenance facilities, • staff and sanitary facilities, • external areas.

Terms	Related definitions
Packaging material	Any material used to: • Contain the product, which depends on the product's physical form and nature. • Protect and prevent the product from mechanical damage due to the hazards of distribution. • Preserve the product, to prevent or inhibit chemical changes, biochemical changes and/or microbiological spoilage. • Inform and communicate about the product, e.g.: legal requirements, product ingredients, usage, brand communication, etc. • Extend the shelf life or to maintain or improve the condition of the product. • Monitor the condition of the packaged product or the environment surrounding the product. • Handling, delivery and presentation of products.
Pest	Any animal or insect such as birds, rodents, cockroaches, flies, and larvae that may carry pathogens and could contaminate raw materials including packaging and the product.
Procedure	Specified way to carry out an activity or process. Procedures shall be implemented and the elaboration of procedures shall be laid out in documents or process descriptions (e.g. flowchart).
Process waters	According to the IFS HPC Standard, process waters are defined as water used within the facilities (e.g. sanitary facilities, etc.) and also water used as an ingredient or used for cleaning activities.
Product	Result of a process or activities transforming inputs into outputs. In the context of this Standard a product is to be considered a HPC product under the scope of application of the IFS HPC Standard (e.g. cosmetics, diapers etc.).
Product Defence	Procedure implemented to assure the protection of products and their supply chain from malicious and ideologically motivated threats (e.g., contamination or adulteration by biological, chemical, physical, or radiological agents).
Product group	Grouping of products due to similar characteristics or legal requirements.
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 HPC Standard, the requirements for the product development chapter, apply even if there is just a product modification, use of new packaging materials or modifications of production processes.
Product integrity	The product safety, quality and other requirements or criteria that are defined by the company or customer.
Product recall	Any measure to achieve the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor.
Product requirements	This is product safety, product quality, product legality, and process and customer specification.

Terms	Related definitions
Product safety culture	Shared values, beliefs and norms that affect mindset and behaviour toward product safety in, across and throughout an organization. Elements of product safety culture are those elements of the product safety and quality management which the senior management of a company may use to drive the product safety culture within the company. These shall include as a minimum: • communication about product safety policies and responsibilities, • training, • employee feedback on product safety related issues, • performance measurement.
Product withdrawal	Any measure aimed at preventing the distribution, display and offer of an out-of-specification product and/or of a product that may be dangerous to the consumer.
Production site	An establishment in a specific physical location where the IFS HPC Audit is conducted in which any stage of production and distribution of HPC 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 provided by the company (which includes footwear and gloves) which are worn by employees, contractors and visitors to protect the products from contamination.
Raw material	A base material used for the manufacture of a product (ingredients, additives, packaging materials, rework).
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.
Reviewer	Person of the certification body in charge of assessing the IFS Audit Report before a certification decision is made (see the role/tasks and requirements for IFS HPC Reviewer in chapter 3.5 a), Part 3).
Risk	A function of the probability of an adverse health effect and the severity of that effect consequential to (a) hazard(s) in products.
Root cause analysis	Process or procedure that helps understanding the initiating causes of a problem. The goal of this process is to determine the missing or inadequately applied controls that will prevent a recurrence.
Safety Data Sheet (SDS)	The SDS provides a mechanism for transmitting appropriate safety information on substances and mixtures under different circumstances. They are principally intended for use by professional users and must enable them to take the necessary measures in regard 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.
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
Sign-off audit	First witness audit of an auditor after having passed the written IFS Examination for the purpose of confirmation of competencies for final approval as IFS HPC Auditor. The sign-off audit shall be performed during a full IFS HPC Certification Audit.
Suspension (of the IFS HPC 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. Typical examples are: • In case of pending investigations by the certification body, following a food 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. System is a planned, sustainable structured course of action. System includes documentation, procedure description, control / monitoring, corrective action, site plan.
Traceability	Ability to trace and follow a product, through all stages of production/ processing and distribution.
Validation	Obtaining evidence that a control measure or combination of control measures is capable of controlling the hazard to a specified outcome.
Verification	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.
Withdrawal (of the IFS HPC 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 audit (by accreditation bodies)	Audit of the conformity audit body when it is carrying out conformity audit services within its scope of accreditation. **Note:** in IFS Standard, Conformity Audit Body is named certification body.
Witness audit every two (2) years, for IFS HPC approved Auditors (monitoring witness audit)	IFS HPC Auditors shall be assessed during a full IFS HPC on-site witness audit every two (2) years by the certification body to evaluate their competencies. For further information, see chapter 3.4, Part 3.

ANNEX 13: Cross reference ISO 22716 (GMPs Cosmetics)

The below cross reference shows the equivalence between the IFS HPC Requirements and the ISO 22716 requirements/chapters (guidelines on good manufacturing practices for cosmetics products). Although, the wording of the requirements in both documents is sometimes different, the general intention remains similar.

Cosmetics GMP´s shall be assessed within the IFS HPC Audit. Moreover, IFS would like some transparency on the following requirements:

IFS HPC Standard	ISO 22716
1.2.1	3.3.2 b)
1.2.3	3.3.1.1 / 3.3.2 a)
2.2.1.1 / 2.1.2	17.1 / 17.2 / 17.3
2.2.1.1	3.3.1.2
3.1.1	3.1
3.2	3.3.2 d) / 3.5
3.3.1	3.6
3.4.1	3.5.2
3.5	3.3.2 f) / 3.4.2
3.5.1	3.4.2.2
3.5.2	3.4.3
3.5.4	3.4.2.5
3.6.5 / 3.6.6	4.6
4.2.1.2	6.4.4
4.2.1.3	6.4.2 / 6.7
4.2.1.4	7.3.1.1
4.4.1 / 4.4.3	6.2
4.4.2	6.1
4.6	4.1
4.7.1	4.4.1 / 4.4.2
4.7.5	4.5.2
4.8.1 / 4.8.2 / 4.8.3	4.2 / 4.5
4.8.7	5.5.2
4.8.8	5.5.2
4.8.9	4.10.4
4.8.10.1 / 4.8.10	12.5.1

IFS HPC Standard	ISO 22716
4.10	4.1.1 / 5.2.1
4.11	4.13.1 / 4.13.2 / 4.13.3 / 12.5.1
4.13.1	6.2 b) / 6.3.2
4.14	4.11 / 12.5.1
4.14.2	12.5.1
4.14.6	12.5.1
4.15.1	5.2.1 / 5.2.2 / 5.2.3 / 5.2.4
4.16.1	5.6.1
4.16.2	6.6.5
4.17.1	5.2.1 / 5.7
5.1.1	16.1 / 16.2
5.4	5.4
5.6.1	9.1.1 / 9.1.2
5.6.3 / 5.6.5	9.2
5.6.7	9.7.1
5.6.12	7.2.5
5.6.9	9.4 / 10.2.1
5.7	6.5 / 8.2
5.8	14.2
5.8.1	14.4.1 / 14.4.2 / 14.4.3
5.10.1	9.5 / 10
5.10.4	9.5.3

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