IFS Food

IFS Food

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

VERSION 8 DRAFT

PUBLIC CONSULTATION APRIL-MAY 2022

ENGLISH

IFS is on its way to IFS Food version 8.
The review of the current version 7 became necessary due to recent developments in the market.

This document sets out the draft requirements of IFS Food version 8 for the IFS Certification Protocol (Part 1) and IFS Audit Checklist (Part 2) as well as the table of compulsory fields and the glossary.

The other parts of the standard (Part 3 and Part 4) will be submitted to the IFS Committees at a later stage.

Your feedback on the draft is very welcome
We kindly invite you to participate in ***the public consultation*** *of the IFS Food v8 draft. It is an essential step in the review process, and your feedback will ensure that it will meet the current needs and expectations of the market.*

After the consultation phase, comments received will be reviewed by the IFS International Technical Committee and IFS Team and, where relevant, the IFS Food Standard will be updated accordingly.

This document is only a draft for consultation: this is not the normative and final version of the standard, as requirements will be subject to change after the consultation.

Thank you for your feedback and for accompanying us on our way to IFS Food version 8!

Please visit our website for information about the IFS Food Standard.

Your IFS Team

VERSION 8 DRAFT

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0 Introduction

0.1 History of the International Featured Standards

In 2003, the German retail federation – Handelsverband Deutschland (HDE) – and its French counterpart – Fédération des Entreprises du Commerce et de la Distribution (FCD), drew up a common food safety and quality standard to enable the audit of food suppliers. The audit provided a uniform approach towards food suppliers. This was the first 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 sector. All IFS Standards follow a risk-based approach, which gives stakeholders the flexibility to implement the requirements into their business based on the specific risks in regard to the products and processes.

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

The IFS Food standard version 8 has been revised by the following international working groups: Extended Core Group, National Working Groups, International Technical Committee and the IFS Technical Team Working Group. Representatives of retailers, industry, food services and certification bodies were part of these outstanding working groups that combined input from Europe, North and South America and Asia.

It will be possible to perform IFS Food v8 audits from XXX. From XXX, IFS Food v8 will be mandatory.

0.2 IFS Objectives, mission and vision

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

The mission of IFS clearly states that IFS Standards go beyond product safety with the aim to "deliver trusted products", which fulfill the expectations of the buying company. With the objective that an IFS Certificate demonstrates that the company has implemented a functional food safety and quality management system, IFS together with its huge 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. Continuous improvement is not only the objective of certified companies; it is also applicable to IFS.

0.3 Coverage of the IFS Food Standard

The IFS Food Standard is applicable to food product manufacturers and can only be used for companies processing food products and/or packing loose food products.

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

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

0.4 Content of the IFS Food standard

The content of the IFS Food standard is laid out as follows:

Part 1 – IFS Food certification protocol

Part 2 – List of IFS Food audit requirements

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

Part 4 – Reporting, Audit Manager software and IFS Database.

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

0.5 Review of the IFS Food standard

The IFS Technical Team and its working groups need to demonstrate control over the content and quality of the IFS Food standard and review it annually, to ensure its compliance with their requirements. The working groups are composed of all participants involved in the audit process: the representatives of retailers, industry, food services and certification bodies. The objective of the working groups is to share experiences, discuss and decide on changes or alignments to the IFS Food standard, the requirements of the audit report and training needs.

PART 1
IFS Food certification protocol

0 Purpose and content

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

1 The IFS Food Certification process

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

The IFS Audit is a crucial part of the certification process, as the company and its production processes will be challenged against all specified requirements laid down in the audit checklist (Part 2), in order to assess the products and production processes' compliance.

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

a) Product and process-based approach

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

IFS Food certification is always specific to one production site. All products and processes of the relevant production site shall be included in the scope of the IFS Food Audit.

During the IFS Food Audit, the auditor shall collect objective evidence to evaluate the compliance of the products and the operating processes with the audit requirements (see audit checklist Part 2), based on chosen product sample(s) by following the audit trail.

One of the key elements for conducting the IFS Food Audit is to follow an audit trail. This audit trail emphasizes the collection of evidence to assess product(s) and related operating processes through selected samples. It consists of the following main steps:

- **Product sampling:**
  The selection of samples shall be risk based but can also follow other criteria. The aim is to make a representative selection of all products and processes included in the certification scope to gain maximum information about the production site and its products.

  The use of relevant product samples (sampled by the auditor on-site at the beginning or in advance of the audit) is a vital element and allows the IFS Auditor to follow a uniform path in order to obtain all necessary evidence. In addition, auditors shall perform a traceability test on the sampled product(s) during the audit.

Note: IFS has published Guidelines (e.g. IFS Auditor Guideline, IFS Good Audit Practices (GAP) Guideline), which provide further information on topics to be checked and/or requested from the auditing company during the IFS Food 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 physical site) in order to allow the auditor sufficient time to comprehensively audit the products and the processes.

  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.
- **Operating process evaluation:**
  Whilst observing and following running production lines, the IFS Auditors shall collect information on key process parameters, such as critical control points (CCPs) and control measures as well as their monitoring in order to cross-check them with the HACCP plan information. They shall also observe and interview employees, inspect product and technology characteristics, take further samples for cross-checking, review recipes used during the manufacturing process, observe actual finished product dispatch or raw material delivery and assess the implemented food safety and quality management system in practice.
- **Documentation and record review and inspection:**
  The on-site evaluation is followed by a comprehensive documentation and record/review, including cross-checking of related documents. This part of the audit aims at verifying the information collected from the on-site evaluation and the evaluation of further requirements.

The above-mentioned activities are important parts of the audit trail the auditors use in order to evaluate the production site's compliance in depth.

b) Auditor qualification

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

c) Annual certification cycle

The production site will go through a full IFS Food Certification process including a comprehensive IFS Food Audit every year. This includes the audit of the full IFS Food Audit checklist (Part 2) and the verification of corrective actions from the last IFS Audit, if applicable. More information on the certification cycle can be found in 4.3, Part 1.

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

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

e) Surveillance and harmonized rules by the IFS Standard owner

As part of the Quality Assurance activities, IFS has implemented procedures for the surveillance of the performance of IFS approved Certification bodies, IFS Auditors and IFS certified Companies: the IFS Integrity Program ensures the quality and the 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 Food Audit

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

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.

In order to prepare the initial audit, the company 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.

2.1 Making a contract with a certification body

In order to undertake an IFS Food Audit, the company shall appoint an IFS approved Certification body, accredited to the ISO/IEC 17065:2012 norm for the IFS Food 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. The company shall ensure that the following topics are addressed:

a) Contract

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 report and certificate 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.

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

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

- All products on-site and related processes covered by the scope of the IFS Food Audit, including decentralised structures.
- Cases where parts of the production activities or products are outsourced to a third-party on behalf of the IFS Food certified Company.
- Overview of the exported products, including the different destination countries where the products are sold to.
- Under exceptional circumstances, any request for exclusion of some product groups. This will be carefully verified by the certification body in order to review if the exclusion is possible.
- History of certification status of IFS or any other GFSI recognized standard, for example type of certification/scope, date of the last certification audit (even if performed by another certification body), year of the last unannounced audit, if a certificate has been withdrawn in the past, etc.

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

If the IFS Food 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 company shall ensure that the certification body is informed in due time about any changes that may affect the company's ability to conform to the certification requirements (e.g. recall, alert on products, changes in organisation and management, important modifications on the products and/or the production methods, changes in contact address and production sites, new address of the production site, etc.). The details shall be defined and agreed between both parties. As required in the IFS Food Audit checklist (Part 2), requirement 1.2.6, some specific situations require a notification to the certification body within three (3) working days.

After receiving such information from the sites (limited to the three (3) specific situations requiring a company notification within three (3) working days), the certification body shall:

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

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

d) Language of the IFS Food Audit

The IFS Food Audit shall be carried out in the working language of the production site. If there is a need for translation (for limited defined situations), the certification body shall provide an interpreter not affiliated with the company. More information can be found in chapter 3.1.2, Part 3.

2.2 Scope of the IFS Food Audit

IFS Food 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 company, including all production lines and products manufactured by the production site (both customer branded products and company's own branded products).

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

Certification is always site-specific in relation to the actual processing activities of the site and cannot be applied to different sites or locations under one certification. Where decentralised structures exist, belonging to the same site, they shall be 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 2.2.2, Part 1.

IFS relies on product scopes (from 1 to 11) and processing steps (technology scopes from A to F), to define the audit scope of the production site. They allow various combinations which reflect the detailed site's processing activities.

They shall be indicated on the IFS Food Certificate and in the IFS Food Audit report.

More information on the determination of audit scope can be found in:

- Annex 3 of this standard
- The guidance on the allocation of the IFS Food Product scopes and Processing steps on the IFS Website.

Example: for a company producing ice cream, the audit scope shall make reference to product scope 4 (dairy) and technology scopes B (pasteurisation), D (freezing/cooling) and F (mixing/packaging). Further technology scopes may be added or deleted, depending on the detailed process(es) of the company.

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

- The different types of products shall be provided with enough details.
  Example of correct practice: production of "fermented sausage, brewed sausage, cooked and smoked sausage, cooked and raw cured ham".
  Example of incorrect practice: production of "meat products"
- The type of packaging materials shall be provided (e.g. "packed in foil (vacuum or modified atmosphere), plastic bag").
- The most characteristic processes that are not self-explanatory and that make the product differentiable from others need to be clearly mentioned, e.g.:
  - Production, cutting, drying, frying and packing of potato chips in tubular bag
  - Production, cutting, milling, baking and packing of potato chips in tubular bags
  - Production of raw cheese or pasteurised cheese in portions packed in carton boxes
- The non-self-explanatory processes/ technologies that are not obvious when naming the finished product shall be described (e.g. pasteurisation, curing, fermentation, smoking).

- Some words are forbidden, for example, storage, transport, sales, distribution, R & D, development/design, as these activities are investigated in an IFS Food Audit. If the storage is linked to a processing step, this step shall be described without using the word storage, for example "ripening/maturation process". As an exception, the word "labelling" shall be mentioned only if it is an essential/ relevant processing step of the company.
- Brand information is forbidden, as it does not provide any information on the products and processes of the company.
- Reference to product claims is acceptable only if there is no alternative way to describe the characteristic of the product. When a claim is mentioned in the audit scope, the following disclaimer shall be provided on the certificate, to avoid any confusion on what is covered by the IFS Food Audit scope: "The designation or claim "*to be specified*" is an inherent characteristic of the products but its assessment is not covered in the scope of the IFS Food Certification". Additional information about the type of claims can be provided in the report.
- Exclusion of production process(es), including storage and transport, is forbidden.
- Exclusion of product(s) is in general forbidden, but may be accepted under specific conditions which are listed in Annex 4.

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

2.2.1 Outsourced processes and IFS Food Audit scope

A partly outsourced process is defined in the IFS Food Standard as a production step or part of a production process (including primary packing and labelling) that is carried out off-site by a third-party on behalf of the IFS Food certified production 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 1: Storage and/or transport activities carried out by a third-party are not part of the above defined partly outsourced processes and shall be evaluated according to the relevant chapters of the IFS Food Checklist (4.14 and 4.15), especially to the requirements 4.14.6 and 4.15.7.

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

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

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

- The requirements 4.4.5, 4.4.6 and 4.4.7 of the audit checklist (Part 2) apply and shall be audited by the auditor, in order to assess if the audited site ensures control over such processes.
- For the audit scope (and for the auditor qualification), the processing steps related to the partly outsourced processes shall not be selected. The audit scope shall only mention the processes managed by the audited company, not by the third-party.
- In the audit report of the audited site (audit overview): a description of the partly outsourced processes and certification status of the third-party shall be provided.
- If the appointed third-party is IFS Food certified, their COID (IFS identification code number) shall also be mentioned.

- If the partly outsourced processes concern freezing and/or thawing activities only, an IFS Logistics certification or any other equivalent GFSI recognised standard certification can also be accepted.
- 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.

A fully outsourced product is a product manufactured, packed and labelled under the own company brand or customer brand by a different company than the audited one.

A traded product is a product manufactured, packed and labelled by and under a different company name to the company being IFS Food certified.

Fully outsourced products and traded products are, by nature, not covered by the IFS Food Certification. Therefore, those products shall not be excluded from the IFS Food Audit scope.

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

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

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

The IFS Audit is production site specific: one production site is subject to one audit and one certificate.

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

1) Single production site

2) Multi-location production sites

3) Multi-legal entity production site

4) Production site with decentralised structure(s).

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

a) Company with head office/central management

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

When the head office/central management does not have processing activities it cannot be subject to an IFS Food Certificate. The company can decide to organise or not a specific audit for the activities managed by the head office/ central management. This shall be defined in advance with the certification body, before the audits take place:

- If no audit is performed: 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, 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 the impact of the head office/central management of the site operations, to determine the appropriate duration of the head office/central management audit.
  - Each site shall get an individual certificate and report.
  - The centrally managed activities, as well as the outcome of the audit shall be described in the audit report of each production site.
  - Deviations identified during the head office/central management cannot be partly solved in the audit reports of each production sites. Deviations can be downgraded, but not fixed or improved.
  - If a non-conformity has been raised during the audit of the head office/central management, all audited production sites are also affected and the certificates of these production sites shall be suspended. Only after a positive follow-up audit of the head office/ central management, suspension of certificates of the production sites can be lifted. Depending on the type of non-conformity which has been issued in the head office/central management, a new audit of the production sites may also be necessary.
  - Both audit dates of the production site and head office/central management shall be visible in the audit report.
  - All COIDs of the production sites linked to the head office/central management shall be mentioned in each audit report.

b) Company without head office/central management

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

3) Multi-legal entity production site:

a) If a production site has multiple legal entities at one physical location with the same scope, one audit shall be conducted. Each legal entity shall have their own COID and the certificate and report shall be duplicated for each legal entity. The COIDs of each legal entity shall be linked in the IFS Database.

b) If a production site has multiple legal entities with different scopes at one physical location, each legal entity shall have their own COID, report and certificate. If a contractual relationship exists, the COIDs of each legal entity shall be linked in the IFS Database. All audits shall be performed by one certification body. 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 maximum 0,5 days (as for multi-location approach).

In both cases, if the certificate of one legal entity is suspended/ withdrawn, the certificates of all legal entities shall also be suspended/ withdrawn, unless the certification body can demonstrate that the other legal entities are not impacted.

4) **Production site with decentralised structure(s):**
A decentralised structure is a facility (for example a workshop or a warehouse) owned by the company where part(s) of the processes and operations of the production site take place. When the 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 included in the audit. Scope and full details shall be documented in the audit overview of the audit report.
If the decentralised structure is a warehouse with logistics activities situated at the same physical location as the production site, the company has the option to either include it in the IFS Food Audit scope or to perform a combined IFS Food/IFS Logistics Audit.

2.3 Type of IFS Food Audits

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

An IFS Food Audit shall always be performed on-site (fully remote audits are not permitted) and during consecutive working days, for both announced and unannounced audit options.

Initial and recertification audits can be performed announced or unannounced (more information on unannounced audits can be found in chapter 2.4).

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 the requirements where a review within a 12-month period is requested. For an unannounced audit, all requirements shall be implemented before the audit time window starts (more information on unannounced audits can be found in chapter 2.4).

Note: under specific 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 pe performed first, followed by a remote part using ICT (Information and Communication Technologies). In order 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

The initial audit is the very first IFS Food Certification audit of a production site during which all the requirements of the IFS Food Audit checklist shall be audited by the auditor.

The "new initial" audit is the IFS Food Audit performed:

- after an interruption in 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 < 75 % or
- after a failed follow-up audit.

In case of new initial audit, the following applies:

- the audit report and action plan from the previous IFS Food 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.
- the certification history (for IFS Food or other GFSI recognised standard audits) shall be checked, also to ensure that the rule on unannounced audit frequency is fulfilled (more information on unannounced audits can be found in chapter 2.4.2).

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

2.3.2 Recertification audit

A recertification audit is a full and thorough audit of a production site, during which all the requirements of the IFS Food Audit checklist shall be audited by the auditor and which is performed to renew the existing IFS Food Certification. The period in which a recertification audit shall be performed is shown on the certificate and the audit shall be performed during this period in order to maintain the certification cycle.

The action plan from the previous IFS Food 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.

If deviations are still present from one audit to the next, or if the scorings deteriorate, 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.

Production sites are responsible for renewing their certification in due time. All IFS Food certified Companies will receive a reminder from the IFS Database three (3) months before certification expiration.

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

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

If the audit is not an initial audit and if the company changes the certification body, the company 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.

2.3.3 Follow-up audit

A follow-up audit is an audit that shall be performed on-site, always announced, in a specific situation where during the main certification audit, one Major non-conformity is issued and the total score is ≥ 75 %.

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

- It shall generally be performed by the same auditor who performed the main 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 company decides not to perform a follow-up audit, a full new initial audit shall be performed and it shall be scheduled no earlier than six (6) weeks after the main audit.
- If failed, a full new initial audit shall be performed and scheduled no earlier than six (6) weeks after the follow-up audit. The report of the failed follow-up audit shall be uploaded in the IFS Database.
- If successful:
  - Information on the positive outcome of the follow-up audit shall be provided in the audit report.
  - Updated report shall be uploaded in the IFS Database.
  - Certification 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.

More information can be found in Annex 5.

2.3.4 Extension audit

An extension audit is an additional audit to extend the current certification scope that shall be performed on-site, always announced, during the validity period of the existing certificate, in the following situations:

- If some production lines were not working during the main certification audit, involving product scopes and/ or technology scopes and/ or HACCP plan (especially the CCPs) different than the ones audited by the auditor during the main announced or unannounced audit. This may happen during announced or unannounced audits.
- In case of seasonal products, to assess products which could not be audited while operating during the main audit. During the following year, there will be one recertification and one extension audit, in order to cover all products and processes. The main audit shall always be performed during the time of production including the most hazardous processing step.
- If significative changes occur to the production process and/ or its environment between two (2) certification audits and the certification body decides, based on a risk assessment, that an extension audit is necessary. The risk assessment shall be based on hygiene and safety risks and shall be documented. This applies, for example, when new processes or products different to those included in the scope of the current certificate were introduced.

The relevant IFS Food Requirements to be audited and the relevant audit duration of the extension audit shall be defined by the certification body.

Conditions for passing the extension audit are the same as for initial or recertification audits, but they will only be focused on specific requirements that have been audited (the original audit score does not change):

- If the extension audit demonstrates compliance, the certificate shall be updated with the new scope (previously and new audited activities) but shall keep the same expiry date as the current certificate. Updated certificate and extension audit report shall be uploaded in the IFS Database.
  Example of a company processing two (2) kinds of products (A and B) in different periods of the year:
  - The main audit is focussed on the processing activities of product A and on the documentation related to the processing of product A and B. After this audit, the certificate and the report will specify: "Production of product A — production of product B will be checked during an extension audit in month X"
  - After the extension audit, the certificate shall be updated specifying "Production of products A and B".
  - After the recertification audit, the certificate and the report shall mention: "Production of products A and B" and an extension audit shall be performed at a later time to verify the processing activities of product B on site. Same annual procedure as above will apply each year.
- In the event of one Major non-conformity, the current certificate shall be suspended within two (2) working days and a follow-up audit shall be performed, based on the same rules as defined for the main audit (2.3.3). If the Major non-conformity is solved, the certificate suspension shall be lifted and the certificate shall be issued with the updated scope in foundation level only.
- In the event of more than one Major non-conformity or one or more D evaluations of a KO requirement, the full audit (including the main one) is failed and the current certificate shall be withdrawn.

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

2.4 IFS Food announced and unannounced Audit options

Before scheduling and performing the IFS Food Audit, the company and certification body shall decide whether the audit is conducted on an announced or unannounced basis, ensuring that at least the third IFS Food Audit is performed unannounced, starting 1st January 2021.

2.4.1 Announced audit option

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

2.4.2 Unannounced audit option

The unannounced audit only applies to initial and recertification and not to extension and follow-up audits.
It 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.

An unannounced audit shall be performed at least once every third IFS Food Audit. For the two other certification audits, the company can decide to perform them either announced or unannounced.
A failed announced audit doesn't count for this rule; only a failed unannounced audit counts.
If the certification cycle is interrupted where an unannounced audit was due, the next certification audit (=new initial audit) shall be conducted unannounced.

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

The certification body shall ensure that this frequency is fulfilled, even if the company (COID) changes its certification body.

The certification body shall decide in which year the first mandatory unannounced audit will be performed and shall inform the company at least six (6) months before the audit due date.

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

When it is the company's choice to perform an unannounced audit, the certification body shall be notified of the registration at latest four (4) weeks before the start of the audit time window (to allow the certification body registering it in the IFS Database).

The following rules apply for unannounced audits:

- The company shall provide the certification body with the name(s) of the on-site person(s) to be contacted on the production site.
- The company 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 company produces seasonal products, the expected seasonal production dates shall be notified to the certification body and the time window [–16 weeks, + two (2) weeks] does not apply. Providing a blackout period is not permitted in this situation and the unannounced audit shall take place at any time during this seasonal production period.
- For multi-location production sites with a head office/central management:
  - Head office/central management shall either be audited through 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).

- An unannounced audit shall be performed in the production sites.
- 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 audit: an unannounced one for centrally organised processes and for the production site. This audit shall start with the production processes.).
- All audits, including that of the head office/central management, shall be performed within a maximum time frame of 12 months.

If any rule related to the performance of unannounced audit is not fulfilled, the status of the audit is no longer "unannounced", but "announced" and the next audit shall be performed unannounced.

An unannounced audit can follow a failed audit in case:

- the site's customer requires an unannounced audit, or
- it is the third IFS Audit and an unannounced audit is due.

2.5 Planning an IFS Food Audit

Before being audited, the company shall review all requirements of the IFS Food Standard and the IFS Food Doctrine.

- 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 of the registration for this audit 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 company with the audit time schedule, where the audit duration shall be indicated.

The audit time schedule shall:

- Include appropriate details on the scope
- Include audit duration
- Be sufficiently flexible to respond to any unexpected event which may arise during the on-site evaluation part of the audit
- Take the review of the audit report and action plan from the previous audit into consideration
- Specify the company's products or product ranges that shall be audited

- In case of audit team: indicate which auditor performs which part of the audit. Information about the audit date and time for each auditor shall be provided in the IFS Database.
- If the IFS Food audit is performed together with another standard/norm: indicate when and which part of each standard/ norm has been audited.

For an announced audit, the time schedule shall be sent to the site before the audit, to ensure the availability of responsible persons on the day of the audit.
For an unannounced audit, it shall be shared during the opening meeting. It might also be modified or adapted due to the availability of the participants to be audited and the current processing times.

3 IFS Food Audit realisation

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

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

If some production lines are not working during the IFS Audit, and if they involve products and/or technology scopes and/ or HACCP plan (especially the CCPs) different than the ones that are operating, two (2) options are possible:

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

3.1 Audit duration

IFS has implemented a mandatory calculation tool, which is available on the IFS Website, to calculate the minimum IFS Food Audit duration to be performed on the physical site, based on the following criteria:

- 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 product scopes
- number of processing steps.

To facilitate the selection of the right product scopes and processing steps, IFS has published a guidance on the allocation of IFS Food Product scopes and Processing steps that is frequently reviewed and updated when necessary. This document is available on the IFS Website.

Note about product scope 7:

- To calculate the audit duration, the additional product scopes for processing the raw materials for product scope 7 shall be selected.

- To determine auditor competences and define the audit scope on the IFS Certificate, these additional product scopes shall not be selected.

The minimum audit duration, as provided by the calculation tool, will always be two (2) days (16 hours). One audit day is equivalent to eight (8) hours (without lunch break) and shall never exceed ten (10) hours.

The determination of the final audit duration is the responsibility of the certification body and the defined duration may be higher than the calculated minimum duration (depending on the specific structure of the company and the complexity of the processes).
Typical factors which may lead to an increase of the minimum calculated duration are the following:

- initial audit: the auditor may require additional time, for example, during opening and closing meetings
- number of production lines, e.g. for making a longer HACCP review
- complexity of the production processes
- size and age of the site
- communication difficulties, e.g. language
- quality of company preparation, e.g. documentation, HACCP plan
- number of deviations/ non-conformities from the previous audit
- difficulties during the audit that require further investigation
- additional storage facilities, locations.

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

Under exceptional circumstances, and only in the limited following cases, the certification body may decide reducing the minimum calculated audit duration by 0,5 day:

- IFS combined audits: e.g. IFS Food/IFS Logistics, IFS Broker/IFS Food, under the condition that some parts are commonly audited for both standards.
- Multi-location companies, if some requirements have already been audited at the head office/ central managing site.
- Multi-legal entity production site: if the legal entities have different scopes at one physical location and a head office/central management has been appointed.
- For sites with labour-intense simple repetitive processes, based on a risk assessment.
- For the main audit of a site where an extension audit shall be performed every year, due to seasonal products/ processes.
- For sites where, during an unannounced audit, it was not possible to audit all processes and an extension audit shall be performed later.

Under exceptional circumstances, and only in the limited following cases, the certification body may decide reducing the minimum calculated audit duration by 0.75 day:

- For a site with product scope 5 (fruit and vegetable), performing simple handling and no activity that significantly transforms the product from its original harvested form (according to GFSI scope BIII).

- For a site with product scopes 3, 6, 8, 9, 10 and/ or 11, that has simple processes limited to:
  - sorting
  - bottling
  - simple packing (e.g. no MAP or vacuum)
  - only for product scope 10: mixing/blending

The certification body/ auditor shall justify the decision for reduction in the IFS Audit report.

A combination of different reasons for reduction, including accumulation of reduction reasons in case of combined IFS Audits, is not possible.

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

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

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) in order to allow the auditor auditing comprehensively the products and the processes. This can be decreased to 1/3 if a site has simple processes (as mentioned above) and when the audit duration is 1,25 days after reduction.

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

- two (2) hours for audit preparation
- 0,5 days (four (4) hours) for audit report writing.

3.2 Audit performance

The audit shall be scheduled based on the following steps:

- Opening meeting. For unannounced audits, the opening meeting and the evaluation of the existing food safety and quality management system shall be kept short, to allow the auditor starting the on-site evaluation as soon as possible (typically 30 minutes after entering the site).
- Evaluation of existing food safety and quality management system, achieved by checking documentation (HACCP plans, quality management documentation, etc.)
- On-site evaluation: detailed observation of all on-site production areas, production lines and production processes, which includes interviews with the working personnel and the gathering of information on key process parameters, such as monitoring of critical control points (CCPs) and other control measures to be cross checked with the HACCP plan 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.

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

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

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

Note: During the audit, the IFS Auditor shall make detailed notes regarding all evaluations against the IFS Food 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 company representative(s) during the audit. This document:

- shall be signed by a representative of the audited production site at the end of each audit day
- shall be signed by the auditor(s) (and if applicable, the trainee, auditor in progress, auditor under observation or observer for witness audit) at the end of each day
- shall state the start, lunch break and end time of each day.

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

3.2.1 IFS Scoring System

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

In the IFS Food Standard, there are six (6) scoring possibilities and the option of non-applicability. Points are awarded for each requirement according to the following chart (chart 1):

Chart 1: IFS Scoring System

Result	Explanation	Points
A	Full compliance.	20 points
B (deviation)	Almost full compliance.	15 points
C (deviation)	Part of the requirement is not implemented.	5 points
D (deviation)	The requirement is not implemented.	–20 points
Major (non-conformity)	A Major non-conformity can be issued to any regular requirement (which is not defined as a KO requirement). Reasons for Major rating are: • There is a substantial failure to meet the requirements of the standard, which includes but is not limited to food 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 food safety.	Major non-conformity will subtract 15 % of the possible total amount; the certificate cannot be issued.
KO requirement scored with a D (non-conformity)	The requirement is not implemented.	KO non-conformity will subtract 50 % of the possible total amount; the certificate cannot be issued.
N/A Not applicable	The requirement is not applicable. N/A can apply to any requirement, except for KO requirements numbers 1, 3 and 5 to 10. The auditor shall provide an explanation in the report.	Not included in the calculation of the total score

KO requirements

There are specific requirements in the IFS Food 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 Food Standard, the following ten (10) requirements are defined as KO requirements:

1) 1.2.1 Governance and commitment
2) 2.3.9.1 Monitoring system of each CCP
3) 3.2.2 Personal hygiene
4) 4.1.3 Customer agreement
5) 4.2.1.3 Raw materials specification
6) 4.12.1 Foreign material risk mitigation
7) 4.18.1 Traceability

8) 5.1.1 Internal audits
9) 5.9.1 Procedures of withdrawals, recalls and incidents
10) 5.11.3 Corrective actions

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

Chart 2: Scoring of a KO requirement

Result	Explanation	Points
A	Full compliance.	20 points
KO B (deviation)	**Small part of the requirement is not implemented, with no impact on food safety, legality, and customer requirements.**	**0 point**
C (deviation)	Part of the requirement is not implemented.	No "C" scoring is possible
D (= KO non-conformity)	The requirement is not implemented.	KO non-conformity will subtract 50 % of the possible total amount, the certificate cannot be issued.

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

- It shall be withdrawn in the IFS Database by the certification body as soon as possible, and at latest two (2) working days after the last audit day.
- In the IFS Database, the certification body shall provide explanations in English about the reasons for withdrawing the current certificate, including the number of requirement's number 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 favourites list will receive an e-mail notification (with explanations about the identified non-conformity/ies) from the IFS Database, informing them that the current certificate has been withdrawn.

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

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

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

The auditor shall provide explanations in the audit report:

- for requirements defined as compulsory fields, even if the requirements are scored with A,

- for all requirements scored with B, C, D,
- for Major non-conformity/ies,
- for requirements audited as not applicable.

The auditor and/or certification body shall issue the action plan template (with the list of findings) and the provisional score in percentage to the company within two (2) weeks.

A provisional report shall be available upon request.

4 Post IFS Food Audit actions

4.1 Action plan

The action plan template shall be used by the company as a basis for drawing up corrections and corrective actions for the issued deviations and non-conformities. More information can be found in Annex 8.

4.1.1 Company's completion of the action plan

The company shall provide the following in the action plan:

- Evidence of implementation of corrections and proposed corrective actions for all deviations (B, C, D), KO requirements scored with a 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 3).

Chart 3: Timescale for corrections and corrective actions

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

Examples of acceptable evidence for the implementation of corrections:

- Training records
- Updated procedures with traceable modifications

- 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 to the certification body/ auditor a completed form
- 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
- Newly monitoring procedure (e.g. for a damaged infrastructure).

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

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

4.1.2 Validation of the action plan

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

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

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

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

The action plan and related evidence shall be stored by the certification body for a period of three (3) years.

4.1.3 Technical review

A technical review of the report shall be conducted by a nominated reviewer from the certification body (see glossary). Unclarity or doubts about the findings and the related scorings need to be clarified between the auditor of the IFS Audit and the IFS Reviewer.

Based on the result of the technical review, the nominated reviewer recommends the issuance of an IFS Food 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 Food 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 4: Scoring and issue of certificate

Audit result	Status	Company action	Report form	Certificate
Total score is ≥ 95 %	Passed at IFS Food higher level following the receipt of the action plan	Send completed action plan within four (4) weeks of receiving the action plan template 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 closed.
Total score is ≥ 75 % and < 95 %	Passed at IFS Food foundation level after receipt of the action plan	Send completed action plan within four (4) weeks of receiving the action plan template 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 closed.
Maximum one Major and total score is ≥ 75 %	Not passed unless further actions taken and validated after follow-up audit	Send completed action plan within four (4) weeks of receiving the action plan template. 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 finally solved during the follow-up audit. The certificate shall only be issued when the corrections are closed.
Total score is < 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
> one Major and/ or total score is < 75 %	Not passed	Actions and new initial audit to be agreed upon	Report including action plan provides status	No

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 if the IFS Food Audit is failed (one or several non-conformity/ies and/ or score < 75%)

Specific rules shall apply, depending on the type and number of non-conformity(ies) issued and the total score.
If only one Major non-conformity is issued, with a total score ≥ 75%, a follow-up audit shall be performed. More information on follow-up audit can be found in chapter 2.3.3.

In all the other situations, the IFS Food Audit is failed, the certificate will not be issued and the following rules apply:

- For a recertification audit: the current certificate shall be withdrawn.
  The deadline for withdrawing the current certificate is:
  - 2 working days if the audit is failed due to one or several non-conformity(ies)
  - 2 weeks if the audit is failed due to a total score < 75 %.
- The audit shall be completed and all requirements shall be evaluated in order to give the company a full overview about its situation.
- The action plan should be completed (recommended) for improvement purposes.
- A full new audit shall be performed no earlier than six (6) weeks after the audit where the non-conformity(ies) was/were issued.

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

More information on failed audits and the certificate withdrawal process can be found in chapter 3.2.1 and in Annexes 6 and 7.

4.2.1.2 Deadlines for issuing the IFS Certificate

If the auditor and the nominated reviewer recommend the IFS Food 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 then be uploaded in the IFS Database between six (6) and eight (8) weeks from the last audit day, based on the following timeframe:

- Auditor sending to the company the action plan template and provisional score in percentage: 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 in the IFS Database: maximum two (2) weeks.

If the total eight (8) weeks deadline is not adhered to, the certification will not be issued and the company shall undergo a full initial or recertification audit.

More information can be found in Annex 2.

4.3 Certification cycle

The validity of the IFS Food 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.

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

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:

- 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 or if the production stopped and the site changed address.
- In case of cancellation of certification contract (between the certification body and the company).
- In case of any false statement which may jeopardise the IFS Certification status, which also includes the GFSI certification history.

Note: It is the certification body's decision do define in which situations the certificate shall be withdrawn.

An IFS Certificate shall be suspended by the certification in the following situations:

- In case of pending investigations by the certification body, following a food safety incident or other event
- In case of non-payment of the current audit by the certification body. The contract between the certification body and the audited company shall take the certification cycle into account
- 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 a Major non-conformity is issued during an extension audit.

If the suspension is lifted, the certification body shall make all necessary modifications to public information, authorisations for use of brands, etc. in order to ensure transparency and that the products/processes continue to be certified.
If a decision to reduce the scope of certification is made as a condition of reinstatement, the certification body shall make all necessary modifications to formal certification documents, public information, authorisations for use of brands, etc., in order to ensure the reduced scope of certification is clearly communicated to the client.

4.4 Distribution and storage of the audit report

Audit reports shall remain the property of the company and shall not be released, in whole or part, to a third-party without the company's prior consent (except where required by law, accreditation bodies and GFSI monitoring activities). The consent for the distribution of the IFS Food 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 store safely and securely a copy of the IFS Food Audit report and associated documentation including the auditor's notes for a period of five (5) years. More information on the access conditions to information about the audit reports in the IFS Database can be found in Part 4.

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

5 IFS Integrity Program

The IFS Integrity Program, launched in early 2010, includes different measures to ensure the quality of the IFS Standards by reviewing IFS Audit reports of certified companies and also by using several measures to analyse the performance of certification bodies and auditors. Furthermore, the IFS Integrity Program aims ensuring 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 commencing 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.

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 issues are clarified with the certification bodies. In this purpose, the IFS Integrity Program is requesting 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 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 suspending the current IFS Certificate.

For each Integrity on-site check, a report is prepared and is only made available to the company and the responsible certification body. In case of complaint-based Integrity on-site checks, the report may also be shared with the complainant.

5.1.3 IFS Integrity certification body office audits

In order to ensure the correct implementation of all procedures described in the IFS Standards and respective normative documents, the IFS Integrity Program carries out regular office audits at certification bodies (Integrity certification body office audits). During these office audits, performance of certification bodies and their personnel are checked by reviewing report samples and information from the database. 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 activities may be used.
If relevant, the complainant will be informed about the result of the analysis.

5.3 Sanctions

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

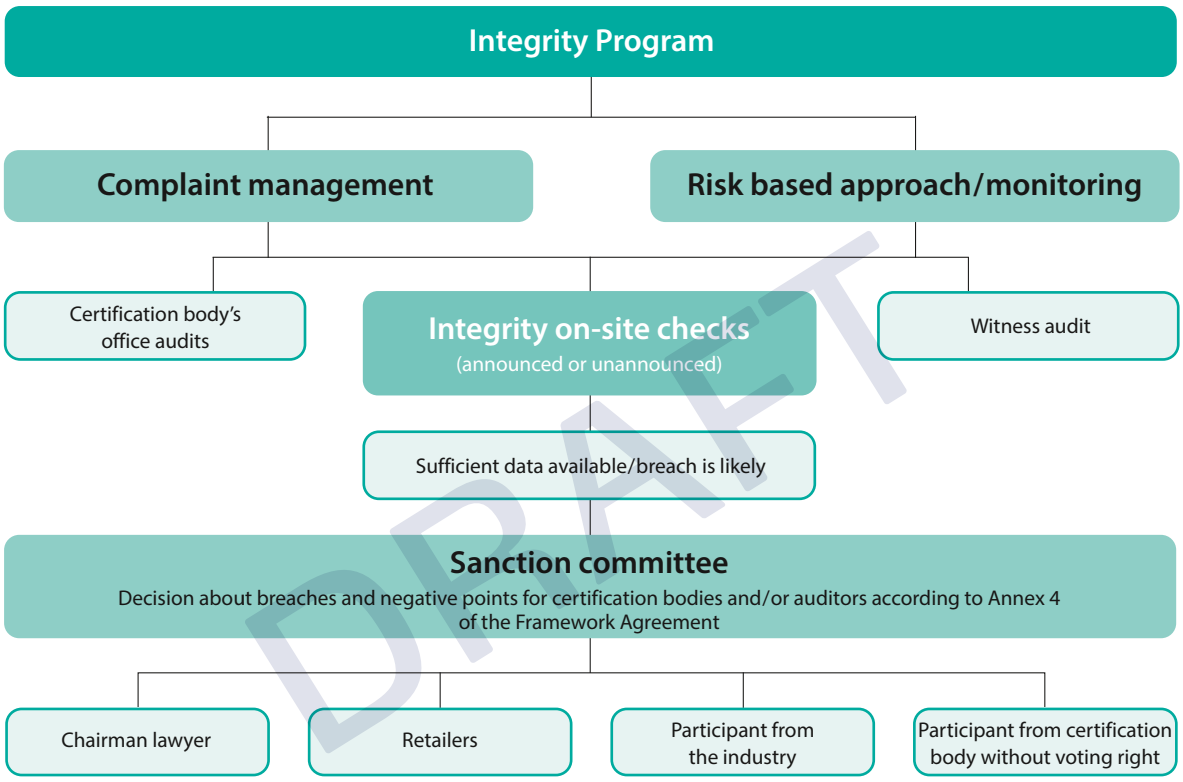
Topics concerning administrative faults of certification bodies based on database investigations can be directly assessed by the IFS Quality Assurance Management but have to be confirmed by the chairman (lawyer) of the sanction committee.

Sanctions and/or penalties will be issued to the certification body and/or its auditors if the sanction committee concludes that a breach has been committed. The type of sanction and/or penalty depends on the severity of the breach.
For each final breach ruling, a certification body and/or an auditor may get a certain amount of "negative points". These "negative points" are accumulated, but the period of limitation is two (2) years (rolling system). Only in very severe cases, certification bodies or auditors might be suspended for a certain time frame or contracts might be cancelled (more information can be found in Annex 4 of the IFS Framework agreement).

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

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

Chart 6: Summary of IFS Integrity Program activities



6 IFS Logos

The copyright of IFS Food 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 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 Food certification/application
These terms and conditions apply for all IFS Logos.

Form, design and colour of the IFS Logos
Only the latest version of the IFS Logos shall be used. When used, the IFS Logo(s) shall comply with the form and colour of the scale drawing. If used in documents, black and white print is also permitted. Companies shall only use the logo of the standard(s) they are certified for.
The general IFS Logo can only be used to express that the certification body or the IFS consultant supports IFS certified companies, or that the certification body offers certification for more than one IFS Standard. All other forms of use shall be agreed with IFS.

The IFS Food 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 Food certified production site, an IFS Food supporting company or an IFS Food 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 Food Logo in promotional material
The IFS Food Logo shall not be displayed on the product itself, primary packaging of the product, 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 Food 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 Food Logo
The IFS Food Logo shall not be used in any way that may imply that IFS Management GmbH is responsible for the certification decision. In case of suspension or withdrawal of the IFS Food Certificate, the audited production site and company have to immediately stop including the IFS Logos on their documents and/or website. In case of exclusion regarding the audit scope, the details about exclusions shall be available upon request. The IFS Food Logo can be used, but the following sentence shall be written at the bottom: "some products are excluded from the scope of the IFS Food audit and exclusion details can be provided upon request".

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

PART 2
List of IFS Food audit requirements – Audit checklist

Requirements with a "*" require compulsory information for the IFS Food report summary.

1 Governance and commitment

1.1 Policy

1.1.1* The senior management shall develop, implement and maintain a corporate policy, which shall include, at a minimum:

- food safety, product quality, legality and authenticity
- customer focus
- food safety culture
- sustainability.

This corporate policy shall be communicated to all employees and shall be broken down into specific objectives for the relevant departments. Objectives shall include, at a minimum, communication about food safety policies and responsibilities, training, employee feedback on food safety related issues and performance measurement.

1.1.2 All relevant information related to food safety, product quality, legality and authenticity 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 food safety and product quality and that mechanisms are ~~in place~~ 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 ~~relevant~~ appropriate resources to meet the product and process requirements.

1.2.3* The department responsible for food safety and quality management shall have a direct reporting relationship to the senior management. An organisational chart shall be ~~available~~ documented and maintained, showing the structure of the company.

1.2.4 The senior management 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 ~~have~~ maintain a system ~~in place~~ to ensure that the company is kept informed of all relevant legislation, scientific and technical developments, industry codes of practice, food safety and product quality issues, and that they are aware of factors that can influence food defence and food fraud risks.

1.2.6* The senior management shall ensure that the certification body is informed of any changes that may affect the company's ability to conform to the certification requirements. This shall include, at a minimum:

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

For the following specific situations:

- any product recall
- any product ~~recall and/or withdrawal by official order~~ authorities for food safety, food fraud and/or legality reasons
- any visit from ~~health~~ authorities which results in mandatory action connected to food safety, food fraud and/or legality of the product(s) ~~notifications and/or penalties issued by authorities~~

the certification body shall be informed within three (3) working days.

~~1.3 Customer focus~~

~~1.3.1 A process shall be in place to identify fundamental needs and expectations of customers. The feedback from this process shall be used as input for the company's continuous improvement.~~

1.3 Management review

1.3.1* The senior management shall ensure that the food safety and quality management system is reviewed at least ~~annually~~ once within a 12-month period, or whenever, ~~or more frequently if~~ significant changes occur.
Such reviews shall include, at a minimum:

- a review of objectives and policies including elements of food safety culture
- results of audits and site inspections
- positive and negative customer feedback
- process compliance
- food fraud
- food defence
- ~~authenticity and conformity~~ compliance issues
- 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 food safety and quality management system. The management review shall be fully documented.

1.3.3 The senior management shall identify and ~~regularly~~ review at least once within a 12 months period, or whenever significant changes occur (e.g. by internal audits or on-site ~~verification~~ inspections) the infrastructure and work environment needed to ~~conform to product requirements~~ ensure food safety, product quality, legality and authenticity.

This shall include, at a minimum:

- buildings
- supply systems
- machines and equipment
- transport
- staff facilities
- environmental conditions
- hygienic conditions
- workplace design
- external influences (e.g. noise, vibration).

Based on risks, he results of the review shall be considered, ~~with due consideration to risks,~~ for investment planning.

2 Food safety and quality management system

2.1 Quality management

2.1.1 Document management

2.1.1.1 A ~~documented~~ procedure shall ~~exist for the~~ be documented, implemented and maintained to control of documents and their amendments. All documents which are necessary for compliance ~~with the product~~ food safety, product quality, legality, authenticity and customer requirements shall be available in their latest version. The reason for any amendments to documents, critical to ~~the product~~ those requirements, shall be recorded.

2.1.1.2 The food 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.

2.1.1.3* All documents shall be ~~clearly~~ legible, unambiguous and comprehensive. They shall be available to the relevant personnel at all times.

2.1.2 Records and documented information

2.1.2.1 Records and documented information shall be legible, properly completed and genuine. They shall be maintained in a way that subsequent revision or amendment is prohibited. If records are documented electronically, a system shall be ~~in place~~ maintained to ensure that only authorised personnel have access to create or amend those records (e.g. password protection).

2.1.2.2* All records and documented information shall be kept in accordance with legal and customer requirements. If no such requirements ~~exist~~ are defined, records and documented information shall be kept for a minimum of one year after the ~~specified~~ 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.

2.1.2.3 Records and documented information shall be securely stored and ~~easily~~ accessible in a timely manner.

2.2 Food safety management

2.2.1 HACCP plan

2.2.1.1* The basis of the company's food safety management system shall be a fully implemented, systematic and comprehensive HACCP based plan, following the Codex Alimentarius principles, good manufacturing practices, good hygiene practices and any legal requirements of the production and destination countries which may go beyond such principles. The HACCP plan shall be specific and implemented at the production site.

2.2.1.2* The HACCP plan shall cover all raw materials, packaging materials, products or product groups, as well as every process from incoming goods up to the dispatch of finished products, including product development.

2.2.1.3 ~~The company shall ensure that the~~ HACCP plan ~~is~~ shall be based upon scientific literature or expert advice obtained from other sources, which may include: trade and industry associations, independent experts and regulatory authorities.
This information shall be maintained in line with any new technical process development.

2.2.1.4 ~~The company shall ensure that in~~ In the event of changes to raw materials, packaging materials, processing methods, infrastructure and/or equipment, the HACCP plan ~~is~~ shall be reviewed to ~~assure~~ ensure that product safety requirements are complied with.

2.3 HACCP analysis

2.3.1 HACCP team

2.3.1.1 **Assemble HACCP team:**
The HACCP team shall have the appropriate specific knowledge and expertise and be a multidisciplinary team which includes operational staff.

2.3.1.2 Those responsible for the development and maintenance of the HACCP plan shall have an internal team leader and shall have received ~~adequate~~ appropriate training in the application of the HACCP principles and specific knowledge of the products and processes.

2.3.2 Describe products

2.3.2.1 A full description of the product ~~including~~ shall be documented and maintained and shall contain all relevant information on product safety ~~such as~~ at a minimum:

- composition
- physical, organoleptic, chemical and microbiological characteristics
- legal requirements for the food safety of the product
- methods of treatment, packaging, durability (shelf life)
- conditions for storage, method of transport and distribution.

2.3.3 Identify intended use and users

2.3.3.1 The intended use of the product shall be described in relation to the expected use of the product by the end consumer, taking vulnerable groups of consumers into account.

2.3.4 Construct flow diagram

2.3.4.1 A flow diagram shall ~~exist~~ be documented and maintained for each product, or product group, and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram ~~shall be dated, and after the determination of control measures~~ shall determine every step and clearly identify each control measures defined for CCPs and other control measures. It shall be dated, and in the event of any changes, the flow diagram shall be updated.

2.3.5 On-site confirmation of the flow diagram

2.3.5.1 Representatives of the HACCP team shall verify the flow diagram, by on-site verifications, at all operation stages and shifts. Where appropriate, amendments to the diagram shall be made.

2.3.6 Conduct a hazard analysis for each step

2.3.6.1 A hazard analysis shall be conducted for all possible and reasonably expected physical, chemical (including radiological and allergens) and biological hazards. The analysis shall also include hazards linked to materials in contact with food, packaging materials and hazards related to the work environment. The hazard analysis shall consider the likely occurrence of hazards and the severity of their adverse health effects. Consideration shall be given to the specific control measures that shall be applied to control each significant hazard.

2.3.7 Determine critical control points and other control measures

2.3.7.1 The determination of relevant control measures defined for CCPs and other control measures shall be facilitated by the application of a decision tree or other tool(s), which demonstrates a logical reasoned approach.

2.3.8 Establish validated critical limits for each CCP

2.3.8.1* For each CCP, ~~the appropriate~~ critical limits shall be defined and validated to ~~clearly~~ identify when a process is out of control.

2.3.9 Establish a monitoring system for each CCP

2.3.9.1* **KO N° 2: Specific monitoring procedures in terms of method, frequency of measurement or observation and recording of results, shall be ~~established~~ 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.**

2.3.9.2 Records of CCP monitoring shall be verified by a responsible person within the company and maintained for a relevant period.

2.3.9.3 The operative personnel in charge of the monitoring of control measures defined for CCPs and other control measures shall have received specific training/instruction.

2.3.9.4 Control measures, other than those defined for CCPs, shall be monitored, recorded and controlled by measurable or observable criteria.

2.3.10 Establish corrective actions

2.3.10.1 In the event that the monitoring indicates that a particular control measures defined for a CCP or control measure ~~other than CCP~~ is not under control, ~~adequate~~ corrective actions shall be ~~taken~~ 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.

2.3.11 Validate the HACCP plan and establish verification procedures

2.3.11.1 Procedures of validation, including revalidation after any modification that can impact food safety, shall be documented, implemented and maintained to ensure that the HACCP plan is suitable to effectively control the identified hazards.

2.3.11.2* Procedures of verification shall be ~~established~~ documented, implemented and maintained to confirm that the HACCP plan is working correctly. Verification activities of the HACCP plan ~~shall be performed at least once a year. Examples of verification activities include,~~ for example:

- internal audits
- ~~analyses~~ testing
- sampling
- deviations and non-conformities
- complaints.

shall be performed at least once within a 12-month period or whenever significant changes occur. The results of this verification shall be recorded and incorporated into the HACCP plan.

2.3.12 Establish documentation and record keeping

2.3.12.1 Documentation and records related to the HACCP plan ~~shall be in place. Examples of documentation include,~~ for example:

- hazard analysis
- determination of control measures defined for CCPs and other control measures
- determination of critical limits
- processes,procedures ~~Examples of records include:~~
- outcome of control measures defined for CCPs and other control measure monitoring activities
- training records of the personnel in charge of the CCP monitoring
- observed deviations and non-conformities and implemented corrective actions shall be available.

3 Resource management

3.1 Human resources

3.1.1 All personnel performing work that affects product safety, quality, legality and authenticity shall have the required competence, appropriate to their role, as a result of education, work experience and/or training.

3.1.2 The responsibilities, competencies and job descriptions for all job titles with an impact on food safety and product quality shall be ~~clearly defined~~ documented, implemented and maintained ~~and in place~~. Assignment of key roles shall be defined.

3.2 Personal hygiene

3.2.1* ~~Documented~~ Risk-based requirements relating to personal hygiene shall be documented, implemented and maintained and shall include, at a minimum, the following areas:

- hair and beards
- protective clothing (including their conditions of use in staff facilities)
- hand washing, disinfection and hygiene
- eating, drinking, smoking/vaping or other use of tobacco
- actions to be taken in case of cuts or skin abrasions
- fingernails, jewellery, false nails/eyelashes and personal belongings (including medicines)
- notification of infectious diseases and conditions impacting food safety via a medical screening procedure.

~~The requirements shall be based on hazard analysis and assessment of associated risks.~~

3.2.2* KO N° 3: The requirements for personal hygiene shall be ~~in place and applied~~ understood and adhered to by all relevant personnel, contractors and visitors.

3.2.3 Based on risks, compliance with personal hygiene requirements shall be ~~checked regularly~~ monitored at least once within a 3-month period.

3.2.4 Visible jewellery (including piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated by hazard analysis and audit of associated risks and shall be effectively managed.

3.2.5 Cuts and skin abrasions shall be covered with a coloured plaster/bandage that shall not pose contamination risks. Plaster/bandage shall be waterproof and coloured different from the product colour. Where appropriate:

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

3.2.6 In work areas where wearing headgear and/or beard snood (coverings) is required, the hair shall be covered completely to prevent product contamination.

3.2.7 ~~Clearly defined~~ Usage rules shall ~~exist~~ be Implemented for work areas/activities where it is required to wear gloves (coloured differently from the product colour).

3.2.8* ~~Suitable~~ Adequate protective clothing shall be ~~available~~ provided and in sufficient quantity for each employee.

3.2.9 All protective clothing shall be thoroughly and regularly laundered in-house, by approved contractors or by employees. This decision shall be documented and based on risks ~~justified by risk assessment~~. The requirements related to laundry ~~Defined requirement~~s shall ensure, at a minimum:

- sufficient segregation between dirty and clean clothing at all times
- ~~defined~~ laundering conditions on water temperature and detergent dosage
- avoidance of contamination until use.

The effectiveness of the laundering shall be ~~appropriately~~ monitored.

3.2.10 In case of any health issue or infectious disease that may have an impact on food safety, actions shall be taken to minimise contamination risks.

3.3 Training and instruction

3.3.1* ~~The company shall implement~~ 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.

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

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

- list of participants (including their signature)
- date
- duration
- contents of training
- name of trainer/tutor.

A procedure or program shall be ~~in place~~ documented, implemented and maintained to prove the effectiveness of the training and/or instruction programs.

3.3.4 The contents of training and/or instruction shall be ~~regularly~~ reviewed and updated when necessary. Special consideration shall be given, at a minimum, to these specific issues:

- food safety
- product authenticity, including food fraud
- product quality
- food defence
- food related legal requirements
- product/process modifications
- feedback from the previous documented training/instruction programs.

3.4 Staff facilities

3.4.1* ~~The company shall provide suitable~~ Adequate staff facilities shall be provided and ~~which~~ shall be proportional in size, equipped for the number of personnel, designed and controlled to minimise food safety risks. Such facilities shall be ~~kept~~ maintained ~~in a~~ clean ~~and good condition~~ and in a way to prevent contamination.

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

3.4.3 Changing rooms shall be located to allow direct access to the areas where unpacked ~~food~~ products are handled. ~~If this is not possible, preventive~~ When infrastructure does not allow it, alternative measures shall be implemented and maintained ~~in place~~ to minimise product contamination risks. ~~Where necessary,~~ Outdoor clothing and protective clothing shall be stored separately unless alternative measures are implemented and maintained to prevent contamination risks.

3.4.4 Toilets shall neither have direct access nor pose contamination risks to areas where ~~food~~ products are handled. Toilets shall be equipped with adequate hand washing facilities. ~~Sanitary~~ The facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.

3.4.5* Hand hygiene facilities shall be provided and shall address, at a minimum:

- adequate number of wash basins
- suitably located at access points to and/or within production areas
- ~~sole use~~ designated for cleaning hands only.

The necessity of similar equipment in further areas (e.g. packing area) shall be based on ~~hazard analysis and assessment of associated~~ risks.

3.4.6 Hand hygiene facilities shall provide:

- running potable water at an ~~appropriate~~ adequate temperature
- ~~appropriate~~ adequate cleaning and disinfection equipment
- ~~appropriate~~ adequate means for hand drying.

3.4.7 Where the processes require a higher hygiene control ~~standard of hygiene~~, the hand washing equipment shall provide in addition:

- hand contact-free fittings
- hand disinfection
- waste container with hand contact-free opening.

3.4.8 ~~Based on hazard analysis and assessment of associated risks,~~ A risk-based program shall be ~~in place~~ implemented and maintained to control effectiveness of hand hygiene.

3.4.9 Where needed ~~it is justified by risk assessment~~, cleaning and disinfection facilities shall be available and used for boots, shoes and further protective clothing.

4 Operational processes

4.1 Customer focus and contract agreement

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

4.1.2 All requirements related to food safety and product quality, within the ~~defined~~ customer agreement ~~with customers~~, and any revision of these clauses, shall be communicated to and implemented by each relevant department.

4.1.3* KO N° 4: Where there are customer agreements related to:

- **product recipe (including raw materials characteristics)**
- **process**
- **technological requirements**
- **testing and monitoring plan**
- **packaging**
- **labelling**

these shall be complied with.

4.1.4 In accordance with customer requirements, the senior management shall inform their affected customers, as soon as possible, of any issue related to product safety or legality, including deviations and non-conformities identified by competent authorities.

4.2 Specifications and formulas

4.2.1 Specifications

4.2.1.1* Specifications shall be ~~available~~ documented and implemented ~~and in place~~ for all finished products. They shall be up to date, unambiguous and in compliance with legal and customer requirements.

4.2.1.2 A procedure to control the creation, approval and amendment of specifications shall be ~~in place~~ documented, implemented and maintained and shall include, where required, the acceptance of the customer(s). Where required by customers, product specifications shall be formally agreed.

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.

4.2.1.3* KO N° 5: Specifications shall be ~~available and in place~~ documented and implemented for all raw materials (ingredients, additives, packaging materials, rework). Specifications shall be up to date, unambiguous and be in compliance with legal requirements and, if ~~existing~~ defined, with customer requirements.

4.2.1.4 Specifications and/or their contents shall be available on site for all relevant personnel.

4.2.1.5* Where ~~customers specifically require that products are~~ products are requested to be labelled and/or promoted with "free from" certain substances or ingredients (e.g. gluten, pork, etc.), or ~~that~~ where certain methods of treatment or production are excluded ~~(e.g. GMOs), verifiable procedures shall be in place~~ measures shall be implemented to demonstrate compliance with such statement.

~~4.2.2 Formulas/Recipes~~

~~**4.2.2.1* KO N° 5: Where there are customer agreements related to:**~~

- ~~**product recipe (including raw materials characteristics)**~~
- ~~**process**~~
- ~~**technological requirements**~~
- ~~**packaging**~~
- ~~**labelling**~~

~~**these shall be complied with.**~~

4.3 Product development/Product modification/Modification of production processes

4.3.1 ~~For each~~ A procedure for new development or modification of products and/or processes shall be documented, implemented and maintained and shall include at a minimum, a hazard analysis and assessment of associated risks ~~shall be conducted~~.

4.3.2* The procedure shall ~~be in place to~~ ensure that labelling complies with current legislation of the destination country/ies and customer requirements.

4.3.3* The ~~product~~ development and/or modification process shall result in specifications about formulation, rework, packaging materials ~~requirements~~, manufacturing processes and process parameters ~~related to the fulfilment of product requirements~~ which comply with food safety, product quality, legality, authenticity and customer requirements. This includes factory trials, product testing and process monitoring. The progress and results of product development/modification shall be recorded.

4.3.4 Shelf life tests or ~~adequate~~ appropriate validation through microbiological, chemical and organoleptic evaluation shall be carried out and consideration shall be given to product formulation, packaging, manufacturing and declared conditions. In accordance with this evaluation, the shelf life shall be defined ~~established~~.

4.3.5 Recommendations for preparation and/or use of food product instructions related to food safety and/or product quality shall be validated and documented ~~established, where appropriate~~.

4.3.6 ~~The company shall demonstrate through studies and/or perform relevant tests to validate~~ Nutritional information or claims which are declared on labelling shall be validated, through studies and/or tests, throughout the shelf life of the products.

~~4.3.7 In the event of changes to process characteristics or product formulation, including rework and/or packaging materials, the company shall ensure that the food safety and product quality requirements are complied with. Labelling shall be reviewed and adapted when necessary.~~

4.4 Purchasing and food fraud mitigation

~~4.4.1 The company shall control purchasing processes to ensure that all externally sourced raw materials, semi-finished products, packaging materials and services, which have an impact on food safety and product quality, conform to defined requirements.~~

4.4.1* A procedure for the sourcing of materials and the approval and monitoring of suppliers (internal and external) shall be developed, implemented and maintained ~~in place~~.
~~The approval and monitoring procedure shall contain clear audit criteria, such as~~ This procedure shall contain, at a minimum:

- raw materials and/or suppliers' risks
- required performance standards (e.g., certification, origin, etc.)
- exceptional situations (e.g. emergency purchase)
  and, based on risks, additional criteria, for example;
- audits performed by an experienced and competent person
- ~~certificates of analyses~~ testing results
- supplier reliability

- complaints
- ~~required performance standards~~
- supplier questionnaire.

4.4.2 The purchased ~~raw~~ materials, ~~semi-finished products and packaging materials~~ shall be ~~checked~~ evaluated, based on risks and suppliers' status, for food safety, product quality, legality and authenticity. The results shall be the basis for the testing and monitoring plans.
~~in accordance with the existing specifications and justified by risk assessment for their authenticity.~~
~~The schedule of these checks shall take into account, at a minimum, defined food safety and product quality risks.~~
~~The frequency and/or scope of sampling shall be based on:~~

- ~~the impact of the raw materials, semi-finished products and packaging materials on the finished products~~
- ~~the supplier's status.~~

4.4.3* ~~The purchased services~~ Based on risks, purchasing processes shall be ~~checked in accordance with the existing specifications~~ controlled to ensure that all services, which have an impact on food safety and product quality, comply with defined requirements.
~~The schedule of these checks~~ This shall take into account, at a minimum:

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

4.4.4* Where a company outsources a part of the product processing and/or primary packa~~g~~ing and/or labelling, ~~the company~~ it shall ~~have it~~ be documented in the food safety and quality management system and ~~ensure control over~~ such processes shall be controlled to guarantee that food safety, ~~and~~ product quality, legality and authenticity are not compromised. Control of such outsourced processes shall be identified and documented. When required by the customer, there shall be evidence that ~~he has~~ they have been informed and ~~has~~ have agreed to such outsourced process.

4.4.5 An ~~written~~ agreement shall be documented and implemented ~~in place~~, covering the outsourced processes and describing any arrangements made in connection with it, including in-process controls, ~~sampling and analyses~~ testing and monitoring plan.

4.4.6 ~~The company shall approve the~~ Suppliers of the outsourced processes shall be approved through:

- certification against IFS Food or other GFSI recognised food safety certification standard or
- documented supplier audit, performed by an experienced and competent person, which shall include, at a minimum, requirements for food safety, product quality, legality and authenticity.

4.4.7* The ~~results from the~~ sourcing of materials and supplier assessments shall be reviewed ~~regularly~~ at least once within a 12-month period or whenever significant changes occur. ~~and this review shall be justified by risk assessment.~~ Records of the reviews and the consequential actions of the assessment shall be documented.

4.4 Product packaging

4.5.1 * Based on ~~hazard analysis, assessment of associated~~ risks and intended use, ~~the company shall define the~~ key parameters for the packaging materials shall be defined in detailed specifications complying with the current relevant legislation and other relevant hazards or risks.
~~The company shall check and verify the~~ Suitability of the packaging materials and existence of functional barrier(s) shall be validated for each relevant product. It shall be monitored and demonstrated by test/analysis, for example: ~~of the consumer unit packaging material for each relevant product test/analysis, such as:~~

- organoleptic tests
- storage tests
- chemical analyses
- migration test results.

4.5.2 For all packaging materials which could have an impact on products, ~~certificates of conformity~~ declarations of compliance, ~~shall exist~~ which attest compliance with legal requirements shall be documented. In the event that no specific legal requirements are applicable, evidence shall be maintained to ~~demonstrate~~ ensure that packaging materials are suitable for use. This applies for packaging materials which could have an influence on raw materials, semi-finished and finished products.

4.5.3 ~~The company shall ensure that the~~ Used packaging and labelling shall correspond to the product being packaged and shall comply with agreed customer product specifications. Labelling information shall be legible and indelible. This shall be monitored and documented at least at the start and end of a production as well as at every product changeover. ~~regularly checked and documented.~~

4.6 Factory location

4.6.1* ~~The company shall investigate the extent to which~~ Potential adverse impact on food safety and/or product quality from the factory environment (e.g. ground, air) shall be investigated ~~may have an adverse impact on food safety and product quality~~. 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.

4.7 Factory exterior

4.7.1 All external areas of the factory shall be clean, tidy and maintained in a way to prevent contamination ~~good condition~~. Where natural drainage is inadequate, ~~a suitable~~ an adequate drainage system shall be installed.

4.7.2 Outdoor storage shall be kept to a minimum. Where goods are stored outside, it shall be ~~justified by risk assessment to ensure~~ ensured that there are no contamination risks or adverse effects on food safety and quality.

4.8 Plant layout and process flow

4.8.1 ~~A~~ Site ~~map~~ plan(s) covering all buildings ~~of the facility shall be available. Plans~~ shall be ~~in place that clearly describe~~ maintained and documented and shall describe, at a minimum, the process flow of:

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

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

4.8.3 In the case of areas sensitive to microbiological, chemical and physical risk(s) ~~which is/are justified by risk assessment,~~ have been identified, they shall be designed and operated to ensure product safety is not compromised.

4.8.4 Laboratory facilities and in-process controls shall not affect product safety.

4.9 Production and storage premises

4.9.1 Constructional requirements

4.9.1.1* Premises where food products are prepared, treated, processed and stored shall be designed, constructed and maintained to ensure food safety.

4.9.2 Walls

4.9.2.1 Walls shall be designed and constructed to ~~prevent the accumulation of dirt~~, meet production requirements in a way to prevent contamination, reduce condensation and mould growth, facilitate cleaning and if necessary, disinfection.

4.9.2.2 The surfaces of walls shall be ~~in good condition~~ maintained in a way to prevent contamination and easy to clean; they shall be impervious and wear-resistant to minimise product contamination risks.

4.9.2.3 The junctions between walls, floors and ceilings shall be designed to facilitate cleaning and if necessary, disinfection.

4.9.3 Floors

4.9.3.1 Floor covering shall be designed and constructed to meet production requirements ~~and shall be in good condition and easy to clean~~ be maintained in a way to prevent contamination and facilitate cleaning and if necessary, disinfection. Surfaces shall be impervious and wear-resistant.

4.9.3.2 The hygienic disposal of water and other liquids shall be ensured. Drainage systems shall be ~~easy to clean and~~ designed, constructed and maintained in a way to minimise product contamination risks (e.g. entry of pests, areas sensitive to transmission of odour or contaminants) and shall be easy to clean.

4.9.3.3 In food handling areas, machinery and piping shall be arranged to allow waste water, if possible, to flow directly into a drain.
Water and other liquids shall reach drainage using appropriate measures without difficulty. Puddles shall be avoided.

~~4.9.3.4 In food handling areas, machinery and piping shall be arranged to allow waste water, if possible, to flow directly into a drain.~~

4.9.4 Ceilings/Overheads

4.9.4.1 Ceilings (or, where no ceilings exist, the inside of roofs) and overhead fixtures (including piping, cableway, lamps, etc.) shall be designed, constructed and maintained to minimise the accumulation of dirt and condensa- tion and shall not pose any physical and/or microbiological contamination risks.

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

4.9.5 Windows and other openings

4.9.5.1 Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in a way to prevent contamination ~~good condition~~.

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

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

4.9.5.4 In areas where unpackaged products are handled, windows shall be protected against breakage.

4.9.6 Doors and gates

4.9.6.1 Doors and gates shall be maintained in a way to prevent contamination ~~good condition~~ and easy to clean. They shall be designed and constructed of non-absorbent materials to avoid:

- splintering parts
- flaking paint
- corrosion.

4.9.6.2 External doors and gates shall be constructed to prevent the access of pests. ~~they shall be self-closing, unless non-essentiality is justified by risk assessment.~~

4.9.6.3 Plastic strip curtains separating ~~the internal~~ areas shall be ~~in good condition~~ maintained in a way to prevent contamination and easy to clean.

4.9.7 Lighting

4.9.7.1 All production, storage, receipt and dispatch areas shall have adequate levels of light.

4.9.8 Air conditioning/Ventilation

4.9.8.1 Adequate natural and/or artificial ventilation shall be designed, constructed and maintained ~~in place~~ in all areas.

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

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

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

4.9.9 Water

4.9.9.1* Water which is used for hand washing, cleaning and disinfection, or as an ingredient in the production process ~~or for cleaning~~ shall be of potable quality at the point of use and supplied in sufficient quantity; this also applies to steam and ice used within the production area.
The quality of water (including recycled water), steam or ice shall be monitored following a risk-based sampling plan ~~based on hazard analysis and assessment of associated risks~~.

4.9.9.2 Recycled water, which is used in the process, shall not pose contamination risks.

4.9.9.3 Non-potable water shall be transported in separate, properly marked piping. Such piping shall neither be connected to the ~~drinking~~ potable water system nor allow the possibility of reflux, to prevent ~~avoid~~ contamination of potable water sources or factory environment.

4.9.10 Compressed air and gases

4.9.10.1* The quality of compressed air that comes in direct contact with food or ~~primary packaging~~ food contact materials shall be monitored based on ~~hazard analysis and assessment of associated~~ risks. ~~If gases are used, they shall demonstrate adequate safety and quality through a declaration of compliance and shall be suitable for the intended use~~. Compressed air shall not pose contamination risks.

4.9.10.2 ~~If~~ Gases ~~are~~ used that come in direct contact with food or food contact materials, ~~they~~ shall demonstrate ~~adequate~~ safety and quality ~~through a declaration of compliance and shall be suitable~~ for the intended use.

~~4.9.10.2 Compressed air shall not pose contamination risks.~~

4.10 Cleaning and disinfection

4.10.1* ~~Based on hazard analysis and assessment of associated risks,~~ Risk-based cleaning and disinfection schedules shall be ~~available~~ validated, documented and implemented. These shall specify:

- objectives
- responsibilities
- the products used and their instructions for use
- dosage of cleaning and disinfection chemicals
- the areas ~~to be cleaned and/or disinfected~~ and timeslots for cleaning and disinfection
- cleaning and disinfection frequency
- Cleaning In Place (CIP) criteria, if applicable
- documentation requirements
- hazard symbols (if necessary).

4.10.2 Cleaning and disinfection activities shall be documented and implemented and shall result in effectively cleaned premises, facilities and equipment. ~~Defined methods shall be adequately implemented, documented and monitored.~~

4.10.3 ~~Monitoring records for cleaning and disinfection shall be available.~~ Cleaning and disinfection activities shall be monitored (four eyes principle) and monitoring records shall be available.

4.10.4* Only ~~qualified~~ competent personnel shall ~~be allowed to undertake~~ perform cleaning and disinfection activities. The personnel shall be trained and retrained to carry out the cleaning and disinfection schedules.

4.10.5* The intended use of cleaning and disinfection equipment ~~utensils~~ shall be clearly identified. ~~Cleaning and disinfection utensils~~ They shall be used and stored in a way ~~that~~ to avoid contamination.

4.10.6 Safety Data Sheets and instructions for use shall be available on-site for ~~chemicals and~~ cleaning and disinfection chemicals ~~agents~~. Personnel responsible for cleaning and disinfection activities shall be able to demonstrate their knowledge of such instructions~~, which shall always be available on site~~.

4.10.7 The effectiveness of the cleaning and disinfection measures shall be verified ~~and justified by risk assessment~~. The verification shall ~~be based on an appropriate sampling schedule and shall consider~~: 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 ~~corrective~~ actions shall be documented.

4.10.8 Cleaning and disinfection schedules shall be reviewed and modified, in the event that changes occur to products, processes or cleaning and disinfection equipment, if necessary.

~~4.10.9* Cleaning and disinfection chemicals shall be clearly labelled, used and stored appropriately, to avoid contamination.~~

~~4.10.10 Cleaning and disinfection activities shall be carried out in periods of non-production. If this is not possible, these operations shall be controlled in order not to affect the products.~~

4.10.9 Where a company hires a third-party service provider for cleaning and disinfection activities, in production areas, all above-mentioned requirements ~~all requirements specified above~~ shall be ~~clearly defined~~ documented in the service contract.

4.11 Waste management

4.11.1* A waste management procedure shall be documented, implemented and maintained ~~in place~~ to ~~avoid~~ prevent cross contamination.

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

4.11.3 Food waste and other waste shall be removed as quickly as possible from areas where food is handled. The accumulation of waste shall be avoided.

4.11.4 Waste collection containers shall be clearly marked, suitably designed and maintained, ~~in a good state of repair,~~ easy to clean, and where necessary, disinfected.

4.11.5 If a company decides to separate food waste and to reintroduce them into the feed supply chain, ~~adequate~~ measures or procedures shall be implemented to prevent a contamination or deterioration of this material.

4.11.6 Waste shall be collected in separate containers in accordance with the intended means of disposal. Such waste shall be disposed by authorised third-parties only. Records of waste disposal shall be kept by the company.

4.12 Foreign material risk mitigation

4.12.1* **KO N° 6: Based on hazard analysis and assessment of associated risks, procedure**(s) **shall be in place** documented, implemented and maintained **to** ~~**avoid**~~ prevent **contamination with foreign materials. Contaminated products shall be treated as non-conforming products.**

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

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

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

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

If, for technological characteristics and/or needs, it is not possible to protect the products, appropriate control measures shall be implemented ~~defined and applied~~.

4.12.3 All chemicals within the facility shall be feat for purpose,labelled, stored and handled in a way to not pose any contamination risk.

4.12.4 Where metal and/or other foreign material detectors are required, they shall be installed to ensure maximum efficiency of detection to ~~avoid~~ prevent subsequent contamination. Detectors shall be subjected to ~~regular~~ maintenance to avoid malfunction at least once within a 12-month period.

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

4.12.6 Potentially contaminated products shall be isolated. Access and actions for the further handling or ~~checking~~ testing of these isolated products shall only be carried out by authorised personnel ~~according to defined procedures. After this check, contaminated products shall be treated as non-conforming products~~.

4.12.7 In areas where raw materials, semi-finished and finished products are handled, the use of glass and/or brittle materials shall be excluded; however where the presence of glass and/or brittle materials cannot be avoided, the risks shall be controlled and the glass and/or brittle materials shall be clean and pose no risks to product safety.

4.12.8 ~~Based on hazard analysis and assessment of associated risks, preventive measures shall be in place~~ Risk-based measures shall be implemented and maintained for the handling of glass packaging, glass containers or other kinds of containers in the production process (turn over, blow, rinse, etc.). After this process step, there shall be no further contamination risks.

4.12.9 Procedure(s) shall be ~~in place~~ documented, implemented and maintained describing the measures to be taken in case of glass breakage and/or brittle materials. Such measures shall include identifying the scope of goods to be isolated, specifying authorised personnel, cleaning and if necessary, disinfection of the production environment and releasing the production line for continued production.

4.12.10 Breakages of glass and brittle materials shall be recorded. Exceptions shall be justified and documented.

4.12.11 Where visual inspection is used to detect foreign materials, the employees shall be trained and operative changes shall be performed at an appropriate frequency to maximise the effectiveness of the process.

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

4.13 Pest monitoring and control

4.13.1 Site premises ~~infrastructure and operations and~~ and equipment shall be designed, built and maintained to prevent pest infestation.

4.13.2* ~~The company shall have adequate~~ Risk-based pest control measures ~~in place which~~ shall be documented, implemented and maintained. They shall ~~in compliance~~ 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, ~~such as~~ 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.

~~The pest control measures shall be based on hazard analysis and assessment of associated risks.~~

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

4.13.4 Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded. Any infestation shall be documented and control measures taken.

4.13.5 Baits, traps and insect exterminators shall be fully functioning, sufficient in number, designed for purpose, placed in appropriate positions and used in a way to avoid ~~that avoids any~~ contamination ~~risks~~.

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

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

4.14 Receipt and storage of goods

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

4.14.2* ~~The~~ A system shall be implemented and maintained to ensure storage conditions of raw materials, semi-finished, finished products and packaging materials, ~~shall~~ correspond to product specifications and shall not have any negative impact on other products. ~~This shall be defined in an implemented and maintained system.~~

4.14.3 Raw materials, packaging materials, semi-finished and finished products shall be stored to minimise contamination risks or any other negative impact.

4.14.4 ~~Appropriate~~ Adequate storage facilities shall be available for the management and storage of working materials, process aids and additives. The personnel responsible for the management of storage facilities shall be trained.

4.14.5* All products shall be ~~clearly~~ identified. Use of products shall be undertaken in accordance with the principles of First In/First Out and/or First Expired/First Out.v

4.14.6 Where a company hires a third-party storage service provider, the service provider shall be certified against IFS Logistics or any other GFSI recognised certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own storage practices shall be fulfilled and this shall be ~~clearly~~ defined in the respective contract.

4.15 Transport

4.15.1* The conditions inside the vehicles, ~~such as~~ for example:

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

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

4.15.2 Where goods are transported at certain temperatures, the temperature inside the vehicles shall be checked and documented before loading.

4.15.3 Procedures to prevent contamination during transport, including loading and unloading, shall be documented, implemented and maintained ~~in place~~. Different categories of goods (food/non-food) shall be taken into consideration, if applicable.

4.15.4 Where goods are transported at certain temperatures, maintaining the ~~adequate~~ appropriate range of temperatures during transport shall be ensured and documented.

4.15.5 ~~Adequate~~ Risk-based hygiene requirements for all transport vehicles and equipment used for loading/unloading (e.g. hoses of silo installations) shall be implemented ~~exist~~. Measures taken shall be recorded.

4.15.6 The loading/unloading areas shall be appropriate for their intended use. They shall be constructed in a way that:

- the risks of pest intake are mitigated
- products are protected from adverse weather conditions
- accumulation of waste is avoided
- condensation and growth of mould are prevented
- cleaning and if necessary, disinfection can be easily undertaken.

4.15.7 Where a company hires a third-party transport service provider, the service provider shall be certified for IFS Logistics or any other GFSI recognised certification standard covering the respective scope of activity. If not, all relevant requirements equivalent to the company's own transport practices shall be fulfilled and this shall be ~~clearly~~ defined in the respective contract.

4.16 Maintenance and repair

4.16.1* ~~An adequate~~ A maintenance plan shall be ~~in place~~, documented, implemented and maintained, that covers all critical equipment (including transport) ~~for compliance with product requirements~~ to ensure food safety, product quality, legality and authenticity. This applies both to internal maintenance activities and service providers. The plan shall include responsibilities, priorities and due dates.

4.16.2 A maintenance plan for production and storage premises shall be developed, implemented, and maintained.

4.16.3 ~~Product requirements and prevention of contamination~~ Food safety, product quality, legality and authenticity shall be ensured during and after maintenance and repair work. Records of maintenance and repair work shall be kept.

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

4.16.5 Failures and malfunctions of ~~plant~~ premises and equipment (including transport) that are essential for food safety and product quality, shall be identified, documented and reviewed to enable prompt actions and to improve the maintenance plan.

4.16.6 Temporary repairs shall be carried out not to compromise food safety and product quality. Such work shall be documented and a short-term deadline set for eliminating the issue.

4.16.7 Where a company hires a third-party maintenance and repair service provider, all the company ~~specified~~ requirements regarding material, equipment and operational rules shall be ~~clearly~~ defined, documented and maintained in the service contract, to prevent any product contamination.

4.17 Equipment

4.17.1* Equipment shall be suitably designed and defined ~~specified~~ for the intended use. Before commissioning, it shall be ~~verified~~ validated that ~~the product requirements~~ food safety, product quality, legality, authenticity and customer requirements are complied with.

4.17.2 For all equipment and utensils which could have an impact on the product ~~with direct food contact, a certificate of conformity shall be in place~~, evidence shall be documented to demonstrate compliance with legal requirements.
In case no specific legal requirements are in place, evidence shall be available, such as:

- certificate of conformity
- technical specifications
- manufacturer's self-declaration

to demonstrate that they are suitable for the intended use.

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

4.17.4 ~~The company shall ensure that all~~ All product equipment ~~is~~ shall be in a condition that does not compromise food safety and product quality.

4.17.5 ~~The company shall ensure that in~~ In the event of changes to equipment, the process characteristics ~~are~~ shall be reviewed to ~~assure that the product requirements, as agreed with customers~~, ensure that food safety, product quality, legality, authenticity and customer requirements are complied with.

4.18 Traceability

4.18.1* KO N° 7: A traceability system shall be documented, implemented and maintained ~~**in place**~~ **that enables the identification of product lots and their relation to batches of raw materials and primary packaging materials food contact packaging materials and/or materials carrying legal and/or relevant food safety information. The traceability system shall incorporate all relevant records of:**

- **receipt**
- **processing**
- **use of rework**
- work in progress
- **distribution.**

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

4.18.2* The traceability system ~~shall be tested on a periodic basis, at least annually and each time the traceability system changes.~~ including mass balance, shall be tested at least once within a 12-month period or whenever significant changes occur. The test samples shall ~~represent~~ verify the complexity of the company's product range. The test records shall ~~verify~~ demonstrate upstream and downstream traceability~~ies~~ (from delivered products to raw materials, and vice versa). ~~The traceability of the finished products shall be per- formed within four (4) hours maximum.~~

4.18.3 The traceability from the finished products to the raw materials and to the customers shall be performed within four (4) hours maximum. Test results, including the timeframe for obtaining the information, shall be recorded and where necessary ~~appropriate~~ actions shall be taken. Timeframe objectives shall be ~~defined and be~~ in compliance with customer requirements if more stringent than four (4) hours.

~~4.18.3 The traceability system shall identify the relationship between batches of finished products and their labels.~~

~~4.18.5 Traceability shall be ensured at all stages, including work in progress, post treatment and rework.~~

4.18.4 Labelling of semi-finished or finished product lots shall be made at the time when the goods are directly packed to ensure clear traceability of goods. Where goods are labelled at a later time, the temporarily stored goods shall have a specific lot labelling. Shelf life (e.g. best before date) of labelled goods shall be ~~established~~ defined using the original production batch.

4.18.5 If required by the customer, identified representative samples of the manufacturing lot or batch number shall be stored appropriately and kept until expiration of the "Use by" or "Best before" date of the finished products and, if necessary, for a determined period beyond this date.

4.19 Allergen risk mitigation

4.19.1 ~~Raw material specifications that identify~~ Information about allergens requiring declarations, including accidental or technically unavoidable cross-contaminations of legally declared allergens and traces, relevant to the country of sale of the finished products shall be documented and maintained for all raw materials. ~~available. The company shall maintain a~~ A continuously up to date listing of all raw materials containing allergens used on the premises shall be maintained. This shall also identify all blends and formulas to which such raw materials containing allergens are added.

4.19.2* ~~Based on hazard analysis and assessment of associated risks, preventive and control~~ Risk-based measures shall be ~~in place~~ implemented and maintained from receipt to dispatch, to ensure that potential cross contamination of products by allergens is minimised. The potential cross contamination risks related to at a minimum:

- environment
- transport
- storage
- raw materials
- personnel (including contractors and visitors)

shall be considered.
~~Control~~ Implemented measures shall be ~~verified~~ monitored.

4.19.3 Finished products containing allergens that require declaration shall be declared in accordance with legal requirements. Accidental or technically unavoidable cross-contaminations of legally declared allergens and traces shall be labelled. The decision shall be based on a hazard analysis and audit of associated risks. The potential cross-contamination with allergens from raw materials processed in the company shall also be taken into account on the product label.

4.20 Food fraud

4.20.1 The responsibilities for a food fraud vulnerability assessment and mitigation plan shall be ~~clearly~~ defined. The responsible person(s) shall have the appropriate specific knowledge ~~and full commitment from the senior management.~~

4.20.2* A documented food fraud vulnerability assessment, including assessment criteria, shall be ~~undertaken~~ documented, implemented and maintained. The scope of the assessment shall cover on all raw materials, ingredients, packaging materials and outsourced processes, to determine the risks of fraudulent activity in relation to substitution, mislabelling, adulteration or counterfeiting. ~~The criteria considered within the vulnerability assessment shall be defined.~~

4.20.3* A ~~documented~~ food fraud mitigation plan shall be developed, implemented and maintained with reference to the vulnerability assessment, and shall include the testing and monitoring methods. ~~implemented to control any identified risks. The methods of control and moni- toring shall be defined and implemented.~~

4.20.4 The food fraud vulnerability assessment shall be ~~regularly~~ reviewed, at least once within a 12-month period or whenever significant changes occur ~~annually, and/or in the event of increased risks.~~ If necessary, the food fraud mitigation plan shall be revised/updated accordingly.

4.21 Food defence

4.21.1 The responsibilities for the food defence ~~plan~~ shall be ~~clearly~~ defined. ~~Those~~ The responsible person(s) shall have the appropriate specific knowledge. ~~and training, and have full commitment from the senior management.~~

4.21.2* A food defence ~~plan and procedure~~ procedure and plan shall be developed ~~based on probability and be implemented in relation to assessed~~ to identify potential threats and define food defence measures. This shall include at a minimum:

- legal requirements
- identification of critical areas and/or practices and policy of access by employees
- visitors and contractors
- how to manage external inspections and regulatory visits
- any other appropriate control measures.

~~The food defence plan shall be reviewed at least annually, and updated when appropriate.~~

4.21.3 The food defence plan shall be tested ~~on the~~ for effectiveness and reviewed at least once within a 12-month period or whenever significant changes occur. ~~of the food defence plan and the related control measures shall be included in the internal audit and the inspection plan.~~

6.4 ~~A documented procedure shall exist for managing external inspections and regulatory visits. Relevant personnel shall be trained to execute the procedure.~~

5 Measurements, analyses, improvements

5.1 Internal audits

5.1.1* **KO N° 8: ~~The company shall have an~~ An effective internal audit program ~~in place~~ shall be documented, implemented and maintained. ~~which shall cover at least~~ and shall ensure that all the requirements of the IFS Standard are assessed within a 12-month period.**
~~Scope and frequency of internal audits shall be determined and justified by risk assessment.~~
The program shall include the management of all identified deviations and non-conformities.
~~The internal audit program~~ It shall also apply to off-site storage locations owned or rented by the company.

5.1.2 ~~Internal audits of activities, which are critical to food safety and product quality, shall be carried out at least once a year.~~ Based on risks, scope and frequency of internal audits shall be determined.

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

5.1.4 Internal audits ~~results~~ shall be documented and results communicated to the senior management and to persons responsible for the concerned activities. ~~Necessary corrective actions and a schedule for implementation shall be determined.~~ Compliances, deviations and non-conformities shall be documented and communicated to the relevant persons. ~~All corrective actions resulting from the internal audits shall be verified.~~

5.2 Site factory inspections

5.2.1* Site and factory inspections shall be planned and carried out for topics, ~~such as~~ 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 ~~justified by risk assessment and be~~ based on risks and on the history of previous ~~experience~~ results.

5.3 Process ~~and working environment~~ validation and control

5.3.1 The criteria for process ~~and working environment~~ validation and control shall be ~~clearly~~ defined.

5.3.2 ~~Where the control of~~ Process ~~and working environment~~ parameters (temperature, time, pressure, chemical properties, etc.) which are essential to ensure the food safety and product quality ~~requirements, such parameters~~ shall be monitored ~~and~~, recorded continuously and/or at appropriate intervals and secured against unauthorised access and/or change.

5.3.3* All rework operations shall be validated, monitored and documented. These operations shall not affect the food safety and product quality requirements.

5.3.4 Procedures shall be ~~in place~~ documented, implemented and maintained for prompt notification, recording and monitoring of equipment malfunction and process deviations.

5.3.5 Process ~~and working environment~~ validation shall be performed using the collected data that is relevant for food safety and the processes. If substantial modifications occur, a re-validation shall be carried out.

5.4 Calibration, adjustment and checking of measuring and monitoring devices

5.4.1* ~~The company shall identify and record the~~ Measuring and monitoring devices required to ensure compliance with food safety and product quality requirements 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 ~~specified~~ defined intervals, ~~with a monitoring system. This system shall be~~ in accordance with defined, recognised standard/methods and within relevant limits of the process parameter values. The results ~~of the checks, adjustments and calibrations~~ 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 ~~necessary, corrections and corrective actions on processes and products shall be carried out.~~ 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 company shall define compliance criteria to control lot quantity.~~ Compliance criteria to control lot quantity shall be defined. ~~A frequent and methodological approach~~ A system on frequency and methodology for quantity control shall be ~~in place~~ implemented and maintained to meet legal requirements of the destination country/ies and customer specifications.

5.5.2 ~~Checks~~ 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 ~~and process analyses~~, testing and environmental monitoring

5.6.1* Testing and monitoring plans for internal and external analyses shall be ~~justified by risk assessment~~ risk-based to ensure that product safety, quality, legality, authenticity and specific customer requirements are met. The plans shall cover ~~topics, such as~~ at a minimum:

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

All test results shall be recorded.

5.6.2* Based on risks, the criteria for environmental monitoring program shall be documented, implemented and maintained.

5.6.3* Analyses which are relevant for food safety, shall preferably be performed by laboratories with appropriate accredited programs/methods (ISO/IEC 17025). If the analyses are performed internally or by a laboratory without the appropriate accredited programs/methods, the results shall be cross-checked ~~verified on a regular basis~~ by laboratories accredited to these programs/methods (ISO/IEC 17025) at least once within a 12-month period.

5.6.4 Procedures shall ~~exist which~~ be documented, implemented and maintained to ensure the reliability of the internal analyses results, based on officially, recognised analysis methods. This shall be demonstrated by ring tests or other proficiency tests.

5.6.5 Results of analyses shall be evaluated promptly by competent personnel. ~~Appropriate corrective actions~~ Immediate corrections shall be ~~undertaken~~ implemented for any unsatisfactory results. ~~The analytical results shall be reviewed regularly in order to identify trends~~ Based on risks and legal requirements, the frequency for review of the testing and monitoring results shall be defined in order to identify trends ~~and, when necessary, corrective actions shall be taken~~. When unsatisfactory trends are identified, the impact on processes and products as well as the need for actions shall be assessed.

5.6.6 Where internal analyses or controls are undertaken, these shall be carried out in accordance with defined procedures, by ~~trained~~ competent and approved personnel, in defined areas or laboratories, using appropriate equipment.

5.6.7 For ~~verification~~ monitoring of the quality of the finished product, internal organoleptic tests shall be carried out ~~regularly~~. These tests shall be in accordance with specifications and related to the impact on respective parameters of product characteristics. The results of these tests shall be documented.

5.6.8 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 safety, quality, legality and authenticity.

5.7 Product release

5.7.1* A procedure for quarantine (blocking/hold) shall be ~~in place~~ documented, implemented and maintained ~~that is justified by risk assessment. The procedure shall~~ to ensure that only raw materials, semi-finished and finished products, and packaging materials ~~conforming to product requirements,~~ complying with food safety, product quality, legality, authenticity and customer requirements, are processed and dispatched.

5.8 Management of complaints from authorities and customers

5.8.1* A procedure shall be ~~in place~~ documented, implemented and maintained for the management of product complaints and of any written notification from the competent authorities—within the framework of official controls—, any ordering action or measure to be taken when non-compliance is identified.

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

5.8.3 Complaints shall be analysed with a view to implementing ~~appropriate~~ actions to avoid the recurrence of the deviations and/or non-conformities.

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

5.9 Management of ~~incidents, product withdrawal~~, product recalls, product withdrawals and incidents

5.9.1* **KO N° 9:** An effective procedure ~~for the withdrawal and/or the recall of all products~~ shall be ~~in place. This procedure shall include a clear assignment of responsibilities and a comprehensive information policy for customers and consumers.~~
~~A procedure shall be~~ documented, implemented and maintained for the management of recalls, withdrawals, incidents and potential emergency situations with an impact on food safety, product quality, legality and authenticity. It shall include, at a minimum:

- the assignment of responsibilities
- the training of the responsible persons
- the decision-making process
- the nomination of a person, authorised by the company and permanently available, to initiate the ~~incident management~~ the necessary process in a timely manner
- ~~the nomination and training of an incident management team~~
- an up to date alert contact list including customer information, sources of legal advice, contacts availability
- a communication plan including customers, authorities and where applicable, consumers.

5.9.2* The procedures ~~for management of incidents and product withdrawal/recall~~ shall be subject to ~~regular~~ internal testing for recall/withdrawal, by covering the end-to-end process, at least once within a 12-month period or whenever significant changes occur ~~a year. This test shall be carried out to ensure the effective implementation and operation of the full procedure and shall include the verification of the updated contact data~~. The outcome of the test shall be reviewed for continuous improvement.

5.10 Management of ~~non-conformities and~~ non-conforming products

5.10.1* A procedure shall be ~~in place~~ 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/~~post treatment~~ 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 ~~conformities~~ are identified, immediate actions shall be taken to ensure that food 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 shall be ~~in place~~ documented, implemented and maintained for the recording, analysis and communication to the relevant persons of deviations and of non-conformities and non-conforming products, with the objective to close the non-compliances and avoid recurrences by ~~preventive~~ corrections and/or corrective actions. This ~~may~~ shall include a root cause analysis at least for deviations and non-conformities related to safety, legality, authenticity and/ or recurrence of deviations and non-conformities.

5.11.2 Where deviations and non-conformoities are identified, corrections shall be implemented.

5.11.3* KO N° 10: Corrective actions shall be ~~clearly~~ formulated, documented and ~~undertaken~~ implemented as soon as possible to avoid the further occurrence of deviations and non-conformities. The responsibilities and the timescales for corrective actions shall be ~~clearly~~ defined.

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

6 Food defence plan

6.1 The responsibilities for the food defence plan shall be clearly defined. Those responsible shall have the appropriate specific knowledge and training, and have full commitment from the senior management.

6.2* A food defence plan and procedure shall be developed based on probability and be implemented in relation to assessed threats. This shall include:

- legal requirements
- identification of critical areas and/or practices and policy of access by employees
- visitors and contractors
- any other appropriate control measure.

The food defence plan shall be reviewed at least annually, and updated when appropriate.

6.3 The test on the effectiveness of the food defence plan and the related control measures shall be included in the internal audit and the inspection plan.

6.4 A documented procedure shall exist for managing external inspections and regulatory visits. Relevant personnel shall be trained to execute the procedure.

Overall summary: Table of compulsory fields for specific defined IFS Food Audit requirements and key elements

Part of the IFS Audit report	N° of IFS Food v8 require-ment	Compulsory information to be added
Policy	1.1.1	Summary*
Corporate structure	1.2.1 KO 1	Summary*
	1.2.3	Summary*
	1.2.5	Summary*
	1.2.6	• Name of the competent authority: [name] • Last visit of the competent authority (also when more than 12 months ago): [date] • Have there been any mandatory actions connected to food safety, food fraud and/or legality of the product(s) ? [Y/N]
Management review	1.3.1	Summary*
Document management	2.1.1.3	Summary*
Records and documented information	2.1.2.2	Summary*
HACCP plan	2.2.1.1	Summary*
	2.2.1.2	Summary*
HACCP analysis	2.3.8.1	There are [number] CCPs in the company. The following different CCPs [listing of all CCPs] are implemented.

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

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

Part of the IFS Audit report	N° of IFS Food v8 require-ment	Compulsory information to be added
Staff facilities	3.4.1	Summary*
	3.4.5	Summary*
Customer focus and contract agreement	4.1.3 KO 4	Which of the following 6 types does the customer agreements relate to [tickbox]: • recipe • process • technological requirements • testing • packaging • labelling **Note:** In case no customer agreements have been defined, N/A evaluation is possible.
Specifications/ finished products	4.2.1.1	• The following finished product specifications (minimum 2) have been reviewed during the evaluation: [material / last date of update] • The finished product specification for retail brands which have been reviewed during the evaluation have been agreed with the customers: [yes/no]
Specifications/ raw materials	4.2.1.3 KO 5	• The following specifications (minimum 5) have been reviewed during the evaluation: [add material and last date of update] • The reviewed specifications were found to be up to date, unambiguous, in compliance with legal and with customer requirements, and were handled in accordance with the procedure to control the creation, approval and amendment of specifications.
Special claims	4.2.1.5	• There are specific requirements from clients, that products are "free of" certain substances/ingredients (e.g. allergens, pork, additives, etc): [yes/no] / [list] • There are specific requirements from clients, that certain treatment or manufacturing methods are excluded (e.g. GMO, irradiation): [yes/no] / [list] • The company works with products that consist of, contain or are produced from GMOs: [yes/no] / [list]
~~**Recipes/ Formulas**~~	~~KO N° 5: 4.2.2.1~~	• ~~Description of customer agreements which were checked during the IFS Assessment, specifying the topics of the customer agreement which were checked in detail.~~ ~~**Note:** In case no customer agreements have been agreed, N/A evaluation is possible.~~
Product development	4.3.2	Summary*
	4.3.3	Summary*

Part of the IFS Audit report	N° of IFS Food v8 require-ment	Compulsory information to be added
Purchasing	4.4.1	Summary*
	4.4.3	Summary*
	4.4.4	Summary*
Packaging materials	4.5.1	• List the kind of food contact packaging materials used for finished products. [list]
Factory location	4.6.1	Summary*
Plant layout and process flows	4.8.2	• Only to be filled in by animal slaughtering sites: [Write if there is an inspection plan in place at lairage and / or evisceration to ensure animals are fit for human consumption or not. Y/N] • If yes: description of the plan.
Constructional requirements	4.9.1.1	• General summary of the conditions of the infrastructure: general condition, control measures, monitoring, what is the risk for product contamination, etc. [Description]
Water supply	4.9.9.1	• Origin of the potable water/used water: • Own source: [yes/no] • Local water supplier: [yes/no] • Internal laboratory: [yes/no] • External laboratory: [yes/no] • Frequency of water analyses: [information] • Performed analyses: • Microbiological (parameters): [list] • Chemical (parameters): [list]
Compressed air and gases	4.9.10.1	Summary*
Cleaning and disinfection procedures	4.10.1	Summary*
	4.10.4	Summary*
	4.10.5	Summary*
~~**Third-party cleaning and disinfection service provider**~~	~~4.10.11~~	• ~~Name of areas cleaned and disinfected by a third-party, where applicable.~~
Waste management	4.11.1	Summary*

Part of the IFS Audit report	N° of IFS Food v8 require-ment	Compulsory information to be added

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

~~**Visual inspection**~~	~~4.12.10~~	• ~~Description of visual detection method, changing frequency for personnel and last training for personnel, where applicable.~~
Pest monitoring/ pest control	4.13.2	• External service provider: [yes/no] • Pest monitoring activities are carried out internally by own employees: [yes/no] • Frequency: [daily, weekly, monthly] • Inspections include: [target organisms] • Last inspection: [date] • The inspection reports show no particular pest activities inside facilities since the last IFS Audit. [or] • The inspection reports show pest activities inside facilities since the last IFS Audit with the following actions: [kind of action(s)]
Receipt and storage of goods	4.14.1	Summary*
	4.14.2	Summary*
	4.14.5	Summary*
Transport	4.15.1	Summary*
Maintenance and repair	4.16.1	Summary*
Equipment	4.17.1	Summary*

Part of the IFS Audit report	N° of IFS Food v8 require-ment	Compulsory information to be added

Traceability	4.18.1
	KO 7
		• During the evaluation the following traceability test was conducted as initiated by the auditor.
		• Origin of the product sample:
		  ◦ Retail outlet: [yes/no]
		  ◦ Selected on site by auditor: [yes/no]
		• Finished product: [article no./product/batch no./BBD/production date]
		• Based on the traceability sample, the traceability (backwards/ forwards) could be proven within the given time; incl. packaging and mass balance: [time]
		• The following ingredients and packaging material specifications have been checked within the framework of the traceability test:
		  ◦ [material / date or version of specification]
		• The result of the traceability exercise during the evaluation has been found to be compliant.

	4.18.2	Summary*
Allergens and cross contamination	4.19.2	• Allergens present at the site: [list] • Mitigation measures in place : [list]
Food fraud	4.20.2	• Which raw material groups/product groups were identified as risky in the vulnerability assessment? • Explain which criteria were selected in the vulnerability assessment. • Provide details of the vulnerability assessment (dates, responsibilities, points of discussion, etc.).
	4.20.4	Summary*
Food defence	**4.21.2**	Summary*
Internal audits	5.1.1 KO 8	Summary*
	~~5.1.2~~	• ~~Which activities has the company identified as critical to food safety and to product quality?~~
Site factory inspections	5.2.1	Summary*
Process and work environment validation and control	5.3.3	Summary*
	~~5.3.2~~	• ~~Description of the sample of use of rework checked during the IFS Assessment.~~

Part of the IFS Audit report	N° of IFS Food v8 require-ment	Compulsory information to be added
Measuring and monitoring devices	5.4.1	Summary*
	5.4.2	Summary*
Quantity checking	5.5.1	• Frequency and methodology of quantity checking: [description] • Company uses "℮" mark on packaging: [yes/no]
Product analyses/ Laboratory	5.6.1	• Internally: the following analyses are performed: [analytic parameter] • Externally: the following analyses are performed: [analytic parameter]
	5.6.2	• List of parameters of environmental monitoring programme: [list] • [Only for animal slaughtering sites to fill in:] There are defined post-slaughter time and temperature parameters in relation to the chilling or freezing of product. [time - temperature parameters]
Product testing and environmental monitoring	5.6.3	Summary*
Product release	5.7.1	Summary*
Complaints management	5.8.1	Summary*
	5.8.2	• Product complaints (within 12 months): • Total: [number] • From Consumers: [number] • From Retailers / Customers: [number] • From Authorities: [number incl. complaint reasons] • Main reasons for complaints from consumers / retailers: [list top 3] • Foreign body complaints (within 12 months): [number] [type of foreign body] • Most frequently complained foreign material: [list top 3]
Withdrawal/ recall	5.9.1 KO 9	• How many withdrawals have been performed since the last audit? • How many recalls have been performed since the last audit? • Description of the cause of withdrawals. • Description of the food safety issue in the case of recalls.
	5.9.2	Summary*
Management of non-conformities and non-conforming products	5.10.1	Summary*

Part of the IFS Audit report	N° of IFS Food v8 requirement	Compulsory information to be added
Management of deviations, non-conformities, corrections and corrective actions	5.11.1	Summary*
	5.11.3 KO 10	Summary*

~~**Food defence plan**~~	~~6.2~~	• ~~Description of the food defence plan:~~
		  ◦ ~~Version and date of the procedure and date of the plan.~~
		  ◦ ~~Date of the annual review and last test.~~

If applicable, additional information		
Note: additional information can also be given for requirements not listed as a compulsory field or any other auditor remark.		

Summary *:no free text but a summary that needs to be checked and validated by the auditor.

Glossary

Allergen (EU/UK)	Food causing an adverse reaction that is mediated by an immunological response. Defined allergens are: • Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof • Crustaceans and products thereof • Eggs and products thereof • Fish and products thereof • Peanuts and products thereof • Soybeans and products thereof • Milk and products thereof (including lactose) • Nuts i.e. Almond (Amygdalus communis L.), Hazelnut • (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illinoiesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia) and products thereof • Celery and products thereof • Lupin and products thereof • Molluscs and products thereof • Mustard and products thereof • Sesame seeds and products thereof • Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/liter expressed as SO_2. Regulation (EU) N° 1169/2011 of the European Parliament and of the Council.
Allergen (US)	There are 8 major allergens recognised in the United States according to the 2009 U.S. Food and Drug Administration (FDA) Model Food Code, Definitions section, page 12. (1) "Major food allergen"means: (a) Milk, egg, fish (such as bass, flounder, cod, and including crustacean shellfish such as crab, lobster, or shrimp), tree nuts (such as almonds, pecans, or walnuts), wheat, peanuts, and soybeans (b) A Food ingredient that contains protein derived from a food, as specified in subparagraph (1) (a) of this definition. (2) "Major food allergen" does not include: (a) Any highly refined oil derived from a food specified in subparagraph (a) of this definition and any ingredient derived from such highly refined oil; or (b) Any ingredient that is exempt under the petition or notification process specified in the Food Allergen Labelling and Consumer Protection Act of 2004 (Public Law 108–282).

~~**Assessment (IFS)**~~	~~Determination process which includes evaluation methods such as auditing and inspection, to determine to what extent a production site and its related processing activities comply with the specified requirements (laid down in Part 2).~~ ~~The IFS Assessment is conducted by following an assessment trail, including an on-site evaluation and a documentation and record review and inspection in which auditing and inspection techniques are applied alternately.~~
Audit time window (unannounced Audit)	Time period during which the unannounced Audit may be performed. The date of reference for this time window is the Audit due date (the date of first certification Audit) in an Audit cycle. Within the IFS Food 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 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 Assessment, auditing is limited to the examination of management processes which lead to a compliant process/product.~~ Process for obtaining relevant information about an object of conformity assessment and evaluating it objectively to determine the extent to which specified requirements are fulfilled. It includes any applicable evaluation activity, such as inspection, testing and management system audit.
Auditor in progress (AIP)	Candidate who is in the process of gaining auditing/assessing experience and has to pass the IFS Examinations to become an IFS Food Auditor. For further information, see chapter 3.4, Part 3 of the Standard.
Batch number	Designation that is printed on a label that allows the history of production to be traced.
Blackout period	Period of time that can be notified by the company to its certification body in which the unannounced Audit cannot take place. This includes a maximum of ten (10) operational days when the production site is not available for Audit (e.g. staff holidays, maintenance days, etc.) as well as non-operating periods. **Note:** The ten (10) operational days can be split into a maximum of three (3) periods. These, together with the non-operating periods, shall be notified to the certification body when registering for the unannounced Audit. The certification body will decide if the unannounced character of the Audit is fulfilled.
Calibration	Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material and the corresponding values realised by standards.

CCP (Critical Control Point)	A step at which a control measure or control measures, ~~can be applied and is~~ essential to control ~~prevent or eliminate~~ a ~~food safety a~~ significant hazard, is/are applied in a HACCP system ~~or reduce it to an acceptable level~~.
~~**Characteristics**~~	~~A designated feature or property of a product.~~
Claim	Any message or representation, including pictorial, graphic or symbolic representation, in any form (product label, packaging, advertisement, specifications, product inserts), which states, suggests or implies that the product has particular characteristic(s) or effect(s) that is/are not inherent to the product and/or is not generally present in similar products. The following list of examples of the particular characteristic(s) and/or effects does not 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 minimise the risk of health diseases, prevent the contamination by spoilage or pathogen microorganisms, etc.) • specific properties, benefits and/or effects for customers and/or consumers due to the usage of the product (e.g. anti-aging effect in cosmetics, extend shelf life of food in packaging, improving or modifying a physiological function or biological activity associated with health in food, etc.). Claims linked to the product can be declared only if: • Evidential support is available to demonstrate their truthfulness, honesty, fairness and legal compliance. • Are approved to be used by the relevant authority, when applicable. • Clear and understandable information is provided to the users (customer, con- sumer 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. Reference to product claims is accepted in the description of the scope when it describes the characteristic of the product. Examples of claims that may be part of the product characteristic: gluten free, vegan, origin. When a claim is mentioned in the audit scope, the following disclaimer shall be provided on the certificate, to avoid any confusion on what is covered by the IFS Food audit scope: "The designation or claim "*to be specified*" is an inherent characteristic of the products but its assessment is not covered in the scope of the IFS Food Certification". Additional information about the type of claims can be provided in the report.

Company	Any establishment in which any stage of production and distribution of food is carried out. The company can have one or several legal entities registered and/or approved by the relevant authority on behalf of the food business operator.
~~**Consumer unit**~~	~~Unit of the product intended to be sold to final users or consumers, which is available on the market, at the point of purchase.~~
Contamination	Introduction or occurrence of a contaminant in food or food environment. A contaminant can be any biological, chemical or ~~agent~~, physical agent, foreign material, or any other substances not intentionally added to food that may compromise food safety or suitability. Contamination can also mean correlation of packages among themselves.
Contractor	A company or person who is contracted by the company to carry out work for the site.
Control measure ~~(former CP)~~	~~Identified by the hazard analysis and risk assessment in order to control the likelihood of introducing or proliferation of a safety hazard in the product and/or the environment. However, the loss of control at this point may not lead to a health problem.~~ Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.
Correction	Action to eliminate a detected deviation and/or non-conformity. For the action plan of the IFS certification Audit, the correction shall be implemented, at latest, before the certificate is issued.
Corrective action	Action to eliminate the cause of a detected deviation and/or non- conformity. For the action plan of the IFS certification audit, the corrective action shall be implemented, at latest, before the recertification audit.
Customer	A customer is a business company or person to whom products are sold either as a finished product or as a semi-finished part of the finished product.
Customer agreement	A negotiated and usually legally enforceable understanding between a customer and the company.
Customer branded product	A product which is manufactured by the production site and sold under the brand name of its customer (e.g. private label).
Decentralised structure	Facility (for example a workshop or a warehouse) owned by the company where part(s) of the processes and operations of the production site take place.
Deviation	In the IFS Food Standard: Non-compliance with a requirement, without any impact on food safety related to products and processes. ~~In the IFS Standard~~, Deviations are requirements scored with a C, D and KO requirements scored with a ∈ B.
~~**End consumer**~~	~~The ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity.~~

Equipment	Machines, instruments, apparatus, utensils or appliances used or intended to be used in or in connection with food handling and includes equipment used or intended to be used to clean and disinfect food premises or equipment.
Factory Inspection (versus internal audit)	Factory inspection covers specific subjects and can be carried out by any appropriate person. That means regular visits to any areas, for any purposes, to check the conformity (hygiene, pest control, product control, fabrication, foreign material hazards, surrounding control, etc.).
Flow diagram	A systematic representation of the sequence of steps ~~or operations~~ used in the ~~processing~~ production or manufacture of ~~a particular~~ food ~~item~~.
~~**Food**~~	~~Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment, and live animals which are offered to the customer or consumer and intended for preparation and consumption by the consumer.~~
Food authenticity	The characteristic of a food in relation to its origin, and/or process of production and/or its inherent properties (e.g. organoleptic or chemical).
Food contact packaging materials	Materials that: • are intended to be brought into contact with food or • are already in contact with food and were intended for that purpose or • can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.
Food defence	Procedures implemented to ensure the protection of food and their supply chain from malicious and ideologically motivated threats.
Food fraud	The intentional substitution, mislabelling, adulteration or counterfeiting of food, raw materials or packaging materials placed upon the market for economic gain. This definition also applies to outsourced processes.
Food fraud mitigation plan	A process that defines the requirements on when, where and how to mitigate fraudulent activities, identified by a food fraud vulnerability assessment. The resulting plan will define the measures and checks that are required to be in place to effectively mitigate the identified risks. The ~~control~~ measures required to be put into place may vary according to the nature of: • the food fraud (substitution, mislabelling, adulteration or counterfeiting) • detection methodology • type of surveillance (inspection, audit, analytical, product certification) • source of the raw materials and packaging materials.

Food fraud vulnerability assessment	A systematic documented form of risk assessment to identify the risks of possible food fraud activity within the supply chain (including all raw materials, food, packaging materials and outsourced processes). The method of risk assessment may vary from company to company, however the systematic methodology for food fraud vulnerability assessment shall include, at a minimum: • The identification of potential food fraud activities, using known and reliable data sources. • The evaluation of the level of risk, both product and supply source. • The evaluation for the need for additional ~~control~~ measures. • The development and implementation of the food fraud mitigation plan, using the results of the vulnerability assessment. • An annual review, or more often if there is increased risk identified by change to defined risk criteria. The criteria used to evaluate the level of risk should be, for example ~~as follows~~: • History of food fraud incidents • Economic factors • Ease of fraudulent activity • Supply chain complexity • Currently implemented ~~control~~ measures • Supplier confidence.
~~**Food handling areas**~~	~~Areas where personnel handle food or handle surfaces likely to come into contact with food. These are areas where food is prepared, manufactured, produced, collected, extracted, processed, stored, transported and delivered.~~
Food safety culture	Shared values, beliefs and norms that affect mindset and behaviour toward food safety in, across and throughout an organisation. Elements of food safety culture are those elements of the food safety management which the senior management of a company may use to drive the food safety culture within the company. These shall include at a minimum: • Communication about food safety policies and responsibilities • Training • Employee feedback on food safety related issues • Performance measurement.
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.
Fully outsourced products	Products that are manufactured, packaged and labelled under the own brand or customer brand by a different company than the audited one.

Global Location Number of GS1 (GLN)	The GLN is required to clearly identify the IFS certified site in the electronic communications in the supply chain. It is mandatory for sites located: • within the European Economic Area (EEA), • ~~as well as for sites located~~ within the United Kingdom ~~if it leaves the EEA on 01.01.2021.~~ • within countries having signed bilateral agreements with the European Union and considered as integrated into the EEA, like Switzerland. GLNs are requested in the IFS Audit report, on the IFS Certificate and in the IFS Database for each certified site(s).
GMO	Genetically modified organism: an organism, with the exception of human beings, in which the genetic material has been modified otherwise than natural multiplication or natural recombination.
HACCP	Hazard analysis and critical control points: a system which identifies, evaluates and controls hazards which are significant for food safety.
HACCP plan	Documentation or set of documents, prepared in accordance with the principles of HACCP to ensure control of significant hazards in the food business.
Hazard	A biological, chemical or physical agent in, ~~or condition of,~~ food with the potential to cause an adverse health effect.
Hazard analysis	The process of collecting and evaluating information on hazards identified in raw materials and other ingredients, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not they ~~which~~ are significant hazards. ~~for food safety and therefore shall be addressed in the HACCP plan.~~
Head office assessment (for accreditation bodies)	Assessment of the conformity assessment body head office. **Note:** In IFS Standards, conformity assessment body is named certification body.
Incident	A situation within the supply chain where there are possible and/or confirmed risks associated with product safety, quality, legality and authenticity ~~integrity~~; or any force majeure event (e.g. critical resources/ services disruption, natural disasters, loss, emergency situations, crisis, etc.) with a direct impact on delivering trusted products.
Ingredient	Any substance, including food additives, used in the manufacturing or preparation of a food which remains in the finished product, even in the modified form.
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 food safety and quality objectives.

Integrity Program	Program implemented by IFS in order to: • Monitor, as preventive actions, performance of auditors and certification bodies as well as audited companies, • Manage, as corrective actions, any complaints addressed to IFS.
Internal audit	General process of audit, for all activities in a company. Conducted by or on behalf of the company for internal purposes. An internal audit is an independent and objective assurance and consulting activity that is designed to add value and improve the operations of an organisation. It helps an organisation accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.
Key roles	Personnel who have significant responsibilities and accountability for the development and maintenance of product safety, quality, legality and authenticity ~~integrity~~.
Legal entity	A legal entity is the registered office of the food business where, according to agreement, the food business operator has its administrative centre. It generally identifies the place where the administrative organisation of the company is located.
Location	One physical address where the production site(s) is/are situated.
Lot number	Combination of numerical digits that are given to a group of products manufactured in the same batch/production unit.
Mass balance	Test performed to measure the quantity of inputs of ingredients and outputs of finished products during a traceability exercise.
Monitoring	Determining the status of a system, a process, a product, a service or an activity. For control measures defined for a CCP and other control measures: the act of conducting a planned sequence of observations or measurements of control parameters to assess whether control measures defined for a CCP and other control measures are under control. ~~See also Codex Alimentarius.~~
Non-conformity	In the IFS standard, defined non-conformities are Majors and D evaluations of a KO requirement. Non-fulfilment of a specified requirement. Non-conformity can be given in case of: • non-respect of legislation, • food safety issues, • internal dysfunctions, and • customer issues. ~~In the IFS Standard, defined non-conformities are Majors and D evaluations of a KO requirement.~~
Non-operating periods	Periods when the production lines are not operating at all, e.g. planned maintenance work, bank holiday, planned company shutdown for holidays, etc.

On-site evaluation	Inspection and audit of the production area of the physical site, which includes 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.
~~**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 (active food contact materials)~~ • ~~Monitor the condition of the packaged product or the environment surrounding the product (intelligent food contact materials)~~ • ~~Handling, delivery and presentation of products.~~
Partly outsourced process	Production step(s) or part(s) of production process carried out off-site by a third-party on behalf of the IFS certified production site. In the IFS Standard, primary packing and labelling are also considered as production steps: if carried out outsourced, these shall be considered as partly outsourced processes.
Pasteurisation	Heat treatment designed to reduce the number of pathogenic and spoilage microorganisms which is consistent with minimal chemical, physical and organoleptic changes in the product (e.g. UHT process, high pressure pasteurisation). It is used in combination with other factors to make food safe over a designated shelf life (pH, Aw, chilled storage).
~~**PDO**~~	~~Protected designation of origin defined under regulation (EU) N° 1151/2012.~~
~~**PGI**~~	~~Protected geographical indication defined under regulation (EU) N° 1151/2012.~~
Potable water	Water fit for human or animal consumption (e.g. drinking, cooking and food preparation) that in principle must be free from microorganisms and other contaminants that may endanger public health.

~~**Primary packaging material**~~	~~The primary packaging material fulfils one or more of the following conditions:~~ • ~~it is in contact and/or intended to be in contact with food~~ • ~~it can transfer their constituents to the food, and, if removed, the quality, safety and legality of its content is affected~~ • ~~it is part of the consumer unit.~~
~~**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).~~
Product	Result of a process or activities for transforming inputs into outputs. It comprises packaging.
Product development	The creation of products with new or different characteristics that offer new or additional benefits to the customer. Product development may involve modification of an existing product or its presentation, or formulation of an entirely new product that satisfies a newly defined customer who wants a market niche. In the IFS Standard, the requirements for chapter product development apply even if there is just a product modification, use of new packaging materials or modifications of production processes.
~~**Product integrity**~~	~~The product safety, quality and other properties or criteria that are defined by the company or customer.~~
Product recall	When unsafe product is removed from the supply chain but has reached consumers, and consumers are advised to take appropriate actions. ~~Any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor.~~
~~**Product requirements**~~	~~Product requirements include: product safety, product quality, product legality, process and specification.~~
Product withdrawal	When out of specification product with no impact on product safety is removed from the supply chain before it has reached consumers. ~~Any measure aimed at preventing the distribution, display and offer of an out-of-specification product and/or of a product that may be dangerous to the consumer.~~
Production area	Part of the production site which includes: • Production processes, • Receipt, storage and dispatch areas, • Good Manufacturing Practices (GMP), including maintenance, hygiene, pest control and cleaning and disinfection activities, • Product development, • On-site laboratory, • Maintenance facilities, • Staff and sanitary facilities, • External areas.

Production site	An establishment in a specific physical location where the IFS Food Audit is conducted in which any stage of production and distribution of food 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 food from contamination.
Raw materials	A base material used for the manufacture of a product (ingredients, additives, packaging materials, rework).
Resources	A stock or supply of money, materials, staff, and other assets that can be drawn on by the company in order to function effectively and continuously achieve objectives.
Reviewer	An IFS Reviewer is either an IFS Food Auditor or an IFS Pure Reviewer. Person of the certification body in charge of assessing the IFS Audit reports before a certification decision is made. The tasks of the IFS Reviewer are, at a minimum: • To check the overall consistency of the IFS Audit reports. • To check if the IFS Audit reports are properly completed (e.g. compulsory fields, etc.). • To check if the findings are well described and matching the evaluation. ~~if the justifications are relevant.~~ • To check if the corrections and corrective actions as well as the deadlines for implementation proposed by the audited company have been validated by the auditor (or by a representative of the certification body) and are relevant. The review shall be documented.
Rework	The process of re-utilisation of food, ingredients, raw materials or packaging materials.
Risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to (a) hazard(s) in food.
~~**Risk assessment**~~	~~The documented information of the process of risk identification, risk analysis and risk evaluation to determine control measures.~~
Root cause analysis	Process or procedure that helps to understand the initiating causes of a problem, in order to identify the proper corrective action ~~The goal of this process or procedure is to determine the missing or inadequately applied controls~~ that will prevent a recurrence.
Safety Data Sheets (SDS)	Safety data sheets (SDS) are safety instructions for handling dangerous substances, they are principally intended for use by professional users and must enable them to take the necessary measures in regards to the protection of health, safety and the environment at the place of work. The safety data sheet may be supplied on paper or electronically, provided that the addressee has the necessary means of receiving it.
Seasonal products	Products which are processed at a specific time in the year, or processes which are used at a specific time in the year, for getting new/different products than those processed all year long.

~~**Securely**~~	~~To retain in a safe location, which is not open to unauthorised personnel or persons.~~
Senior management	Executive management.
Service provider	Organisation that provides ~~a network, storage or processing~~ services to another company, for example, transport, storage, order picking, ~~or other outsourced services~~ (e.g. pest control, cleaning and disinfection, etc.
~~**Shifts**~~	~~Scheduled working time after which employees change or rotate.~~
Sign-off audit	First witness audit of an auditor after having passed the IFS Examinations for the purpose of confirmation of competencies for final approval as an IFS Food Auditor. The sign-off audit shall be performed during a full IFS Food Certification Audit.
Staff facilities	Areas within a site, other than food handling areas, that are used by personnel, e.g. cloakrooms, toilets, canteens and rest rooms.
Sterilisation	Heat treatment applied to a product in final packaging, designed to destroy pathogens and produce commercially sterile products with an extended (long) shelf life under ambient temperature (e.g. autoclave for products canned). The main concern is inactivation of the most heat resistant pathogenic spore, namely C. botulinum.
Suspension (of IFS Food Certificate)	When the intention is to reinstate the exact same certificate (with same issue number, same validity, etc.). Examples: pending payment of audit fee, pending investigation following a food safety incident, when a Major non-conformity is issued during an extension audit or during the audit of the head office.
System	Set of interrelated or interacting elements. A system is a planned, sustainable structured course of action. Depending on the complexity, documentation is recommended. A system includes: documentation, procedure description, control/monitoring, corrective action, site plan.
Traceability	Ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production and distribution.
Traded products	Products manufactured, packaged and labelled by and under a different company name to the company being IFS Food certified and which are not customer branded products.
Validation	~~Obtaining evidence that a control measure or combination of control measures is capable of controlling the hazard to a specified outcome.~~ Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Validation of control measures defined for CCPs and other control measures is obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome. Note: For pre-existing HACCP plans, continuously conducted and documented verification procedures may act as validation.

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.~~ Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled. The verification of control measures defined for CCPs and other control measures is the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.
Withdrawal (of IFS Food Certificate)	When it is neither intended nor possible to reinstate the exact same certificate (with same issue number, same validity, etc.). Examples: cancellation of certification contract with immediate effect, when KO and/ or Major non-conformity(ies) is/ are issued, false statement on the certificate which may jeopardise the IFS certification status. **Note:** after a new initial audit or a successful follow-up audit, it is expected that a new certificate is issued, with new issue number and new validity.
Witness assessment (by accreditation bodies)	Assessment of the conformity assessment body when it is carrying out conformity assessment services within its scope of accreditation. **Note:** In IFS Standard, conformity assessment body is named certification body.
Witness audit to be performed every two (2) years, for approved IFS Food Auditors (monitoring witness audit)	Every IFS Food Auditor shall be assessed during a full IFS Food on-site witness audit every two (2) years by the certification body, in order to evaluate her/his competencies. This audit can be performed at any time during the second calendar year after the year in which last witness audit has taken place. The witness auditor: • shall not be part of the audit (as a team member). • shall be an experienced IFS Auditor (see requirements under 3.2, Part 3). It is not mandatory that the auditor is qualified for all product and technology scope(s) of the audit. The certification body shall specify the name of the witness auditor in the participants' list of the IFS Audit report and shall be able to provide, on request, a witness audit report of this witness audit. Every second time (every four (4) years) it can be replaced by a full on-site witness audit during another GFSI recognised food safety post-farm processing certification standard audit accredited against ISO/IEC 17065:2012 norm. **Note 1:** In case of an audit team in which the team can split during the audit (as both auditors have company's product and technology scopes), it is not possible to perform a witness audit by a witness auditor, as the auditor who is witnessed doesn't perform a full IFS Audit. But if the team does not split, it is possible to perform a witness audit by an observer for the lead auditor, as it will be possible to witness the auditor during a full IFS Audit. **Note 2:** Accreditation witness assessments performed by accreditation bodies are accepted as a replacement of a witness audit performed by an observer from the certification body. **Note 3:** Witness audits performed by IFS Integrity Program during a full IFS Food Audit can also be accepted.

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Avis de l'Anses
Saisine n° 2016-SA-0076
Saisine liée n° 2011-SA-0117

Le directeur général

Maisons-Alfort, le 11 avril 2022

AVIS
de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail

relatif à la mise à jour des fiches de description de danger biologique transmissible par les aliments

L'Anses met en œuvre une expertise scientifique indépendante et pluraliste.
L'Anses contribue principalement à assurer la sécurité sanitaire dans les domaines de l'environnement, du travail et de l'alimentation et à évaluer les risques sanitaires qu'ils peuvent comporter.
Elle contribue également à assurer d'une part la protection de la santé et du bien-être des animaux et de la santé des végétaux et d'autre part à l'évaluation des propriétés nutritionnelles des aliments.
Elle fournit aux autorités compétentes toutes les informations sur ces risques ainsi que l'expertise et l'appui scientifique technique nécessaires à l'élaboration des dispositions législatives et réglementaires et à la mise en œuvre des mesures de gestion du risque (article L.1313-1 du code de la santé publique).
Ses avis sont publiés sur son site internet.

L'Anses s'est autosaisie le 30 mars 2016 pour effectuer la mise à jour de la fiche de description de danger biologique transmissible par les aliments relative à *Staphylococcus aureus* et aux entérotoxines staphylococciques (saisine n°2016-SA-0076).

1. CONTEXTE ET OBJET DE LA SAISINE

Afin d'aider les professionnels de la filière agroalimentaire à maîtriser la sécurité sanitaire et à rédiger des guides de bonnes pratiques d'hygiène, l'Anses met à leur disposition des fiches de description des dangers biologiques transmissibles par les aliments.

Ces travaux concernent la mise à jour d'une de ces fiches.

2. ORGANISATION DE L'EXPERTISE

L'expertise a été réalisée dans le respect de la norme NF X 50-110 « Qualité en expertise – Prescriptions générales de compétence pour une expertise (Mai 2003) ».

L'expertise relève du domaine de compétences du Comité d'experts spécialisé « Évaluation des risques biologiques dans les aliments » (CES BIORISK). Sur la base d'une fiche de danger initiale rédigée par des rapporteurs, les travaux concernant la mise à jour de la fiche relative à *Staphylococcus aureus* et aux entérotoxines staphylococciques (saisine n°2016-SA-0076) ont été validés en séance le 13 septembre 2016. Cette fiche a ensuite été relue par deux experts en juillet 2020 concernant l'aspect zoonotique, puis a été mise à jour en mars 2022 concernant les sérotypes décrits et les données épidémiologiques.

L'Anses analyse les liens d'intérêts déclarés par les experts avant leur nomination et tout au long des travaux, afin d'éviter les risques de conflits d'intérêts au regard des points traités dans le cadre de l'expertise. Les déclarations d'intérêts des experts sont rendues publiques via le site internet https://dpi.sante.gouv.fr/.

3. ANALYSE ET CONCLUSIONS DU CES BIORISK

Suite à l'expertise collective, la fiche de danger biologique transmissible par les aliments relative à *Staphylococcus aureus* et aux entérotoxines staphylococciques (saisine n°2016-SA-0076) a été mise à jour et est jointe en annexe.

4. CONCLUSIONS ET RECOMMANDATIONS DE L'AGENCE

L'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail endosse la fiche de danger biologique transmissible par les aliments mise à jour par le CES BIORISK. L'Anses rappelle par ailleurs que d'autres contextes d'expositions à la bactérie *Staphylococcus aureus* peuvent conduire – avec des mécanismes biologiques différents - à des risques sanitaires significatifs, comme elle avait eu l'occasion de le pointer dans son avis 2016-SA-0108 relatif à la sécurité des protections intimes.

Dr Roger Genet

MOTS-CLÉS

Danger biologique ; aliments ; *Staphylococcus aureus,* entérotoxines staphylococciques

Biological hazards ; food ; *Staphylococcus aureus,* Staphylococcal enterotoxins

CITATION SUGGÉRÉE

Anses. (2022). Avis relatif à la mise à jour de la fiche de description de danger biologique transmissible par les aliments relative à *Staphylococcus aureus* et aux entérotoxines staphylococciques (saisine 2016-SA-0076). Maisons-Alfort : Anses, 7 p.

ANNEXE 1

Fiche de description de danger biologique transmissible par les aliments : *Staphylococcus aureus* et entérotoxines staphylococciques

Saisine n°2016-SA-0076, mise à jour : mars 2022

Saisine n°2016-SA-0076
Mise à jour : Mars 2022

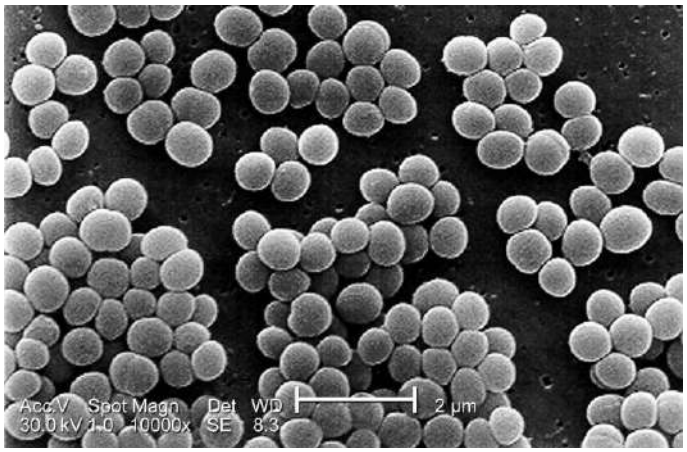
Staphylococcus aureus et entérotoxines staphylococciques

Famille des *Staphylococcaceae*

Genre *Staphylococcus*

Bactérie

Agent zoonotique [1]



Staphylococcus aureus **(microscopie électronique à balayage) © CDC/ Matthew J. Arduino, DRPH**

Caractéristiques et sources de *Staphylococcus aureus* et des entérotoxines staphylococciques

Principales caractéristiques microbiologiques

La maladie humaine d'origine alimentaire est une intoxination due à l'ingestion d'entérotoxines staphylococciques (SE[2]), protéines thermorésistantes préformées dans l'aliment, dans lequel *S. aureus* ou tout autre staphylocoque producteur de SE a pu se développer et produire sa (ou ses) toxine(s).

S. aureus est un coque à coloration de Gram positive. Il mesure de 0,5 à 1 µm de diamètre, ne sporule pas, est immobile, aéro-anaérobie facultatif et possède une catalase et une coagulase. *S. aureus*, espèce type du genre *Staphylococcus*, parfois appelée staphylocoque doré, produit de nombreuses toxines dont les SE, produites par certaines souches (celles portant les gènes de ces toxines) et qui sont responsables de toxi-infections alimentaires. À ce jour, 27 sérotypes (SEA à SEE, SEG à SElZ, SEl26, SEl27) ont été décrits. Pour six d'entre eux seulement, l'implication dans des cas d'intoxinations a pu être clairement démontrée : SEA (sérotype le plus fréquemment détecté lors d'intoxinations) à SEE et SEH. Cependant le caractère émétique des toxines de type SEG, SEI, SER, SES et SET ayant été démontré chez l'animal, il conviendrait de les prendre en compte lors de la caractérisation d'épisodes toxiques.

D'autres espèces de staphylocoques producteurs de coagulase peuvent également produire des SE, notamment *S. pseudintermedius*, mais leur part dans les intoxinations demeure à ce jour très peu documentée. Par ailleurs, dans les aliments, les staphylocoques producteurs de coagulase sont essentiellement représentés par l'espèce *S. aureus*. Pour la majorité des souches, la production de SE est généralement associée à une densité de population de l'ordre de 10^5 bactéries par gramme.

Tableau 1 : Caractéristiques de survie, de croissance et de toxinogenèse de *S. aureus* (en conditions de laboratoire)

Croissance*			
	Min.	**Opt.**	**Max.**
Température (°C)	6	35 - 41	48
pH	4	6 -7	10
a_w	0,83	0,99	0,99
NaCl (%)	/	/	20
Atmosphère	Aéro-anaérobie	Aérobie	Aéro-anaérobie
Production de toxines (SE)*			
	Min.	**Opt.**	**Max.**
Température (°C)	10	34 - 40	45
pH	5	7 - 8	9,6
a_w	0,86	0,99	0,99
NaCl (%)	/	/	10
Atmosphère	Aéro-anaérobie	Aérobie	Aéro-anaérobie
* Les valeurs extrêmes indiquées dans le tableau ne sont observées que pour certaines souches			

Sources du danger

Si les SE sont présentes en quantité suffisante dans l'aliment, elles peuvent déclencher les symptômes de l'intoxination (**tableau 2**). Les staphylocoques sont des bactéries ubiquitaires présentes sur la peau, les muqueuses et la sphère rhinopharyngée chez les animaux à sang chaud (mammifères, oiseaux) et en particulier chez l'Homme (portage intestinal : 20 à 30 %; portage nasal : 20 – 55 %, portage manuel 10 %). Les staphylocoques producteurs de coagulase sont responsables de mammites cliniques et sub-cliniques chez les vaches et chez les autres ruminants.

Ces bactéries sont également isolées de l'environnement naturel (sol, eau douce et eau de mer, poussière, air), de l'environnement domestique de l'Homme (cuisine, réfrigérateur), de l'environnement hospitalier, des ateliers de préparation alimentaire (formation de biofilms) ainsi qu'à partir de denrées alimentaires. La peau et les muqueuses de l'Homme et des animaux constituant l'habitat de *S. aureus*, la présence de ce micro-organisme dans l'environnement est vraisemblablement due à une contamination par l'Homme ou les animaux.

Voies de transmission

Exceptés les cas contractés en laboratoire, tous les cas d'intoxination à SE décrits à ce jour sont d'origine alimentaire. La contamination de l'aliment est le plus souvent d'origine humaine. Cette contamination de l'aliment par l'Homme peut avoir lieu par contact direct ou indirect (squames contaminés, plaies, gouttelettes issues des voies respiratoires contenant le micro-organisme).

La contamination des aliments peut aussi être d'origine animale, la plus fréquente étant la contamination du lait en cas

[1] Agent responsable de maladie ou d'infection qui peut se transmettre de l'animal à l'Homme ou de l'Homme à l'animal.

[2] SE : sigle en langue anglaise (*staphylococcal enterotoxin*) retenu pour ce document, compte tenu de son emploi généralisé dans la littérature, toutes langues confondues.

de mammites.

S. aureus peut causer une gamme très large d'infections d'origine non alimentaire (du panaris à la septicémie), parfois mortelles.

Des souches *de Staphylococcus aureus* résistant à la méthicilline (SARM), une des causes majeures d'infections nosocomiales en Europe, ont été isolées chez des animaux de compagnie, des animaux de production (porcins, bovins, volailles) et dans les denrées alimentaires d'origine animale. Néanmoins, le rôle de l'alimentation dans la transmission du SARM à l'Homme n'est pas clairement établi.

Recommandations pour la production primaire

Les mesures de prévention en production primaire doivent intégrer la surveillance de l'état sanitaire des animaux (notamment les mammites), les bonnes pratiques de manipulation, le nettoyage et la désinfection du matériel et des locaux, ainsi qu'une hygiène rigoureuse des mains et une protection des plaies.

Maladie humaine d'origine alimentaire

Nature de la maladie (tableau 2)

La durée d'incubation et la sévérité des symptômes dépendent de la quantité d'entérotoxines ingérées et de la sensibilité de chaque individu.

Population sensible[3] : pas de population particulièrement sensible.

Relations dose-effet[4] et dose-réponse[5]

La dose minimale d'entérotoxine à ingérer pour provoquer les premiers symptômes reste encore mal définie. Une étude récente montre que la dose produisant un effet chez 10 % des personnes exposées (« benchmark dose $BMDL_{10}$ »)[6] est de 6 ng par personne pour l'entérotoxine SEA.

Épidémiologie

La surveillance des intoxinations staphylococciques est assurée par la déclaration obligatoire (DO) des toxi-infections alimentaires collectives (TIAC) (**tableau 3**). Il faut souligner que de nombreux foyers, notamment les foyers familiaux, sont certainement non déclarés ou non diagnostiqués. En tenant compte des facteurs de sous-déclaration et de sous-diagnostic, le nombre annuel de cas d'intoxinations staphylococciques a été estimée par Santé publique France à 73 021 cas (Intervalle de crédibilité (Icr) 90 % 21 058 – 271 056) dont 486 cas hospitalisés (Icr90 % 141 – 1827) pour la période 2008-2013.

En Europe en 2019, *S. aureus* était responsable de 7,5 % des foyers de TIAC déclarés : 77 foyers, 1468 malades, 144 hospitalisations, aucun décès. L'incidence estimée peut varier de façon importante selon le système de surveillance mis en place dans chaque État membre. De nombreux auteurs considèrent que les intoxinations à staphylocoques constituent une des causes majeures de maladies d'origine alimentaire dans le monde.

Rôle des aliments

Principaux aliments à considérer

S. aureus peut être isolé d'aliments très variés. Quatre conditions sont requises pour que survienne la contamination d'un aliment par *S. aureus* et ses entérotoxines :

- une source de staphylocoques producteurs d'entérotoxines (matière première, porteur sain ou malade, etc.) ;
- un moyen de transmission à l'aliment (outil de découpe souillé, mauvaises pratiques d'un porteur sain ou d'un malade, etc.) ;
- un aliment présentant des caractéristiques physicochimiques favorables à la croissance de *S. aureus* et à la toxinogenèse ;
- une température favorable pendant le temps nécessaire à une multiplication bactérienne importante et à la toxinogenèse (**tableau 1**).

Les aliments les plus souvent associés aux toxi-infections alimentaires sont :

- les aliments recontaminés après un traitement thermique ou tout autre procédé éliminant la microflore banale. Plus l'aliment est manipulé, plus le risque est élevé. Ces aliments sont, par exemple, les produits carnés cuits et tranchés, les salades composées y compris les salades de riz ou de légumes, les gâteaux à la crème et les plats cuisinés manipulés après cuisson ;
- les aliments fermentés à acidification lente permettant la croissance de *S. aureus* durant la fermentation, par exemple,

Tableau 2 : Caractéristiques de la maladie humaine d'origine alimentaire

Durée moyenne d'incubation	Principaux symptômes	Durée des symptômes	Durée de la période contagieuse	Complications
30 min - 8 h (3 h en moyenne)	- Caractéristiques: nausées suivies de vomissements incoercibles en fusées Autres symptômes décrits : - Douleurs abdominales - Diarrhées - Vertiges - Frissons - Faiblesse générale parfois accompagnée d'une fièvre modérée Lors des cas les plus sévères, des maux de tête, une prostration et une hypotension ont été rapportés.	18 - 24 h Les diarrhées et la faiblesse générale peuvent durer 24 h de plus.	Aucune contagiosité. Entérotoxines non transmissibles de personne à personne.	La mortalité reste exceptionnelle (taux de mortalité : 0,02 %), atteignant les individus les plus vulnérables à la déshydratation (nourrissons et personnes âgées) et les personnes atteintes d'une pathologie sous-jacente. Taux d'hospitalisation estimé : 16 % des cas confirmés.

[3] Les personnes ayant une probabilité plus forte que la moyenne de développer, après exposition au danger par voie alimentaire [dans le cas des fiches de l'Anses], des symptômes de la maladie, ou des formes graves de la maladie.

[4] Relation entre la dose (la quantité de cellules microbiennes ou de toxines ingérées au cours d'un repas) et l'effet chez un individu.

[5] Pour un effet donné, relation entre la dose et la réponse, c'est-à-dire la probabilité de la manifestation de cet effet, dans la population.

[6] La BMDL correspond à la borne inférieure de l'intervalle de confiance à 95 % de la Benchmark dose (BMD) : dose correspondant à un niveau spécifié de réponse obtenue par modélisation de la relation dose-réponse à partir de données expérimentales ou épidémiologiques.

Tableau 3 : Données épidémiologiques françaises relatives aux toxi-infections alimentaires collectives causées par les entérotoxines staphylococciques – Mise à jour Mars 2022 (Source : Santé publique France)

Année	2012	2013	2014	2015	2016	2017	2018	2019	2020
TIAC confirmées[1] à *S. aureus*									
Foyers (%[2])	5 (2,3 %)	15 (8 %)	14(6 %)	22 (7 %)	25 (7 %)	19 (6 %)	26 (7 %)	17 (4 %)	13 (5 %)
Malades (%)	67 (2,8 %)	140 (6 %)	172 (6 %)	243 (8 %)	197 (4 %)	213 (4 %)	391 (9 %)	107 (2 %)	265 (13 %)
Hospitalisations	5 (2,6 %)	10 (6 %)	14 (5 %)	19 (7 %)	15 (6 %)	8 (3 %)	17 (5 %)	8 (3 %)	8 (4 %)
TIAC suspectées à *S. aureus*									
Foyers (%)	295 (36,7 %)	321 (36 %)	345 (36 %)	382 (42 %)	328 (35 %)	308 (40 %)	328 (34 %)	428 (39 %)	221 (40 %)
Malades (%)	1867 (28,5 %)[3]	2080 (30 %)	2164 (29 %)	2431 (35 %)	1579 (23 %)	1847 (31 %)	1603 (22 %)	2369 (27 %)	1954 (30 %)[3]
Hospitalisations	176 (39,4 %)	147 (37 %)	138 (40 %)	118 (41 %)	90 (28 %)	88 (30 %)	92 (25 %)	89 (39 %)	53 (38 %)

[1] Foyers dans lesquels l'agent est isolé dans un échantillon d'origine humaine et / ou dans les aliments consommés par les malades

[2] % par rapport au total des cas ou foyers avec des agents déterminés

[3] Deux décès ont été recensés, un en 2012 et un en 2020.

certains fromages ou certaines salaisons fermentées, telles que des salamis ;
- les produits séchés ou à teneur en eau réduite, dans lesquels la croissance de *S. aureus* a pu être favorisée à une des étapes de fabrication ou de stockage par une température favorable avant réduction de l'a_w. Ces aliments sont, par exemple, le lait en poudre, les pâtes, les poissons séchés.

Les staphylocoques producteurs d'entérotoxines représentent la première cause de TIAC impliquant le lait et les produits laitiers.

Traitements d'inactivation en milieu industriel (tableau 4)

Contrairement à la bactérie, les SE sont stables dans les conditions de traitements thermiques généralement appliqués aux aliments. Si la stérilisation (du lait par exemple, type traitement UHT) peut causer une dénaturation partielle des SE, elle laisse néanmoins subsister un risque d'intoxination. De plus, les SE résistent à la plupart des autres traitements appliqués en industries agroalimentaires. Il faut donc considérer qu'une fois formées dans la matière première ou l'aliment, les entérotoxines ne peuvent pas être suffisamment inactivées pour supprimer le risque d'intoxination.

Surveillance dans les aliments

Le règlement (CE) n°2073/2005 modifié, relatif aux critères microbiologiques applicables aux denrées alimentaires, fixe :

- un critère d'hygiène des procédés relatif aux staphylocoques producteurs de coagulase (SCP)[9] dans les laits et produits laitiers, et dans les coquillages et crustacés décoquillés et décortiqués cuits ;
- un critère de sécurité relatif aux entérotoxines staphylococciques dans le lait et les produits laitiers (n=5, m= pas de détection dans 25g), en cas de non-respect du critère d'hygiène si des SCP sont dénombrés à une concentration supérieure à 10^5 ufc/g.

Le dénombrement des SCP se fait selon la norme NF EN ISO 6888[10] - parties 1, 2 et 3. Les deux premières parties sont des techniques classiques de comptage des colonies sur milieu sélectif gélosé après inoculation directe de dilutions décimales de l'aliment et incubation à 37 °C. La troisième partie décrit une méthode de recherche et de dénombrement par la technique du nombre le plus probable après une étape d'enrichissement. La détection des entérotoxines staphylococciques de types SEA à SEE se fait selon la norme EN ISO 19020, utilisant des outils de type immunochimique qualitatif.

Tableau 4 : Impact des traitements en milieu industriel

Traitement	Conditions	Impact	Matrice
Température	La destruction de *S. aureus* peut être assurée par la pasteurisation. Valeurs de D[6] (variation selon l'aliment et la souche de *S. aureus* testée) : $D_{60\,°C}$ = 0,8 – 10 min $D_{72\,°C}$= 0,1 – 1 s		Aliments ayant une a_w de 0,99 et un pH compris entre 6,5 et 7
Désinfectants	Sensible à tous les désinfectants autorisés en IAA, sous réserve du suivi des modalités d'utilisation recommandées.		
Hautes pressions	600 MPa pendant 15 min à 20 °C	3 réductions décimales	Viande de volaille
	600 MPa pendant 6 min à 31 °C	2,67 réductions décimales	Viande de bœuf marinée (a_w = 0,985)
		1,12 réduction décimale	Jambon cuit (a_w = 0,978)
		0,55 réduction décimale	Jambon sec (a_w = 0,89)
Rayonnements ionisants	*S. aureus* : D_{10}[7] = 0,45 kGy Entérotoxines : D_{10}= 27 à 95 kGy		

Données issues de la littérature scientifique, il convient de s'assurer de l'autorisation et des conditions d'utilisation de certains des traitements mentionnés dans ce tableau.

[7] D est le temps nécessaire pour diviser par 10 la population du danger microbiologique initialement présente.

[8] D_{10} est la dose (en kGy) nécessaire pour réduire une population à 10 % de son effectif initial.

[9] Dans les aliments, les staphylocoques producteurs de coagulase sont essentiellement représentés par l'espèce *S. aureus*.

[10] Microbiologie de la chaîne alimentaire – Méthode horizontale pour le dénombrement des staphylocoques à coagulase positive (*Staphylococcus aureus* et autres espèces).

Recommandations aux opérateurs

- Le nettoyage et la désinfection du matériel et des locaux doivent être particulièrement rigoureux compte tenu de la forte adhésion des staphylocoques aux surfaces.
- Pour tenir compte du fait que de très nombreux opérateurs sont des porteurs sains, le lavage rigoureux des mains et le port d'une coiffe et d'un masque bucco-nasal sont des bonnes pratiques d'hygiène (BPH) essentielles à respecter en fonction des conclusions de l'analyse des dangers.
- Les manipulateurs de denrées alimentaires présentant des lésions cutanées doivent être écartés de la manipulation des denrées non conditionnées et/ou emballées, tant que les lésions ne sont pas correctement couvertes (port de gants adaptés). Eu égard à la forte proportion de porteurs sains, et au fait que le portage n'est pas constant chez la plupart des individus, le dépistage de *S. aureus* lors des visites médicales n'est pas utile. La prévention des contaminations consiste en l'application rigoureuse des BPH rappelées ci-dessus.
- Il est nécessaire de détruire les staphylocoques par un traitement adapté, thermique ou autre, avant qu'ils ne se soient multipliés, ou bien d'empêcher leur multiplication en maintenant les aliments en-dessous de 6 °C. Le respect de la chaîne du froid est donc capital en ce qui concerne les staphylocoques.
- Tout processus technologique alimentaire appliqué dans une zone de température dangereuse (de +10 °C à + 45 °C) doit être de courte durée ou doit s'appuyer sur d'autres paramètres que la température pour stopper la croissance de la bactérie, tel qu'un pH inférieur à 5.
- Les staphylocoques étant thermosensibles alors que leurs entérotoxines sont thermostables, l'assainissement d'un produit fortement contaminé par *S. aureus* n'est pas garanti par un traitement thermique. Ce dernier détruira les bactéries mais pas leurs entérotoxines si elles sont présentes. Une fois formées dans l'aliment, les entérotoxines ne peuvent être efficacement éliminées.

Hygiène domestique

Recommandations aux consommateurs

- Il est recommandé de respecter les bonnes pratiques d'hygiène lors de la manipulation et de la préparation des aliments (lavage des mains, nettoyage du matériel, etc.).
- Avant la préparation des repas, désinfecter et protéger les plaies ou les boutons purulents avec un pansement étanche ou utiliser des gants.
- Il est essentiel de respecter la chaîne du froid. Les aliments cuisinés doivent être refroidis et placés au réfrigérateur dans un délai de deux heures s'ils ne sont pas consommés immédiatement.

Liens

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Liens utiles

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