IFS HPC

IFS HPC

Standard for auditing products/processes of suppliers manufacturing household and personal care products

VERSION 2

APRIL 2016

ENGLISH

Contact details of the IFS offices

BRASIL | AQUIDAUANA
IFS Office Brasil
Rua Antônio João 800
79200-000 Aquidauana/MS Brazil
Phone: +55 (0)67 81 51 45 60
Email: cnowak@ifs-certification.com

CANADA | TORONTO
PAC – Packaging Consortium
1 Concorde Gate, Suites 607
Toronto ON, M3C 3N6, Canada
Phone: +14 16 4 90 78 60
Email: pacinfo@pac.ca

CHILE | SANTIAGO CHILE
IFS Office Chile
Av. Apoquindo 4700, Piso 11,
Las Condes, Santiago, Chile
Phone: + 56 27 77 61 53
Email: ifs-chile@ifs-certification.com

CHINA | SHANGHAI
Man Po International Business Center Rm 204,
No. 660, Xinhua Road, Changning District,
Shanghai 200052, China
Phone: +86 1 80 19 98 94 51
Email: china@ifs-certification.com
Email: asia@ifs-certification.com

FRANCE | PARIS
IFS Office Paris
14 rue de Bassano
F-75016 Paris
Phone: +33 (0)1 40 76 17 23
Email: ifs-paris@ifs-certification.com

GERMANY | BERLIN
IFS Management GmbH
Am Weidendamm 1 A
D-10117 Berlin
Phone: +49 (0)30 72 61 053-74
Fax: +49 (0)30 72 62 50 79
Email: info@ifs-certification.com

ITALY | MILAN
IFS Office Milan
Federdistribuzione
Via Albricci 8
I-20122 Milano
Phone: +39 02 89 07 51 50
Fax: +39 02 6 55 11 69
Email: ifs-milano@ifs-certification.com

POLAND | WARSAW
IFS Office Central & Eastern Europe
ul. Serwituty 25
PL-02-233 Warsaw
Phone: +48 6 01 95 77 01
Email: ifs-poland@ifs-certification.com

USA | CANADA
IFS Americas
Pius Gasser
Email: gasser@ifs-certification.com

IFS HPC

IFS HPC

Standard for auditing products/processes of suppliers manufacturing household and personal care products

VERSION 2

APRIL 2016

ENGLISH

Acknowledgements

IFS would like to thank to all members of the International Technical Committee and specially the IFS HPC Review Committee who contributed to develop and to improve the new version of the IFS HPC Standard. Your input and opinions were a big support to IFS. We appreciate the time you have taken to enthusiastically participate in this review process.

Members of the IFS International Technical Committee

Andrea Artoni	CONAD, on behalf of ANCD (Associazone Nazionale Cooperative (tra Dettaglianti), Italy
Fayçal Bellatif	Eurofins Certification, France
Sébastien Bian	Groupe Casino, France
Sabrina Bianchini	Det Norske Veritas, Italy
Cristina Diez	Palacios Alimentación, Spain
Andreas Dörr	Coop, Switzerland
Antonella Donato	Coop, Italy
Gerald Erbach	METRO AG, Germany
Ricardo Fabregat	Consum Cooperativa, Spain
Frank Ferko	US Foods, USA
Massimo Ghezzi	Carrefour, Italy
Cécile Gillard-Kaplan	Groupe Carrefour, France
Almudena Hernandez	AENOR, Spain
Luc Horemans	Scamark – Groupement Leclerc, France
Dr. Horst Lang	GLOBUS SB-Warenhaus, Germany
Maria Lopez de Montenegro	DIA Group, Spain
Flavia Maré	Carrefour, Italy
Aline Maysse	Europe Snacks, France
Dr. Joachim Mehnert	DQS, Germany
Dr. Angela Moritz	REWE Group; REWE-Zentral-AG, Germany
Renate Pascarelli	Coop, Italy
Alberto Peiro	Mercadona, Spain
Bizhan Pourkomailian	Mc Donalds Europe, United Kingdom
Dr. Jürgen Sommer	Freiberger Lebensmittel GmbH & Co KG, Germany
Gabriele Speri	Agricola Italiana Alimentare S.p.A., Italy
Stephen Thome	Dawn Food Products, USA
Bert Urlings	Vion Food, The Netherlands
Karin Voß	EDEKA Zentrale AG & Co. KG, Germany

Members of the IFS HPC Review Committee

Sabine Beresheim	Ontex Global, Belgium
Carinne Contremoulin	Scamark, France
Dirk Convens	McBride, Belgium
Brigitte Driaux	Carrefour, France
Jürgen Eichmann	Kaufland, Germany
Anne Farouk	Eurofins, France
Christine Flöter	TÜV Nord, Germany
Frauke Heinemann	SCA, Germany
Christian Kraule	TÜV Nord, Germany
Anne-France Loaëc	Groupe-Casino, France
Mónica Mascato	Zelnova, Spain
Joachim Mehnert	DQS, Germany

Andrea Niemann-Haberhausen	Hygenius, Germany
Alejandra Pulido	DIA Group, Spain
Steven Tierelers	Ontex Global, Belgium
Laurent Valera	Carrefour, France
Nina Zhelyaznik	Metro, Germany

The IFS is also pleased to acknowledge the helpful contributions provided by the following persons for the review process:

Stéphanie Lemaître	Bureau Veritas, France (special thanks)
Franck Courtray	IFS HPC Expert, France
Sebastian Fischer-Rombach	IFS HPC Expert, Germany
Valerio Garavaglia	IFS HPC Expert, Italy
Valérie Midena	IFS HPC Expert, France
Christian Zolesi	IFS HPC Expert, France
Verena Schilling	dm, Germany

IFS Team

Helga Barrios	IFS HPC Standard Manager
Chryssa Dimitriadis	Head of Standard Management
Nevin Rühle	Director Business Development

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

Contents

PART 1
Audit Protocol

PART 2
List of audit requirements (Checklist IFS HPC)

PART 3
Requirements for accreditation bodies, certification bodies and auditors

PART 4
Reporting

PART 1

PART 1
Audit Protocol

1 The History of International Featured Standards

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

The associated members of the German Retail Federation—Handelsverband Deutschland (HDE)—and of its French counterpart—Fédération des Entreprises du Commerce et de la Distribution (FCD)—drew up a quality and food safety Standard for retailer branded food products, namely the IFS Food, which is intended to allow the assessment of suppliers' food safety and quality systems, in accordance with a uniform approach. This Standard is now managed by IFS Management GmbH, a company owned by FCD and HDE, and applies to all the post-farm gate stages of food processing. IFS Food Standard has been benchmarked against the GFSI Guidance Document and is recognised by GFSI (Global Food Safety Initiative). The first version implemented, version 3 of the IFS Food Standard was developed by the HDE and launched in 2003.
In January 2004, an updated version, version 4, was designed and introduced in collaboration with the FCD. During 2005/2006, the Italian retail associations Associazione Nazionale Cooperative Consumatori (ANCC), Associazione Nazionale Cooperative tra Dettaglianti (ANCD) and Federdistribuzione also joined the International Food Standard (currently International Featured Standards) and the development of version 5 was a collaboration of Retail Federations from, France and Germany as well as retailers from Switzerland and Austria.

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

The fundamental objectives of the IFS Household and Personal Care Products Standard as well as other IFS Standards are:

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

IFS started with the publication of IFS Food and then developed further standards, such as IFS Logistics, IFS Broker, IFS Wholesale/Cash & Carry, IFS PACsecure, IFS Food Store, IFS Global Markets – Food and this Standard IFS Household and Personal Care Products (HPC).

The IFS HPC Standard is one of the Standards belonging to the umbrella brand IFS (International Featured Standards).

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

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

In 2006, to satisfy these consumer expectations, IFS together with international stakeholders (industries, retailers, certification bodies, etc.) from France, Germany and Italy started creating the first version of the IFS Household and Personal Care Products Standard (IFS HPC). The Standard was developed in order to cover key aspects of the Quality Management System of the companies manufacturing household and personal care products (e.g. risk management, traceability, customer specifications, corrective actions, etc.).

The aim of this customised Standard is to audit products/processes of suppliers manufacturing household and personal care products.

The new version 2 of the IFS HPC Standard will come into force in October 1, 2016. There will be a transition period for the application of this new version, during which companies may continue to be audited on the basis of version 1. Until December 31, 2016, the companies can choose to be audited either to version 1 or version 2. After January 1, 2017, only audits to version 2 of the IFS HPC Standard will be accepted.

3 Introduction

3.1 Purpose and contents of the Audit Protocol

This Audit Protocol describes the specific requirements for the organisations involved with IFS Household and Personal Care audits.

The purpose of the Protocol is to define the criteria to be followed by a certification body performing audits against the IFS requirements, and in accordance with the accreditation standard ISO/IEC 17065. It also details the procedures to be followed by the companies being audited, and clarifies the importance of the need for the audit.

Certification bodies which are already accredited to ISO/IEC 17065 for IFS Food or any other IFS Standard will require a specific extension of scope for IFS HPC.

Only those certification bodies that are accredited to ISO/IEC 17065 with the scope of IFS HPC, and which have signed an Agreement with the scheme owner, can perform audits against the IFS HPC Standard; therefore granting IFS HPC certificates. The IFS requirements for certification bodies are clearly described in Part 3 of this Standard.

3.2 Specific information that the certified company shall address with the certification body

In accordance with ISO/IEC 17065, the company shall inform its certification body about any change that may affect its ability to conform to the certification requirements (e.g. recall, alert on products, organization and management, modification to the products or the production method, contact address and production sites etc.). The details shall be defined and agreed between both parties.

The information shall be communicated within three (3) working days.

3.3 General requirements for the Quality Management System

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

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

All processes and procedures shall be clear concise and unambiguous, and the key personnel shall understand the principles of the Quality Management System.

The Quality Management System is based on the following methodology:

- to identify the processes needed for the quality management system,
- to determine the sequence and interaction of these processes,
- to determine the criteria and methods required to ensure the effective operation and control of these processes,
- to ensure the availability of information necessary to support the operation and monitoring of these processes,
- to measure, monitor and analyse these processes, and implement the necessary action to achieve planned results and continuous improvement.

4 Types of audit

4.1 Initial audit

An initial audit is either a company's first audit to the HPC Version 2 or the audit after an interruption of the certification cycle. It is performed at a time and date agreed upon between the company and the selected certification body. During this audit, a full and thorough audit of the entire company's systems and procedures shall be made. During the audit, all criteria of the IFS requirements shall be assessed by the auditor. In the case of a pre-assessment, the auditor who performs this assessment shall be different from the auditor who performs the initial audit.

4.2 Follow-up audit

A follow-up audit is required in a specific situation when the results of the audit (an initial audit or a renewal audit) have been such as to not allow the awarding of the certificate (see chart nº 5). During the follow-up audit, the auditor focuses on the implementation of the actions taken to correct the Major non-conformity determined within the previous audit. The follow-up audit shall be performed within a six (6) months period, from the date of the previous audit. In general, the auditor who performed the audit where a Major non-conformity has been identified shall perform the follow-up audit.

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

If there is no follow-up audit performed after six (6) months from the date of the previous audit, then a complete new initial audit is necessary. **If the company decides not to perform a follow-up audit but to start with a new full audit, the new audit shall be scheduled not earlier than six (6) weeks after the audit where the Major non-conformity was issued.**

In the event that the follow-up audit establishes that requirements remain inadequate, a complete new audit is necessary, **which shall be scheduled not earlier than six (6) weeks after the follow-up audit.** The closure of Major non-conformities shall always be established by an on-site audit by the auditor.

After a successful follow-up audit, the company shall be granted certification at Foundation level only (see chart nº 6).

4.3 Renewal audit (for recertification)

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

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

The date of the renewal audit shall be calculated from the date of the initial audit and not from the date of issue of the certificate. Furthermore, the renewal audit can be scheduled at earliest eight (8) weeks before and at latest two (2) weeks after the anniversary initial audit date (see also section 7.2).

Companies are responsible for maintaining their certification. All IFS HPC certificated companies will receive a reminder from the IFS database three (3) months before certification expiration.

The certification bodies shall contact companies in advance in order to set a date for a new audit. In general, the expected date of each audit shall be uploaded in the IFS database, in the diary function and at latest two (2) weeks (14 calendar days) before the last possible audit date (it is possible to change the day short term).

4.4 Extension audit

In specific situations, such as where new products and/or processes are to be included in the audit scope between two certification audits or each time the audit scope would need to be updated on the certificate, then, for an IFS HPC certified company, it is not necessary to perform a full audit, but to organize an on-site extension audit during the validity period of the existing certificate.

If this is required, the certified company shall immediately inform its certification body, who shall perform a risk assessment to decide whether an extension audit should be performed or not. The result of this risk assessment is based on hygiene and safety risks and shall be documented.

The certification body is responsible for determining relevant requirements to be audited and audit duration. The report of this extension audit shall be represented as an annex to the current audit report. Conditions for passing the extension audit (relative score ≥ 75 %) are the same as any other audit, but will only be focused on specific requirements which have been audited.

- If the extension audit demonstrates compliance, the certificate shall be updated with the new scope and uploaded in the IFS database (the original audit score does not change). The updated certificate shall keep the same due date of end of validity as the current certificate.
- If the relative score is < 75 %, the extension audit is failed and it is not possible to update the certificate with the extended products/processes.
- In the event that a Major non-conformity or a KO (Knock Out non-conformity) has been identified, the full audit is failed and the current certificate shall be suspended as described in sections 6.8.1 and 6.8.2.

5 Coverage of the Standard and scope of the audit

5.1 Coverage of the Standard

The IFS HPC Standard is a Standard for auditing products/processes of suppliers manufacturing household and personal care products.

The Standard can only be used when the product is "processed" and/or if there is a risk of contamination during the primary packing of household and personal care products.

For example, filling companies can be certified against the IFS HPC Standard, as they do manage unpackaged products.

The Standard may be applicable to products under retail brand (private labels), or branded or unbranded for use by other organizations.

If the HPC manufacturing company also trades goods and they would like to have them covered by a certification, it is possible to perform a combined IFS HPC/IFS Broker audit. If the requirements of both checklists are fulfilled, two separate reports shall be written and two separate certificates shall be issued and uploaded in the database.

The auditor (or the audit team) shall fully assess both checklists.

For clarification of the scope of application between IFS HPC and other IFS Standards (IFS Food, IFS PACsecure, IFS Wholesale/Cash & Carry, IFS Broker, IFS Logistics, IFS Global Markets – Food and IFS Food Store), see Annex 1.

5.1.1 Scopes of the IFS HPC Standard

Scope 1: Cosmetic products
Examples: shampoos, toothpastes, cosmetics wipes, eau de cologne, perfumes, nail polish, coverage creams, tanning products, eye liners, concealers, lipsticks, lubrication strip of shavers, shaving products, some medical devices class I (like physiological serum without the sterile condition, adhesive cream for dentures, etc.), etc.

Scope 2: Household chemical products
Examples: detergents (including professional use), cleaning and polishing agents, detergent pre-charged foam sponges, air fresheners, toilet rim blocks, aroma sticks, shoe polish, softeners, candles/candles to provide aroma, matches, household insecticides, etc.

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

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

Note 1: some medical devices classes 1 have been included in the scope of the IFS HPC Standard, as they may be found in retail assortments. These products have been allocated either in scope 1 or 4.

Note 2: for further information on right allocation of IFS HPC products in each product scope, see "IFS HPC product examples' chart", which is available on the IFS website.

Products which are excluded from the IFS HPC scope

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

Note: companies producing food contact materials exclusively for other professional companies may use the IFS PACsecure Standard.
In circumstances where the company produces food contact materials for both markets (professional users and end consumers), the company can choose either the IFS HPC or the IFS PACsecure Standard.

5.2 Scope of the audit

The IFS HPC audit scope shall be defined according to the following requirements:

- it shall be agreed between the company and the certification body before the audit takes place. The scope shall be clearly and unambiguously stated in the contract between the company and the certification body, in the audit report and on the certificate. The audit scope will also be reviewed by the auditor during the opening meeting of the audit,
- it shall include the complete activity of the company (i.e. the same kind of production on several lines for products under supplier brands and private labels) and not only the production line(s) for private labels,
- the audit shall take place when products of the audit scope are being processed. For example, it is not possible to include in the scope of the IFS HPC certification production lines of the audited site which are not operating during the audit, unless those production lines involve the same risk assessment study and the same products and scopes as the lines which are audited when operating. If, during the audit, some lines are not operating at the audited site and involve different risk assessment study(ies), product(s) and scope(s), the auditor can ask the company to run the production line(s) later during the first audit day or the following audit day(s), so that the line(s) is/are assessed later during the audit. If this is not possible for the company to run the production line(s) during the audit, the auditor shall come back to audit the line(s) when operating, during an extension audit (in case the company wants to include those products under the current certificate and/or if exclusion is not possible),

- production process exclusions are not allowed. If, **under exceptional cases,** the company would like to exclude specific products from the audit scope, the certification body may allow it if the contamination risk between included and excluded products is properly controlled (and verified by the certification body/auditor). If documented and justified, the exclusion shall always be specified on the certificate and in the company profile of the audit report,
- the audit shall be "product" and "site" specific. Where decentralized structures exist and the audit of a certain location is insufficient for gaining a complete view of the company's processes, then all other relevant facilities owned by the company shall also be included in the audit. Full details shall be documented within the company profile in the IFS audit report,
- in case of outsourced processes, the certification body shall be made fully aware of such arrangements. It shall clearly be described and specified in the report and on the certificate. Furthermore, a specific requirements within the checklist shall be assessed by the auditor when auditing the production site being audited.

Auditing of multi-location companies with central management (audit management, audit duration, certification process, etc.)

A managing site having processing activities shall be audited and subjected to own IFS HPC report and certificate.
A managing site not having processing activities may be audited but cannot be subjected to an IFS HPC report and certificate. If a company has several production sites and a non-processing managing site where defined processes are centrally organised (e.g. purchasing, personnel management, complaint management), the certification body shall ensure that during the audit of the production sites, all necessary information from the managing site is available and can be assessed. This can be ensured either by an audit of the managing site or by other means (e.g. a representative of the managing site should attend at the audit(s) of the production site(s), managing site documents could be checked on-site at production sites, etc.). This shall be defined by the certification body, based on information provided by the company.

If the certification body decides performing an audit of the managing site:

- audit duration of each production site may be decreased by a maximum of half a day (as related requirements would have been already audited at the managing site),
- relevant audit requirements outcome shall be considered in the audit reports of each production site,
- the audit of the managing site shall always take place before the audit of each production site,
- each production site shall be audited separately in a period of maximum 12 months after the managing site and shall have its own report and certificate,
- all KO requirements shall be audited at all sites even if some of them are partly managed at the central managing site,
- in the audit report of each site, only the audit date of the respective site shall be stated; the audit date of managing site is not additionally necessary,
- in the event that a Major non-conformity or a KO scored with D has been issued during the audit of the managing site, all audited production sites are also affected and the certificates of these sites shall be suspended. After a successful audit of the managing site (or after positive follow-up after a Major was issued in the central managing site), the certificates of the production sites can be reinstated. Depending upon the non-conformity that has been issued at the managing site, a new audit of the production sites may also be necessary.

6 The certification process

6.1 Preparation of the IFS HPC audit

Before being audited, the company shall review all aspects of the IFS Household and Personal Care Standard in detail and, if existing, IFS Doctrine and Erratum.

On the day of the audit, the current version of the Standard shall be available at the site being audited. The company is responsible for acquiring the current version of the Standard. In order to prepare for an initial audit, a company may carry out a pre-assessment, which is only intended to be used in-house. The pre-assessment cannot include any recommendations.

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

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

6.2 Certification body selection– contractual arrangements

In order to undertake the IFS HPC audit, the company shall appoint a certification body which is approved to perform such audits. Only those IFS HPC approved certification bodies–which shall be accredited ISO/IEC 17065 for the IFS HPC and shall have signed a contract with IFS (see Part 3 of the Standard)–can carry out IFS HPC audits and issue certificates. The list of all IFS international approved certification bodies by country, is available on the website www.ifs-certification.com

A contract shall exist between the company and the certification body detailing the scope of the audit, the duration and reporting requirements. The company shall clearly inform its certification body about all products and the related processes they carry out in its production site.

The contract shall have a clear reference to Integrity Program (see section 13), in relation to the possibility of on site audits organized by Quality Assurance Management of the IFS offices.

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

The audit shall preferably be carried out in the language of the company and the certification body shall make every attempt to appoint an auditor whose native language is the language of the company. If this is not possible, the audit shall be performed in English language.

6.3 Duration of an audit

The certification bodies shall have an appropriate system for estimating the minimum time needed for an audit. A number of factors, which are detailed in the contract between the certification body and the company, play a role in determining the time required for a comprehensive audit.

Minimum audit duration shall be two (2) working days, but the certification body shall decide increasing this duration, based on the following factors:

- the size of the site (manufacturing area + storage area),
- the type of production process,
- the scope of the audit,
- the number of the different risk assessment studies and the number of production lines involved,
- the number of personnel employed at the site,
- if the audit is combined (e.g. IFS HPC/IFS Broker),
- if a translator is needed (audit duration shall increase by 20 %),
- the number of non-conformities found during the previous audit.

The daily audit duration is eight (8) hours and shall never exceed ten (10) hours.
The above mentioned requirements shall apply equally to renewal audits, which shall be considered as completely new audits.
The site inspection activity within the audit (excluding document checking) shall take at least 1/3 of the total audit time.

Independently from audit duration, besides on-site audit:

- preparation of audit shall be at least two (2) hours,
- preparation of the relevant audit report shall require at least half a day (0.5).

6.4 Drawing up an audit time schedule

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

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

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

The audit shall be scheduled based on the following steps:

- the opening meeting, during which the scope shall be reviewed and agreed,
- the evaluation of existing quality and safety systems; achieved by checking documentation (risk assessment, quality management),
- the on-site audit and interviewing of the personnel,
- the final conclusions drawn from the audit,
- the closing meeting.

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

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

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

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

6.5 Evaluation of requirements

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

6.5.1 Scoring a requirement as a deviation

In the IFS HPC, there are four scoring possibilities:

Scoring with:

A: full compliance with the requirement mentioned in the Standard.

B: almost full compliance with the requirement mentioned in the Standard, but a small deviation was found.

C: only a small part of the requirement has been implemented.

D: the requirement in the Standard has not been implemented.

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

Chart N° 1: scoring

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

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

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

6.5.2 Scoring a requirement as a non-conformity

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

6.5.2.1 Major

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

Major non-conformity can be in substantial failure to meet requirements of legislation, internal dysfunctions (e.g. completely not regulated and controlled processes), and customer issues.

A Major shall also be given when the identified non-conformity could lead to a serious health hazard.

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

Chart N° 2: evaluation of a Major

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

See also section 6.8.2 for the general management of audit process in case of Major non-conformity(ies).

6.5.2.2 KO (Knock out)

KO requirements (KO – Knock out) are pre-defined requirements in the IFS HPC Standard.

These requirements are elementary and include essential topics to be ensured by an efficient quality management system to reach compliance with a safety and quality standard.

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

In the IFS HPC Standard, the following 6 requirements are defined as KO requirements:

1.2.3 Responsibility of the senior management

2.2.3.8 Establish a monitoring system for each critical control point

4.2.2.2 Product specifications

4.14.1 Traceability

5.9.4 Withdrawal/recall procedure

5.11.2 Corrective actions

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

Chart N° 3: scoring for KO requirement

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

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

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

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

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

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

N/A is not possible for KO requirements, except for 2.2.3.8.

Furthermore, N/A is not possible for requirement 2.2.3.6 about determination of CCP (as even if a company does not have any CCP's, the company shall document a logical approach which needs to be assessed by the auditor).

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

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

6.6 Determination of the audit frequency

For all products and for all certification levels, the audit frequency for IFS HPC audits is 12 months, starting from the date of the audit and not the date of issue the certificate. Further regulations are described in section 7.2 (certification cycle).

6.7 Audit report

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

- If the auditor has a different native language than **English,** and if this language is the language of the company, the auditor can perform the audit using her/his native language. The audit report shall be written in this language. In this case, the auditor/certification body shall also translate into **English** language, further compulsory information (see section 6.7.3.2).
- If the auditor does not have as native language the language of the company, the audit shall be performed in **English** language and the audit report shall be written in **English** language.

6.7.1 Structure of the audit report

The audit report shall provide transparency and confidence to the reader and will be completed by the auditor. The audit report is divided in different sections. For a detailed information, see Part 4 of the Standard.

- Cover of the IFS audit report (basic information about the certification body and the audited company).
- Audit Overview (including audit scope, audit result, company profile, etc.).
- Audit Report (including summary for all chapters listing the number of assessed scores for each chapter, observations on KOs and Majors, table of compulsory fields, etc.).
- Detailed audit report (IFS HPC Checklist).

All deviations (B, C, D) and KO requirements scored with a B, non-conformities (Major, KO requirement scored with a D) identified during the audit are presented in a separate action plan.

Following the allocation of a grade and non-conformities, **the company has to complete a corrective action plan.** In this way, the reader of a report can see the non-conformities and also the corrective actions that the company is initiating.

6.7.2 Steps of the audit report completion

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

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

The auditor shall describe/explain some compulsory information, even in case of A scoring, for some pre-determined requirements (see Part 4 of the Standard).

The action plan shall include all the requirements which are not evaluated with A or N/A. The outline action plan shall conform to the auditXpressX™ software (IFS audit report writer assistant). It shall include the elements of the following chart.

The auditor shall complete all of Field A in chart nº 4 explaining and justifying the deviations and non-conformities finding before sending the company the outline action plan and the pre-report of the audit.

The certification body or the auditor shall send the company both the pre-report of the audit and the outline action plan within two (2) weeks of the audit date.

Chart N° 4: outline action plan

Number of the requirement	IFS HPC requirement	Evaluation	Explanation (by the auditor)	Corrective action (by the production site)	Responsibility/Date and status of implementation (by the production site)	Release by the auditor
			Field A	**Field B**	**Field C**	**Field D**
1.2.1	An organisation chart …	B				
1.2.2	Competences and responsibilities …	C				
1.2.3 KO	The senior management shall ensure …	KO/D				
1.2.4	Employees with influences …	Major				
1.2.6	The senior management shall provide …	D				
4.2.2.2 KO	Current and approved finished product specifications …	KO/B				

6.7.2.2 Company's completion of the corrective action plan

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

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

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

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

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

6.7.2.3 Auditor validation of the action plan

The auditor or a representative of the certification body shall validate the relevance of the corrective actions in the last column of the action plan before preparing the final audit report (Field D of the chart nº 4). If the corrective actions are not valid or irrelevant, the certification body shall return the action plan to the company for completion in due time.

6.7.3 Further rules about the audit report

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

When the auditor scores a requirement with C or D, corrective actions shall be implemented before the renewal audit. If not, the auditor has the possibility to score the requirement with a Major. This means the certification body shall read the audit report and the action plan of the previous audit, even if the report was issued by another certification body.

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

6.7.3.2 Specific translation requirements in case the audit report is written in the language of the company (but not in English language)

As the IFS Standards are used internationally, it is important that customers understand the audit report; this is particularly important in relation to **deviations** and **non-conformities** identified by the auditor, as well as **corrective actions** proposed from the audited company.

The corrective actions related to these deviations and non-conformities shall also be translated into **English** language in the action plan (chart nº 5, Field B):

Chart N° 5: outline action plan for translation

Number of the requirement	IFS HPC requirement	Evaluation	Explanation (by the auditor)	Corrective action (by the production site)	Responsibility/Date and status of implementation (by the production site)	Release by the auditor
			Field A	**Field B**		
1.2.1	An organisation chart …	B				
1.2.2	Competences and responsibilities …	C				
1.2.3 KO	The senior management shall ensure …	KO/D				
1.2.4	Employees with influence …	Major				
2.2.3.8 KO	Establish a monitoring system for each critical …	KO/B				

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

Moreover, in the **IFS audit report** the following topics shall be translated into **English** language.

- Company profile (see Part 4 of the Standard for further information).
- Table of compulsory fields for specific defined IFS HPC audit requirements (see Part 4 of the Standard).
- Requirements evaluated with a C or D.
- Major non-conformities.
- KO requirements scored with a B or a D.
- The audit scope (on the relevant page of the audit report).

6.8 Scoring, conditions of issuing IFS audit report and certificate

Chart N° 6: scoring and awarding of certificates

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

The total score is calculated as following:

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

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

6.8.1 Specific management of the audit process (report, certificate, uploading) in case one or several KO's has/have been scored with D during the audit (see also Annex 3)

In the event that one or several KO is/are scored with D during the audit, the current IFS certificate shall be suspended in the IFS database by the certification body as soon as possible and a maximum two (2) working days after the audit date.

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

Note: all users having access to the IFS database and having mentioned the respective company in their favourites list will get an email notice from the IFS database that the current certificate has been suspended.

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

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

The **IFS audit report** where **one or several KO** have been scored with D shall always be uploaded into the IFS database together with the action plan (it will only be visible by IFS, the certification body and the audited company and not by other IFS users).

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

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

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

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

Note: all users having access to the IFS database and having mentioned the respective company in their favourites list will get an E-Mail notice (with explanations about the identified non-conformity(ies)) from the IFS database that the current certificate has been suspended.

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

In cases where **more than one Major non-conformity** have been identified, **a completely new audit** shall be performed. The new audit shall be scheduled no earlier than six (6) weeks after the audit where Major non-conformities were issued. It is recommended to complete the action plan for improvement purposes.

The **IFS audit report** where **one or several Major non-conformity(ies)** has/have been identified shall always be uploaded into the IFS database together with the action plan (it will only be visible by IFS, the certification body and the audited company and not by other IFS users).

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

- the certification body shall mention on the updated IFS audit report:
  - In the "date" section: specify the date of the follow-up audit in addition to the date of audit when the Major non-conformity was identified.
  - In the "final result of audit" section: specify that a follow-up audit has taken place and that the Major non-conformity has been solved.
  - In the "observations regarding KO non-conformities and Majors" section explain on which requirement the Major non-conformity has been resolved.

The company cannot be certified with higher level even:

- if the final total score is equal or more than 95 %,
- the same valid date of the certificate remains in the certification cycle as described in 7.2.

It shall be defined on the certificate the date of initial audit and date of follow-up audit.

Example:

Initial audit date 1:	01. October, 2016
Date of issue of certificate:	26. November, 2016
Certificate valid until:	25. November, 2017
Renewal date (audit where Major has been issued) 2:	25. September, 2017
Follow-up audit:	03. December, 2017
Latest date of validity of the certificate:	25. November, 2018

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

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

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

7 Awarding the certificate

A certificate shall be issued to one specific site or specific product groups of that site.

Translation of the audit scope on the certificate
To make use of the IFS Standards internationally and to make it widely understandable, the audit scope on the IFS HPC certificate shall always be translated into English language.

It is an obligation and the responsibility of the certification bodies to translate the audit scope.

Detailed minimum mandatory information to be published on the IFS HPC certificate is determined in Part 4 of the Standard.

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

7.1 Deadlines for awarding certificate

The certification body is responsible for the decision to award or not award the IFS Household and Personal Care certificate. The decision is made by person(s) other than those who have carried out the audit.

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

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

In total six (6) weeks between the date of audit and uploading the audit report to the IFS database and awarding the certificate:

- target time: six (6) weeks,
- maximum time: eight (8) weeks.

The **validity of the IFS certificate** is established as follows:

- date of starting validity of the certificate: the validity starts with the date of issuing a certificate
- end of validity of certificate: last day of the initial audit date + eight (8) weeks – one (1) day + one (1) year.

The **date** of the **renewal audit** shall be calculated from the date of the anniversary of the intial audit and not from the date of issue the certificate.

7.2 Certification cycle

Even if the renewal audit date changes every year and does not completely correspond to the anniversary date, the certificate validity date shall remain the same each year.

This time cycle will avoid gaps between two consecutive certificates and will prevent a company scheduling the audit earlier losing some months of certificate validity.

Example:

Initial audit date: 01. October, 2016

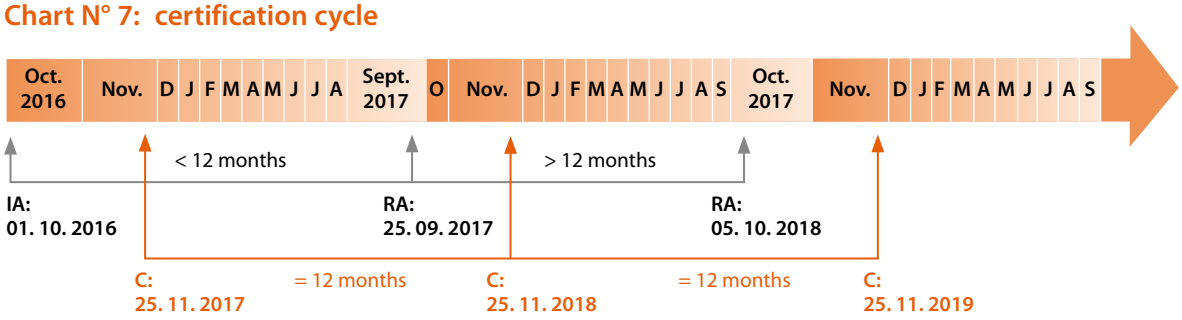
Date of issue of certificate: 26. November, 2016

Certificate valid until: 25. November, 2017

Renewal audit date: 25. September, 2017

Certificate valid until: 25. November, 2018 (independently from the renewal audit date).

Chart N° 7: certification cycle



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

Note: the certificate shall always be issued on the basis of a certification decision and after the several steps of certification decision in accordance with ISO/IEC 17065.

The renewal audit shall be scheduled at earliest eight (8) weeks before and at latest two (2) weeks after the audit due date (due date is anniversary date of the initial audit). Not respecting the mentioned rules in due time will lead to a certification cycle break.

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

7.3 Information about conditions of withdrawal of certificate

Withdrawal of certification by the certification body is only permitted where there is evidence that the product(s) no longer comply with the requirements of the certification system.

The contract between certification body and audited company shall be harmonized with the certification cycle (see above chart n° 7).

8 Distribution and storage of the audit report

Audit reports shall remain the property of the company and shall not be released, in whole or part, to a third party without the company's prior consent (except where required by law). This consent for distribution of the audit report must be in writing and can be granted by the company vis-à-vis the certification body and/or vis-à-vis the retailer. The certification body will keep a copy of the audit report. The audit report shall be stored safely and securely for a period of five (5) years.

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

9 Supplementary action

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

10 Appeal procedure

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

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

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

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

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

11 Ownership and usage of the IFS HPC Logo

The copyright of the IFS Household and Personal Care Standard and the registered trademark is fully owned by IFS Management GmbH. The IFS HPC Logo can be downloaded via the secured part of the IFS database.

Furthermore, the terms and conditions stated below shall be checked by the auditor during the audit and results of this check shall be described in the company profile of the audit report as a mandatory field (see also Part 4 of the Standard).

In case the auditor identified that the company doesn't fulfil those terms and conditions, IFS offices shall be informed accordingly.

Terms and conditions for IFS HPC certified companies: Use of the IFS HPC logo and communication about the IFS HPC certification

Application
These terms and conditions apply for IFS HPC logo and IFS logos in general.

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

An IFS HPC certified company may–subject to the provisions mentioned below–use the IFS HPC logo in its documents (for example invoices).

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

Restriction of comment and interpretation
When an IFS HPC certified company or an IFS HPC certification body publishes documents bearing the IFS logo, comments and interpretations referring to the IFS shall be clearly identifiable as such.

Use of the IFS HPC logo in promotional material
An IFS HPC certified company may use the IFS logo for promotional reasons and publish information about its IFS certification provided that it is not visible by the end-consumer. The IFS HPC logo and the information about the certification may be used in correspondence with relevant IFS users, but not in correspondence with the end-consumer. The IFS HPC logo may not be displayed on vehicles, the products themselves, or any kind of advertising document likely to reach the end-consumer (e.g. public exhibitions for end consumers, brochures). As for the particular case of websites which are not exclusively dedicated to a professional use, the logo may appear only on web sites related to household and personal care quality and safety.

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

Further restriction on the use of the IFS HPC logo
The IFS HPC logo shall not be used in a way that could provide the interpretation that the IFS owners are responsible for the certification requirements. In case of suspension or withdrawal of the IFS HPC certificate, the audited company has to immediately stop the inclusion of the IFS logo

on its documents and/or website etc. and stop the communication about IFS.

Communication about the IFS HPC certification
All the above mentioned rules apply to any communication about IFS HPC. This also means that using the words "IFS", "IFS Household and Personal Care Standard" or "IFS HPC" or similar is not allowed. This, of course, includes the communication on finished products, which are available by the end consumer.

12 Review of the Standard

The Standard shall be subjected to formal internal review annually and, where appropriate revised to demonstrate control of the quality and content of the Standard.

The Review Committee in charge of it shall be formed from all participants involved in the audit process: the representatives of the retailers, representatives of the industry and certification bodies. The objective of the Review Committee is to share experiences, discuss and decide about the changes to the requirements of the Standard and the courses for auditors.

13 IFS Integrity Program

The IFS Integrity Program was launched in early 2010 and includes different measures to assure the quality of the IFS certification scheme, with a focus on the review of audits conducted by the IFS certification bodies and their auditors.

There are two cornerstones of this program:
a) Preventive quality assurance actions
Quality assurance activities monitor the entire IFS system. Surveillance audits at the certification body offices and on-site supplier audits are carried out on a regular basis in order to assess the IFS system. These audits are undertaken regardless of whether or not a complaint has been made. The sampling for these surveillance audits is based on a random selection process and by use of objective criteria. These criteria are both economic criteria (e.g. number of issued certificates) and quality criteria (e.g. the review and analyses of IFS certification processes and corresponding reports).

A surveillance office audit of a certification body takes place at the accredited certification body's premises to verify the correct application of the IFS regulations at the certification body offices and to promote continuous improvement.

Additionally, surveillance on-site supplier audits at certified companies may be undertaken. In general, surveillance on-site supplier audits are announced 48 hours before the audit date. In these audits the documentation reviewed in the office audit of the certification body, or in the IFS database, is compared with the real situation found at the company.

Witness audits can also be performed. In this case, Integrity auditors assess an IFS auditor during a real IFS audit.

b) Quality assurance actions after complaint notification

A detailed complaint management process analyses all necessary information. Retailers or any other interested parties have the right to forward any possible non-conformity to IFS for investigation as part of the Integrity Program.

The IFS Offices collect complaints concerning IFS audits, reports, certificates or other circumstances in which the integrity of the IFS brand is in question. Retailers, certification bodies, employees of IFS certified companies or any person can use the complaint form on the IFS website www.ifs-certification.com or can send an e-mail to complaintmanagement@ifs-certification.com to inform IFS about a certain issue. In addition to any complaints received, IFS also analyses the IFS database using analytical tools in order to identify any deficiencies.

If IFS Quality Assurance Management is informed of significant discrepancies between the results of an IFS audit and a subsequent retailer audit, this will be investigated within the complaint management process as described below.

The IFS offices will gather all necessary information in order to investigate the cause of the complaint and to establish if there are deficiencies by certified companies, accredited certification bodies or IFS-approved auditors in meeting IFS requirements. Appropriate steps are taken to fully investigate a complaint, which may include a request to a certification body to carry out internal investigations and provide a statement on the outcome of their investigations to IFS.

In the event that a complaint cannot be successfully resolved by the investigation undertaken by the certification body, an on-site investigation audit will be undertaken at the certified company(s). In general, investigation audits are announced 48 hours before the audit date, however in special cases unannounced audits are undertaken.

Witness audits can also be performed. In this case, Integrity auditors assess an IFS auditor during a real IFS audit.

Audits carried out as part of the Integrity Program are conducted by auditors employed by IFS and completely independent of the auditees.

Sanctions

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

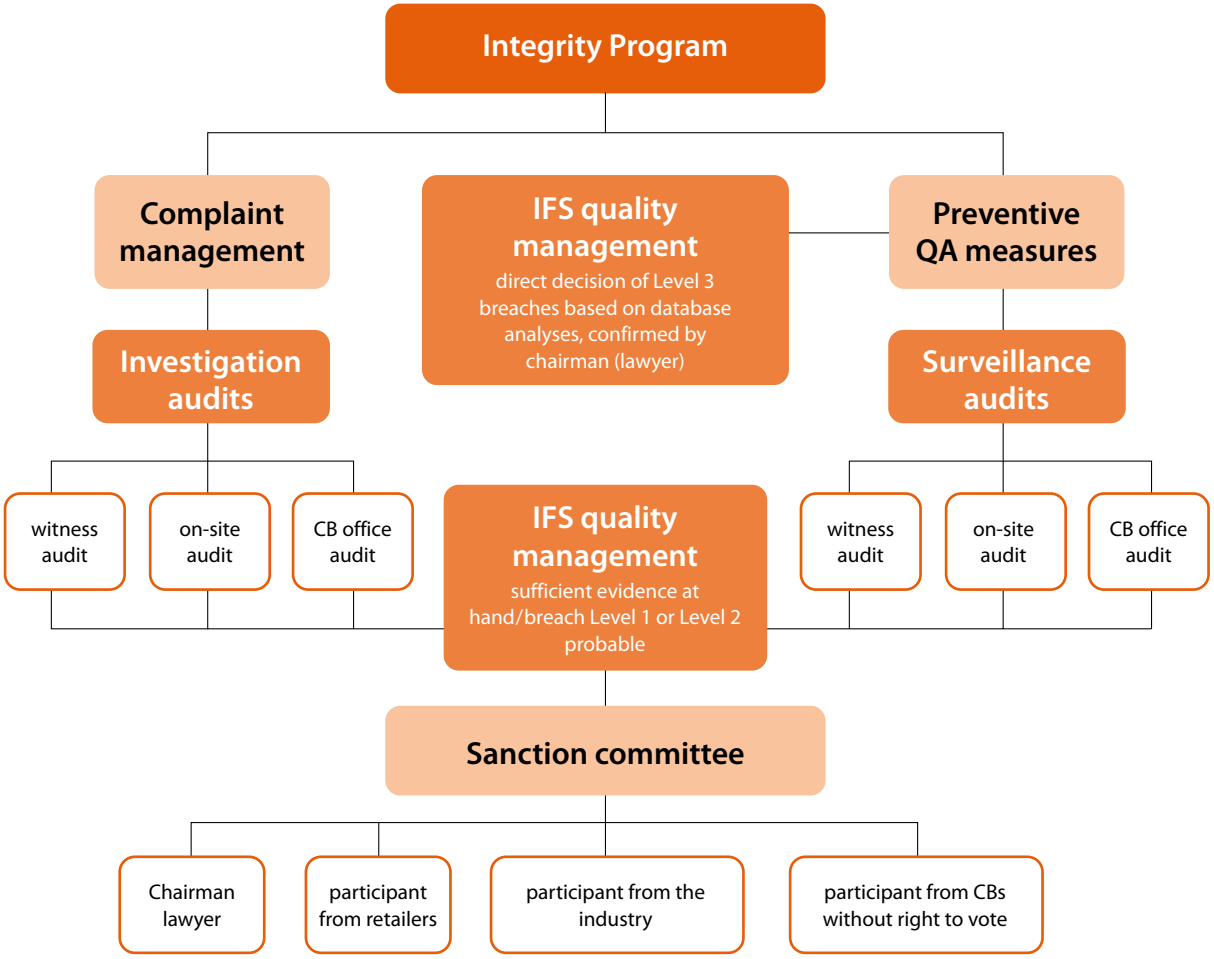
Topics concerning administrative faults of certification bodies based on database investigations can be directly assessed by the IFS Quality Assurance Management, but have to be confirmed by the chairman (lawyer) of the Sanction Committee.

Sanctions 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 depends on the number of breaches previously committed by the auditor and/or the certification body as well as the level of severity of such breaches. IFS Management informs the appropriate accreditation body if a breach for a certification body and/or for an auditor has been established.

All these procedures are laid down in the contract between IFS and each certification body and all stakeholders of the IFS system are informed of the process. The IFS Integrity Program strengthens the reliability of the IFS scheme by checking the implementation of the IFS Standard in practice.

Chart N° 8: summary of IFS Integrity Program activities



ANNEX 1: Scope of application of the different IFS Standards

IFS Food

Standard for auditing food product processors/manufacturers

IFS Food shall be used when a product is processed or where there is a hazard for product contamination during the primary packing.

IFS HPC

Standard for auditing household and personal care processors/manufacturers

IFS HPC shall be used when a product is processed or where there is a hazard for product contamination during the primary packing.

IFS PACsecure

Standard for auditing food and non-food packaging material manufacturers and applies to packaging processing and/or converting companies.

IFS Broker

Standard for auditing persons and/or companies who may, or may not own the products, and typically do not take physical possession of the products (e.g. which do not have warehouses, packing stations or truck fleet), but are legal entities which provide broker or agent services.

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

If a manufacturing company has also broker services and wants to certify both activities (processing and broker services), a combined audit may be performed (IFS Food or IFS HPC or IFS PACsecure respectively in combination with IFS Broker).

IFS Wholesale/Cash & Carry

Standard which covers all wholesaling activities of food, HPC and PACsecure products in Cash & Carry or wholesaling companies. Furthermore certain treatment and/or processing activities are covered by this standard. This standard also covers packing companies for fruit, vegetables and/or eggs.

IFS Logistics

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

If a production company has own logistics activities, they are already covered by the IFS product Standard under the specific sub-chapter about transport and/or storage. Therefore, it is not necessary to perform a combined audit for IFS Food, IFS HPC or IFS PACsecure with IFS Logistics.

IFS Global Markets – Food

The IFS Global Markets – Food is a standardized food safety assessment program for companies which wish to supply branded food products.
The program is meant to support "small and/or less developed businesses" in the development of their food safety management systems and if whished making the first step towards the implementation of the IFS Food Standard.

IFS Food Store

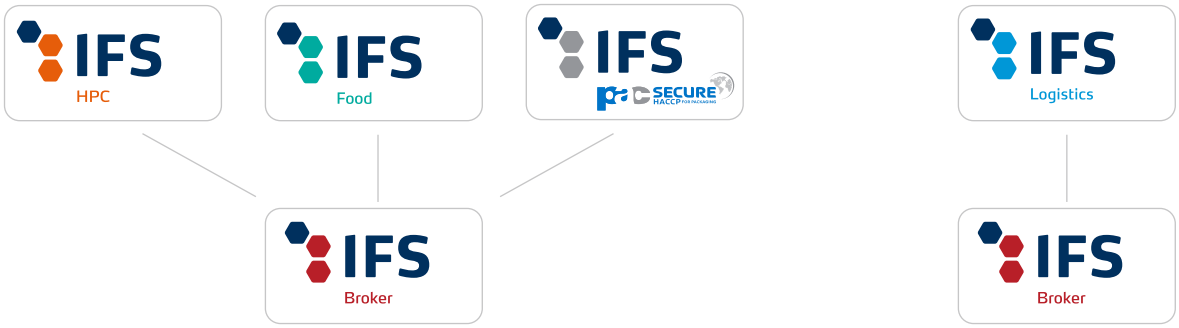
Standard for inspecting the food safety activities in retail stores. All food retail activities shall be evaluated, regardless if they are managed directly by the store owner or by a subcontracted service provider.

IFS combined audits

The different IFS product Standards can be combined with the IFS Broker as long as the manufacturing company also trades food and/or non-food products.

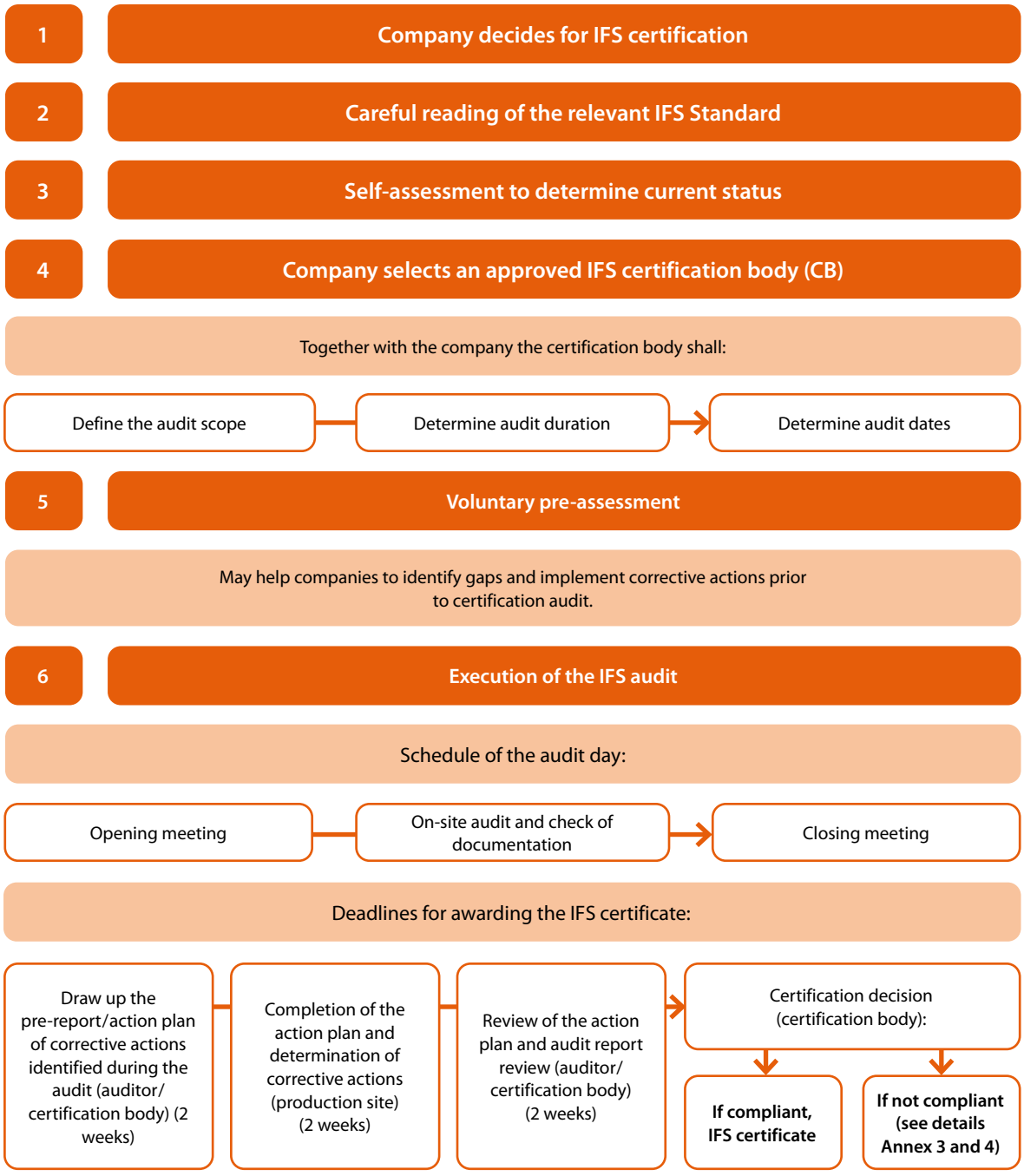
A combined IFS Logistics/IFS Broker certification can be applicable if a logistics company also has trading activities with food, HPC and/or packaging products.

Same combined audit can be performed, if a Broker also has own logistics activities, such as storage and/or transport.



In every case, the auditor/audit team shall ensure that both checklists are properly assessed and, if successful, the company shall get two (2) reports and two (2) certificates.

ANNEX 2: Certification process

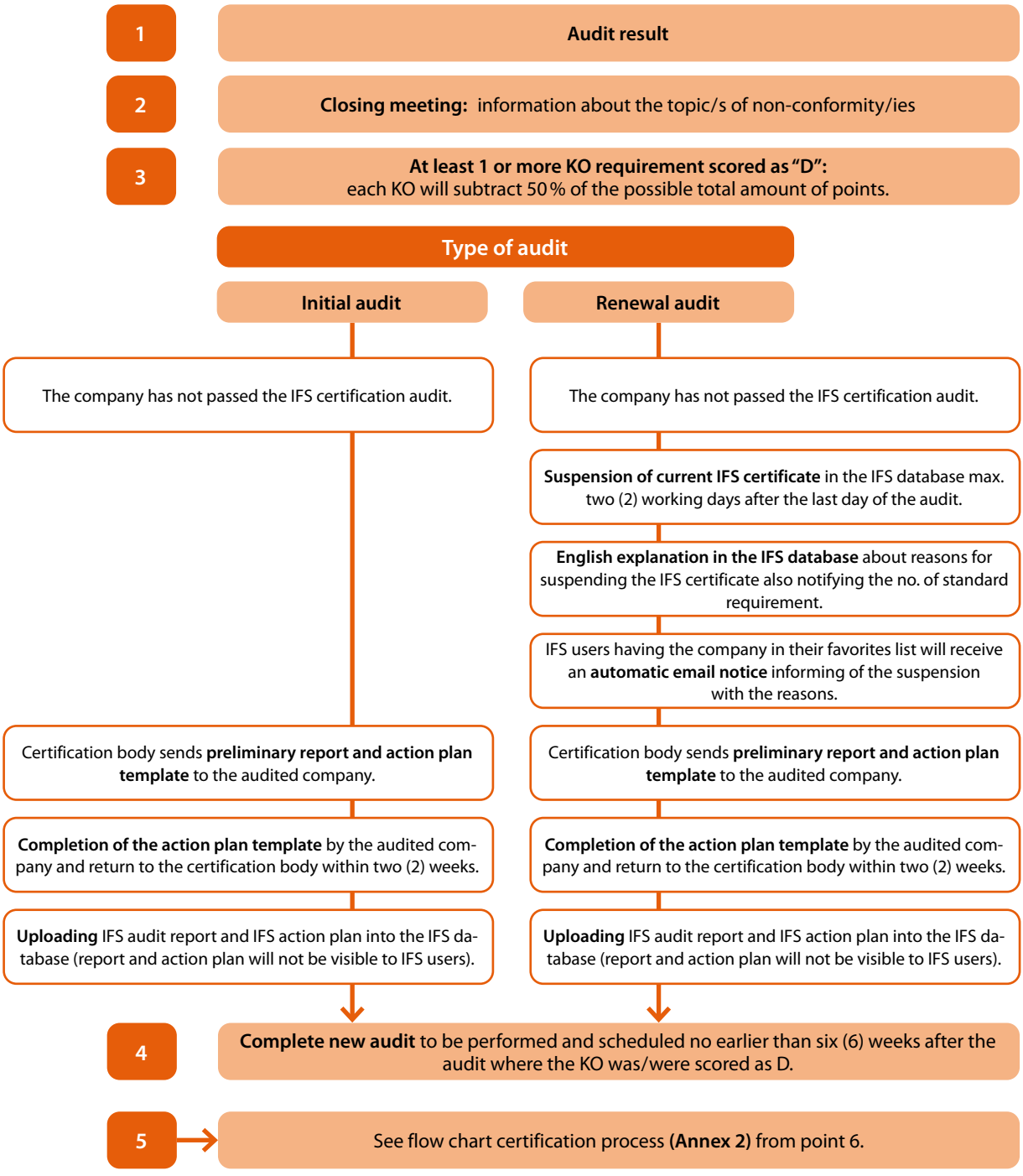


Three (3) months before the certificate expires, a reminder will be sent to the company using the IFS database for scheduling a new audit with the certification body. The audit shall be scheduled no later than the last possible renewal audit date notified in the report and on the certificate.

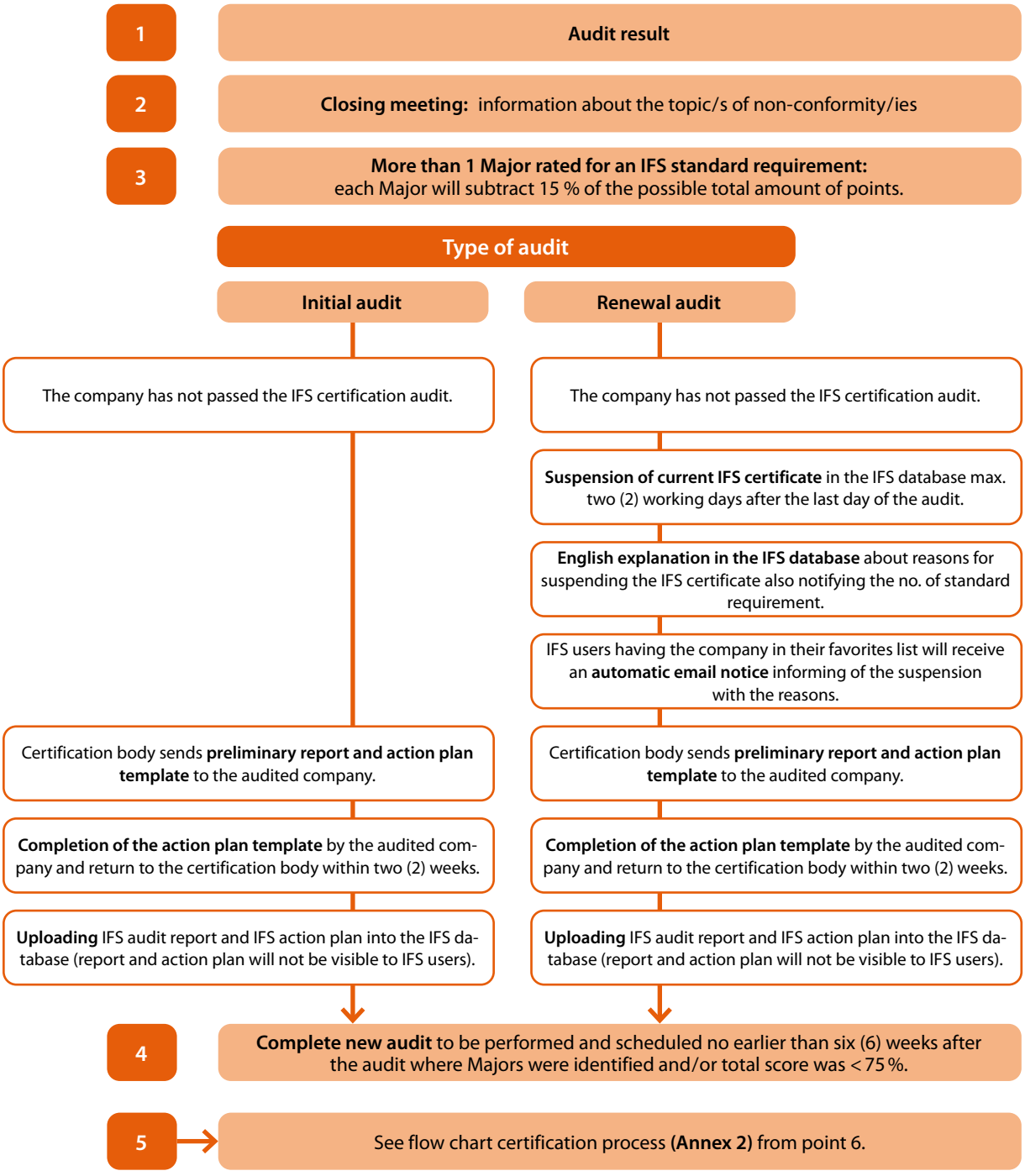
For further information see Part 1 (Audit Protocol) of the IFS HPC Standard.

Visit www.ifs-certification.com to download the IFS Standards and to find an approved certification body.

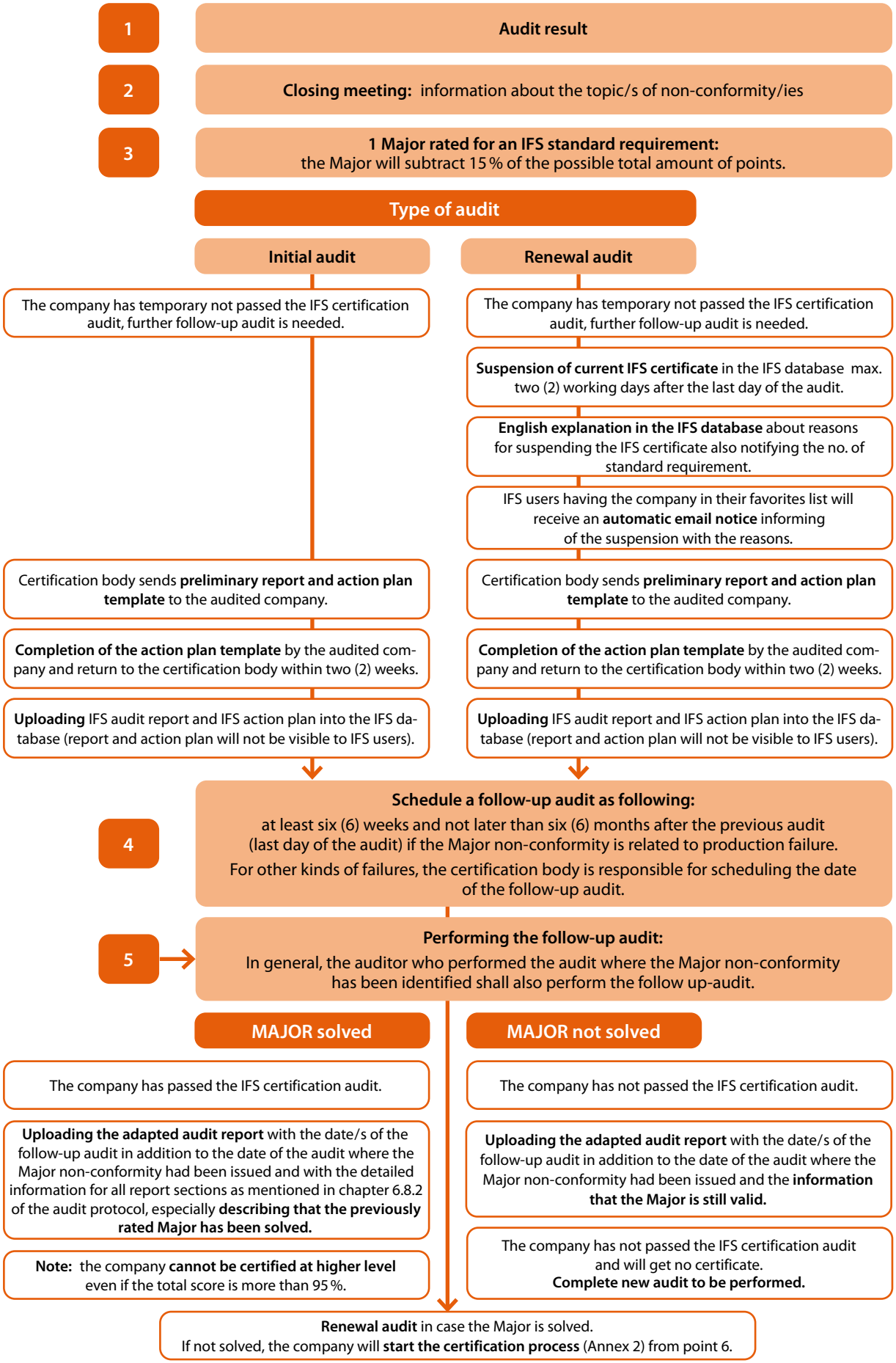
ANNEX 3: Flow chart for management of KO scored with D



ANNEX 4: Flow chart for management of Major non-conformities:
A: More than 1 Major and/or total score < 75 %



Annex 4: Flow chart for management of Major non-conformities: B: Maximum 1 Major and total score ≥ 75 %



PART 2

PART 2
List of audit requirements (Checklist IFS HPC)

1 Senior Management Responsibility

1.1 Corporate policy/Corporate principles

1.1.1 The senior management shall draw up and implement a corporate policy. The corporate policy shall include as a minimum reference to:

- customer and consumer focus,
- environmental responsibility,
- occupational health,
- buildings,
- machines and equipment,
- product requirements (includes: product safety, quality, legality, process and specification).

The corporate policy shall be communicated to all employees.

1.1.2 The content of the corporate policy shall have been broken down into specific objectives for the relevant departments. The responsibility and the time scale for achievement shall be defined for each department of the company.

1.1.3 From the corporate policy, the quality and product safety objectives shall be communicated to the employees in the respective departments and shall be effectively implemented. The company shall ensure that all relevant information is communicated effectively and in a timely manner to the relevant personnel.

1.1.4 The senior management shall ensure that the achievement of all objectives is regularly reviewed, as a minimum the objectives shall be reviewed annually.

1.2 Corporate structure

1.2.1 An organization chart shall be available showing the structure of the company.

1.2.2 Competences and responsibilities, including deputation of responsibility shall be clearly specified.

1.2.3 KO N°1: The senior management shall ensure that employees are aware of their responsibilities relating to product safety and quality. Senior management shall also ensure that mechanisms are in place to monitor the effectiveness of the operation of the employees. Such mechanisms shall be clearly identified and documented.

1.2.4 Employees with influence on product safety, legality and quality shall be aware of their responsibilities defined within job descriptions, and shall be able to demonstrate understanding of their responsibilities.

1.2.5 The company shall have an IFS representative nominated by senior management.

1.2.6 The senior management shall provide sufficient and relevant resources to meet the product requirements.

1.2.7 The department responsible for quality and product safety management shall have a direct reporting relationship to the senior management.

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

1.3 Customer focus

1.3.1 A documented process shall be in place to identify fundamental needs and expectations of customers.

1.3.2 The results of this process shall be evaluated and considered to determine quality and product safety objectives.

1.4 Management review

1.4.1 Senior management shall ensure that the quality and product safety management systems are reviewed at least annually, or more regularly, if changes occur. Such reviews shall contain at least:

- results of audits,
- customer feedback,
- process compliance and product conformity,
- status of preventive and corrective actions,
- follow up actions from previous management reviews,
- changes that could affect the product safety and quality management system,
- complaints from authorities,
- recommendations for improvement.

1.4.2 This review shall include the evaluation of measures for the control of the quality and product safety management system and for the continuous improvement process.

1.4.3 The company shall identify and review regularly (e.g. by internal audits or factory inspection) the infrastructure needed to achieve and maintain conformity to product requirements. This shall include for example, the following criteria:

- buildings,
- supply systems,
- machines and equipment,
- laboratory equipment,
- transport.

The results of the review shall be considered, with due consideration to risk, for investment planning.

1.4.4 The company shall identify and review regularly (e.g. by internal audit or factory inspection) the work environment needed to achieve and maintain conformity to product requirements. This shall include for example, the following criteria:

- staff facilities,
- environmental conditions,
- hygienic conditions,
- workplace design,
- external influences (e.g. noise, vibration).

The results of the review shall be considered, with due consideration to risk for investment planning.

2 Quality and Product Safety Management System

2.1 Quality Management

2.1.1 Documentation requirements

2.1.1.1 The quality and product safety management system shall be documented and implemented, and shall be retained in one location (it can be an electronic documented system).

2.1.1.2 A documented procedure shall exist for the control of documents and their amendments.

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

2.1.1.4 All documents which are necessary for compliance with the product requirements shall be available in their latest version.

2.1.1.5 The reason for any amendments to documents, critical for the product requirements shall be recorded and approved.

2.1.1.6 Documents shall be removed from the job area and destroyed if they are outdated.

2.1.2 Record keeping

2.1.2.1 All relevant records necessary for the product requirements shall be completed, detailed and securely maintained (e.g. with backup system) and shall be available on request.

2.1.2.2 Records shall be legible and genuine. They shall be maintained in a way that subsequent manipulation of records is prohibited.

2.1.2.3 All records including records showing the effective control of process, product safety and quality shall be kept in accordance with legal requirements and customer specifications (this includes, for instance and where relevant, the cosmetic product information file).
These records shall be kept for a minimum of one year after the end of shelf life period. For products which have no shelf life, the duration of record keeping shall be in line with customers' requirements.

2.1.2.4 Any amendments to records shall only be carried out by authorized persons.

2.2 Product Safety Management

2.2.1 Risk management system (Hazard analysis and risk assessment)

2.2.1.1 Before developing a risk management system, the company shall have implemented all necessary Good Manufacturing Practices (GMP's) which are commonly used in its scope of activity.

2.2.1.2 The basis of the company's product safety control system shall be a fully implemented, systematic and comprehensive risk management system. It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The risk management system shall be implemented at each production site. The risk management system shall cover all raw material groups, products or product groups, as well as every process (included outsourced process) from goods receipt to product dispatch, including product development and product packaging.

2.2.1.3 The company shall ensure that the risk management system is based upon scientific literature, or technical verified specifications relating to the manufactured products and procedures. The risk management system shall be maintained in line with any new technical and scientific process development.

2.2.1.4 The risk management system shall be reviewed and necessary changes shall be made when any modification is made in the product, process or any change that could affect product requirements.

2.2.2 Risk management team

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

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

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

2.2.3 Hazard analysis and risk assessment

2.2.3.1 Describe product

The assessment shall make reference to the full description of the product including all applicable relevant information on product safety and regulation such as:

- composition (raw materials, rework, reprocessing, etc.),
- physical, chemical and microbiological parameters,
- methods of treatment,
- packaging, labeling,
- durability (shelf life),
- conditions for storage,
- method of transport.

2.2.3.2 Identify intended use

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

2.2.3.3 Construct flow diagram

A flow diagram shall exist for each product, product groups, raw material groups, etc., and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall be dated, and clearly identify each critical control point with the number assigned to it. In the event of any changes the flow diagram shall be revised.

2.2.3.4 On-site confirmation of the flow diagram

The risk management team shall review the processes at all operation stages against the flow diagram. Where relevant, amendments of the diagram will be made.

2.2.3.5 Conduct a hazard analysis and risk assessment for each step

2.2.3.5.1 A hazard analysis shall be available for all physical, chemical and biological hazards that may be reasonably expected.
A hazard analysis and a risk assessment shall be conducted for each step from raw materials to the finished products including development and packaging material validation.

2.2.3.5.2 Based on the hazard analysis, the risk assessment shall demonstrate the actions required if a hazard is a risk, taking into account the probability of harm to the consumer and the severity of damage (effect, potential consequences). The methodology for assessing risk shall be documented.

2.2.3.6 Determine critical control points

Based on level of acceptability of risk, critical control points shall be identified and documented.

2.2.3.7 Establish critical limits for each critical control point

For each critical control point, the appropriate critical limits shall be defined and validated in order to clearly identify when a process is out of control.

2.2.3.8 Establish a monitoring system for each critical control point

KO N° 2: Specific monitoring procedures shall be established for each critical control point to detect any loss of control. Records of monitoring shall be maintained for a relevant period. Each defined critical control point shall be under control at all times. Monitoring and control of each critical control point shall be demonstrated by records. The records shall specify the person responsible, as well as the date and result of the monitoring activities.

2.2.3.9 Establish corrective actions

For each critical control point, corrective actions shall be established. In case the monitoring indicates that a particular critical control point is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any non-conforming products.

2.2.3.10 Establish verification procedures

Procedures of verification shall be established to confirm that the risk management system is effective. Verification of the risk management system shall be performed at least once a year. Examples of verification activities include:

- internal audits,
- analyses,
- sampling,
- evaluations,
- complaints by authorities and customers.

The results of this verification shall be incorporated into the risk management system.

3 Resource management

3.1 Human resources management

3.1.1 All personnel performing work that affects product safety, legality and quality shall have the required competence (demonstrated by education, work experience and/or training) based on hazard analysis and assessment of associated risk.

3.2 Personnel hygiene management

3.2.1 Personnel hygiene

3.2.1.1 There shall be documented requirements relating to personnel hygiene. These include, as a minimum the following criteria:

- protective clothing,
- hand washing and disinfection,
- eating and drinking,
- smoking,
- actions to be taken in case of cuts or skin abrasions,
- fingernails, jewelry and personal belongings,
- hair and beards.

The requirements shall be based on hazard analysis and assessment of associated risk in relation to product and process.

3.2.1.2 The requirements for personnel hygiene shall be in place and applied by all relevant personnel, contractors and visitors. Compliance with the requirements shall be checked regularly.

3.2.1.3 Visible jewelry (incl. piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated based on hazard analysis and assessment of associated risk.

3.2.1.4 Cuts and skin abrasions shall be covered by a colored plaster/bandage (different from the product color). Any exceptions shall have been comprehensively evaluated based on hazard analysis and assessment of associated risk.

3.2.1.5 Based on hazard analysis and assessment of associated risk, there shall be a program to control effectiveness of hand hygiene.

3.2.2 Protective clothing for personnel, contractors and visitors

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

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

3.2.2.3 Clearly defined usage rules shall exist for work areas/activities where it is required to wear gloves (colored differently from the product color). Compliance with these rules shall be checked on a regular basis.

3.2.2.4 Suitable protective clothing and devices to ensure personnel safety shall be available in sufficient quantity for each employee, when required.

3.2.2.5 When required, all protective clothing shall be thoroughly and regularly laundered. Based on hazard analysis and assessment of associated risk, taking into consideration the processes and products, the company shall determine if clothing shall be washed by a contract laundry, on-site laundry or by the employee.

3.2.2.6 Guidelines shall exist for laundering of protective clothing and a procedure shall be in place for checking its cleanliness, when required.

3.2.2.7 The company shall review that implemented preventive measures to ensure personnel safety related to hazardous working conditions are effective.

3.2.3 Procedures applicable to infectious diseases

3.2.3.1 There shall be written and communicated measures for personnel, contractors and visitors in case of any infectious disease which may have an impact on product safety. In case of declaration of infectious disease, actions shall be taken in order to minimize risk of contamination of products.

3.3 Training and instruction

3.3.1 The company shall implement documented training and/or instruction programs with respect to the product requirements and the training needs of the employees based on their job which shall include:

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

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

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

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

There shall be a procedure or program in place to prove the effectiveness of the training and/or instruction programs.

3.3.4 The contents of training and/or instruction shall be reviewed and updated regularly and take into account company's specific issues, product safety, product related legal requirements and product/process modifications.

3.4 Staff facilities, sanitary facilities and equipment for personnel hygiene

3.4.1 The company shall provide staff facilities, which shall be proportional in size, equipped for the number of personnel and designed and operated so as to minimize product safety risk. Such facilities shall be kept clean and in good condition.

3.4.2 There shall be in place rules and facilities to ensure the correct management for personnel belongings and food and other materials brought to work by personnel and shall include, food from dining room and from vending machines. The food and other materials shall only be stored and/or consumed in designated areas.

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

3.4.4 Changing rooms shall be separated from production area and shall be sited so that they allow direct access to the areas where products are handled.
Based on hazard analysis and assessment of associated risk, exceptions shall be justified and managed.

3.4.5 Toilets shall not have direct access to an area where products are handled. The sanitary facilities shall be equipped with adequate hand washing facilities. Sanitary facilities shall have adequate natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area shall be avoided.

3.4.6 Adequate hand hygiene facilities shall be provided near points of entry to and within production areas, as well as at staff facilities. Based on hazard analysis and assessment of associated risk, further areas shall be similarly equipped.

3.4.7 Hand washing facilities shall provide as a minimum:

- water,
- liquid soap,
- appropriate equipment for hand drying.

3.4.8 If necessary, the following additional requirements regarding hand hygiene shall also be provided:

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

4 Planning and production process

4.1 Contract agreement

4.1.1 The requirements which are defined in the contract with the customer shall be established, agreed upon and reviewed concerning their acceptability before a supply agreement is concluded. All clauses related to quality and product safety shall be known and communicated to each relevant department.

4.1.2 Changes of existing contractual agreements shall be documented, communicated and updated between the contract partners.

4.2 Specifications and formulas

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

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

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

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

4.2.1.3 A reevaluation of the suitability of raw materials shall be in place, in cases where raw materials are close to the best before date, or when they are returned to storage or other relevant parameters given by the supplier.

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

4.2.1.5 Where relevant, raw material specifications identifying allergens requiring declaration shall be available. The company shall maintain a continuously up to date listing of all raw materials containing allergens used at its premises, which also identifies all blends and formulas to which such raw materials containing allergens are added.

4.2.2 Finished product specifications

4.2.2.1 Specifications shall be available for all final products and shall be agreed upon in writing with customers. The specifications shall be up to date, traceable, unambiguous, available to relevant personnel and always in conformance with legal and customer requirements.

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

4.2.2.3 Where customers specifically require that products are "free from" certain substances or ingredients, or that certain methods of treatment or production are excluded, verifiable procedures shall be in place.

4.2.2.4 There shall be a procedure for the creation, the modification and approval of specifications for all parts of the process, which shall include the preliminary acceptance of the customer, if specifications have been agreed with customers.

4.2.2.5 The specification control procedure shall include the update of finished product specification in case of any modification requested by the customer and/or defined by the company, related to:

- raw material,
- formula/recipe,
- process with influence on the final product,
- packaging with influence on the final product.

4.3 Legislative framework and R & D process

4.3.1 Legislative framework

4.3.1.1 The company shall comply with the current applicable legislation and shall be able to demonstrate its own role in the supply chain.

4.3.1.2 The company shall have a system in place to ensure that it is kept informed of all relevant legislation regarding product safety and quality issues, scientific and technical developments and industry codes of practice. Legislation shall be understood and applied.

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

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

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

4.3.1.6 A process shall be in place to ensure that labeling complies with current legislation of destination country and customer requirements.

4.3.1.7 The conformity of the product with its labeling shall be reviewed each time before a new label is issued for use. Such review shall take into account the product requirements and particular relevant legislation in the destination countries.

4.3.2 R&D process

4.3.2.1 The company shall have an implemented procedure for R&D that takes into account risk and patents and that demonstrates that all existing and new products are designed to meet legal requirements.

4.3.2.2 The progress and the results of R&D shall be properly recorded.

4.3.2.3 Without the authorization from the patent holder, the company shall not use raw materials, or composition and shall not process finished products that are already patented.

4.3.2.4 Product formulation, manufacturing processes and the fulfillment of product requirements shall have been ensured by factory trials, performance tests, stability tests, organoleptic assessments (where relevant) and product testing.

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

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

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

4.3.2.8 Where relevant, pilot equipment(s) shall be available and used in order to warranty good formulation's industrialization.

4.3.2.9 The consumer packaging shall be designed and labeled to prevent non intended use in order to protect the safety of the potential user. The risk assessment shall address this topic.

4.3.2.10 If required by law and based on hazard analysis and assessment of associated risk, the company shall verify the acceptability of the packaging material for each relevant product (e.g. organoleptic tests, storage tests, chemical analysis).

4.4 Purchasing

4.4.1 The company shall control purchasing processes to ensure that all externally sourced materials (raw materials, including packaging materials) and services, which have an impact on product safety and quality, comply with requirements. Where a company chooses to outsource any process that may have an impact on product safety and quality, the company shall ensure control over such processes and fulfill requirements ref. 4.4.8.

4.4.2 Purchased products and services shall conform to current specifications and contractual agreements.

4.4.3 The schedule of these checks shall take into account the product requirements, supplier status and the impact of raw materials on the finished product.

4.4.4 There shall be a procedure for approval and monitoring of suppliers (internal and external), outsourced production and sub-processes. In case of any kind of outsourced production, the customer shall always be informed.

4.4.5 The approval and monitoring procedure shall contain clear assessment criteria such as: audits, certificates of analysis, supplier reliability and complaints, as well as required performance standards based on hazard analysis and assessment of associated risk.

4.4.6 The results of supplier's assessment shall be reviewed regularly. There shall be records of the reviews and of the actions taken as a consequence of assessment.

4.4.7 There shall be records to identify which raw material including packaging and semi-finished products are sourced from each supplier.

4.4.8 Outsourced production (if applicable)

4.4.8.1 Control of outsourced processes shall be identified, risk assessed and documented within the product safety and quality management system.

4.4.8.2 A contract shall exist between the company and its subcontractor.

4.4.8.3 Based on hazard analysis and assessment of associated risk, the company shall regularly audit the subcontractor, by using an audit checklist covering IFS HPC requirements (including e.g. relevant documented risk management system, control plan, traceability system, crisis management, etc.). Documents of such checks shall be available.

4.4.8.4 The checks performed at the subcontractor shall be performed by a qualified auditor/inspector.

4.4.8.5 If relevant, the company shall check the products on receipt from its subcontractor.

4.5 Factory location

4.5.1 Site security

4.5.1.1 Senior management shall ensure that hazards related to site security (fire, explosions, electrical devices, flooding) are identified and preventive measures are managed.

4.5.1.2 The production and storage areas of the site shall be effectively secured by controlled access in order to prevent unauthorized entry.

4.5.2 Factory exterior

4.5.2.1 The company shall investigate to what extent the factory environment (e.g. ground, air) may have an adverse impact on product safety and product quality.
In each case, appropriate measures shall be established. The effectiveness of the established measures shall be periodically reviewed (examples: extremely dusty air, strong smells).

4.5.2.2 The factory exterior shall be sustainable maintained, clean and tidy. The external condition of the premises shall be considered within the internal audit process.

4.5.2.3 All grounds within the site shall be in good condition. Where natural drainage is inadequate, a suitable drainage equipment shall be installed.

4.5.3 Plant layout and process flow

4.5.3.1 Plans clearly describing internal flows of finished products, raw materials including packaging materials, waste, personnel, water, etc. shall be in place. A site map covering all buildings of the facility shall be available.

4.5.3.2 The process flow, from receipt of goods to dispatch, shall be organized so that a contamination of raw materials including packaging materials, semi-processed, rework and finished products is avoided. The risk of cross-contamination shall be minimized through effective measures.

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

4.5.3.4 If production areas are identified as microbiologically sensitive (e.g. clean room technology), a positive air pressure equipment shall be installed. Assessment of the level of the microorganisms shall be performed at risk based intervals.

4.5.4 Buildings and facilities

4.5.4.1 Buildings and internal structures

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

4.5.4.1.2 Rooms where the products are prepared, treated, processed and stored shall be designed and constructed, so that product compliance and product safety is ensured.

4.5.4.1.3 Walls shall be constructed to prevent the accumulation of dirt, to reduce condensation and mold growth, and to facilitate cleaning.

4.5.4.1.4 Floors shall be in good condition and shall be designed to meet production requirements (e.g. mechanical loads, cleaning materials, etc.) and to facilitate cleaning and disinfection, where required.

4.5.4.1.5 Ceilings (or, where no ceilings are fitted, the undersides of roofs) and overhead fixtures (incl. piping, cables, lamps) shall be suitable for the process and shall be designed and constructed to minimize the accumulation of dirt, the detachment of paints or other coating materials, condensation and mold growth. Ceilings and overheads shall be designed to facilitate cleaning and prevent product contamination.

4.5.4.1.6 Windows and other openings shall be designed and constructed to avoid the accumulation of dirt and shall be maintained in good condition.

4.5.4.1.7 Doors and gates shall be in good condition and easy to clean.

4.5.4.1.8 Drainage equipment shall be designed to facilitate cleaning and to minimize the risk of product contamination (e.g. adverse impact, ingress of pests, environment impact etc.). The hygienic disposal of waste water shall be ensured.

4.5.4.1.9 Where relevant, for laboratories:

- location of laboratories at the factory shall not affect product safety,
- microbiological laboratory shall be physically separated from chemical laboratory,
- suitable equipment and environment shall be available for all tests performed.

4.5.4.2 Lighting, air conditioning/ventilation

4.5.4.2.1 All working areas shall have adequate lighting.

4.5.4.2.2 Based on hazard analysis and assessment of associated risk, all lightning equipment and electric fly killer units shall be protected.
The factory areas where this clause shall apply:

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

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

4.5.4.2.3 Adequate natural and/or artificial ventilation shall exist in all areas.

4.5.4.2.4 If ventilation equipment is installed, filters and other components which require cleaning or replacement shall be easily accessible.

4.5.4.2.5 The use of air in the production (e.g. compressed air supply) shall avoid contamination and be based on hazard analysis and assessment of associated risk.

4.5.4.2.6 Dust extraction equipment shall be installed in areas where considerable amounts of dust are generated.

4.5.4.3 Water quality

4.5.4.3.1 All process waters (including water used as an ingredient) shall be tested regularly for compliance with chemical, physical and microbiological specifications. Special attention shall be paid after periods of no water consumption (e.g. after a weekend or holiday period). The risk assessment shall address this topic.
The company shall demonstrate the effectiveness of its water treatment and usage.

4.5.4.3.2 A water monitoring program (especially in the case of cold mixing operations) shall verify that the water treatment is adequate and effective on a risk based plan.

4.5.4.3.3 Recycled water which is used in the process shall not pose a contamination risk. The water shall comply with applicable legal requirements for potable water; records of compliance testing shall be available.

4.6 Cleaning and disinfection

4.6.1 Based on hazard analysis and assessment of associated risk, cleaning and disinfection schedules shall be available and implemented. These shall specify:

- objectives,
- responsibilities,
- the products used and their instructions for use,
- the areas to be cleaned and/or disinfected,
- cleaning frequency,
- documentation requirements,
- hazard symbols (if necessary).

These schedules shall be documented.

4.6.2 Where relevant, only qualified personnel shall be allowed to undertake cleaning and disinfection. The personnel shall be trained and retrained to carry out the cleaning schedules.

4.6.3 Based on hazard analysis and assessment of associated risk, the effectiveness and safety of the cleaning and disinfection measures shall be verified, validated for equipment and documented according to a sampling schedule by using appropriate procedures.
Resultant corrective actions shall be documented.

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

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

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

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

4.6.8 Where a company hires a third-party service provider for cleaning and disinfection activities, all requirements specified within section 4.6 shall be clearly defined in the respective contract.

4.7 Waste disposal

4.7.1 A waste management procedure shall exist and shall be implemented to avoid cross contamination.

4.7.2 All current legal requirements for waste disposal shall be met.

4.7.3 Waste collection containers and, where existing, compactors shall be clearly marked, suitably designed, in good state of repair, easy to clean, and disinfected where necessary.

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

4.8 Risk of foreign materials

4.8.1 Based on hazard analysis and assessment of associated risk, procedures shall be in place to avoid contamination with foreign material.

4.8.2 In all areas, i.e. handling of raw materials including packaging materials, processing and storage, where risk assessment has identified the potential for product contamination, the use of wood shall be excluded. Where the use of wood cannot be avoided, the risk shall be controlled.

4.8.3 Where metal and/or other foreign material detectors are required, they shall be installed to ensure efficiency of detection, in order to avoid subsequent contamination.

4.8.4 The accuracy of detectors shall be specified. Checks of proper function of detectors shall be carried out regularly. In case of malfunction or failure of foreign material detector, corrective actions shall be defined, implemented and documented.

4.8.5 Potentially contaminated products shall be isolated. Access and actions for further handling or checking for these isolated products shall be carried out only by authorized personnel according to defined procedures. If product's contamination is confirmed, those shall be treated as non-conforming products.

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

4.9 Pest monitoring/pest control

4.9.1 The company shall have a pest control system in place which is in compliance with local legal requirements, and as a minimum shall cover the following criteria:

- the factory environment (potential pests),
- site plan with area for application (bait map),
- identification of the baits on-site,
- responsibilities (in-house/external),
- used products/agents and their instructions for use and safety,
- the frequency of inspections.

The pest control system shall be based on hazard analysis and assessment of associated risk.

4.9.2 The company shall have qualified and trained in-house staff and/or employ the services of a qualified external provider. Where an external provider is used, the activities required on-site shall be specified in a written contract.

4.9.3 Pest control inspections and resulting actions shall be documented. Implementation of actions shall be monitored and recorded.

4.9.4 Baits, traps and insect exterminators shall be functioning, in sufficient number and placed in an appropriate position. They shall be constructed and positioned as not to cause any contamination.

4.9.5 Incoming deliveries shall be checked on receipt for the presence of pests. Any infestation shall be documented and control measures taken.

4.9.6 If windows pose a risk of a source of contamination such as the ingress of pests, windows and roof glazing shall remain closed and sealed during production.
If they are designed to be opened for ventilation purposes, they shall be sealed by easy removable pest screens or other measures in order to avoid any contamination.

4.9.7 Based on hazard analysis and assessment of associated risk, external doors and gates shall be designed to prevent the ingress of pests; if possible, they shall be self-closing.

4.10 Receipt of goods and storage

4.10.1 All incoming goods, including packaging materials, shall be identified and checked for conformity against specifications/other legally required documentation and to a determined control plan. The control plan shall be risk based. Test results shall be documented.

4.10.2 The storage conditions and locations of raw materials including packaging materials, semi-processed and finished products as well as working materials shall in each case correspond to product requirements, shall not be detrimental to other products and shall minimize cross contamination.

4.10.3 Where relevant, for semi-finished products, maximum duration for storage shall be defined. When this duration is reached, the semi-finished product shall be re-evaluated before use.

4.10.4 Outdoor storage shall be kept to a minimum. Where goods are stored outside, hazard analysis and assessment of associated risk shall be undertaken in order to ensure that there is no risk of contamination or adverse effect on quality and product safety.

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

4.10.6 Products shall be clearly identified on receipt and when stored. Use of products shall be undertaken in accordance with the principles of First In/First Out and/or First Expired/First Out, in accordance with relevant industry best practices.

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

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

4.11 Transport

4.11.1 Before loading transport vehicles, their condition (e.g. absence of strange smells, high dust load, adverse humidity, absence of contamination, pests, mold) shall be checked and actions taken, if necessary. At the raw materials and packaging materials receipt, checks shall be made in order to assess that transportation has taken place under good conditions.

4.11.2 In case of transport of dangerous goods, the company shall ensure that all the relevant legislative requirements are fulfilled.

4.11.3 Adequate hygienic requirements for all transport vehicles and equipment used for loading/unloading (e.g. hoses of silo installations) shall exist. There shall be records of the actions taken.

4.11.4 Where relevant, loading and unloading areas shall have equipment in place to protect transported products from external influences.

4.11.5 Security of transport vehicles shall be appropriately maintained.

4.11.6 Where a company hires a third-party transport service provider all the requirements specified within section 4.11 shall be clearly defined in the respective contract or the service provider shall be subject to IFS Logistics requirements.

4.12 Maintenance and repair

4.12.1 An adequate system of maintenance shall be in place. This system shall be maintained and documented, covering all critical equipment (incl. transport) for compliance with product requirements. This applies both for internal and external maintenance activities.

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

4.12.3 All materials used for maintenance and repair shall be fit for the intended use.

4.12.4 Failures of plant and equipment (incl. transport) covered by the maintenance system shall be documented and reviewed so as to adapt the maintenance system accordingly.

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

4.12.6 Where a company hires a third-party maintenance and repair service provider, all the company specified requirements regarding material and equipment shall be clearly defined, documented and maintained.

4.13 Equipment

4.13.1 Equipment shall be suitably designed and specified for the intended use. Before commissioning, it shall be verified that the product requirements are complied with.
Consumables used for equipment should not affect the quality of the product.

4.13.2 Equipment shall be designed and locationed so that cleaning and maintenance operations can be effectively performed.

4.14 Traceability

4.14.1 KO N° 4: A traceability system shall be in place which enables the identification of product lots and their relation to batches of raw materials, packaging in direct contact with product and packaging intended or expected to be in direct contact with product. The traceability system shall incorporate all relevant processing and distribution records. Traceability shall be assured and documented until delivery to the customer.

4.14.2 Downstream and upstream traceability records (from production sites to the customers) shall be available. The timeframe for producing these records for review shall be compliant with customer's requirements.

4.14.3 Traceability shall be in place to identify the relationship between batches of final products and their labels.

4.14.4 The traceability system shall be tested on a periodic basis at least annually, and each time the traceability system changes.
The test shall verify downstream and upstream traceability (from raw materials to delivered products and vice versa), including quantity checking. Test results shall be recorded.

4.14.5 Based on hazard analysis and assessment of associated risk, on legal requirements and on customer specifications, traceability shall be ensured at all stages, including work in progress, post treatment and rework.

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

4.14.7 Identified samples representative of the manufacturing batch shall be stored appropriately and kept until expiration date of the finished product and, if necessary, for a determined period beyond this date ("sample bank").

5 Measurements, analyses, corrective actions and management of incidents

5.1 Internal audits

5.1.1 Effective internal audits shall be conducted according to a defined agreed audit program and shall cover at least all requirements of the IFS HPC Standard. Scope and frequency of internal audits shall be determined by risk assessment. This is also applicable for off-site storage locations owned or rented by the company.

5.1.2 Internal audits shall be carried out at least once a year in all departments.

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

5.1.4 Audit results shall be communicated to the senior management and to responsible persons of relevant department. Necessary corrective actions and a schedule for implementation shall be determined, documented and communicated to every relevant person.

5.1.5 It shall be documented, how and when the corrective actions resulting from the internal audits shall be verified.

5.2 Factory inspections

5.2.1 Regular factory inspections shall be planned and carried out to assess criteria such as product control, hygiene, foreign material hazards, personal hygiene and housekeeping.
Any deviation and the associated corrective actions shall be documented.

5.3 Manufacturing process validation and control

5.3.1 The criteria for process validation and control shall be clearly defined. All processes critical to product safety and product compliance shall be validated.

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

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

Where applicable, a batch number shall be assigned.

5.3.3 In circumstances where the control of process and working environment parameters (temperature, time, pressure, chemical properties, etc.) is essential to ensure the product requirements are met, such parameters shall be monitored and recorded continuously and/or at appropriate intervals.

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

5.3.5 Where relevant, all rework operations shall be validated, monitored and documented. These operations shall not affect the product requirements.

5.3.6 There shall be appropriate procedures for prompt notification, recording and monitoring of equipment malfunction and process deviations.

5.3.7 Process validation shall be performed using the collected data that is relevant for product safety and the processes. If substantial modifications occur, a revalidation shall be carried out.

5.4 Calibration, adjustment and checking of measuring and monitoring devices

5.4.1 The company shall identify the measuring and monitoring devices required to ensure compliance with product requirements. These devices shall be listed and clearly identified.

5.4.2 All measuring devices shall be checked, adjusted and calibrated, under a monitoring system, at specified intervals and in accordance with defined recognized standard/methods.
The results of these checks, adjustments and calibrations shall be documented. Where necessary, corrective actions on devices, on processes and products shall be carried out.

5.4.3 All measuring devices shall be used exclusively for their defined purpose.

5.4.4 The calibration status of the measuring devices shall be clearly identified (labeling on the device or on a list of tested devices).

5.5 Quantity checking (quantity control/filling quantities)

5.5.1 The frequency and methodology of quantity checking shall be determined so that the legal requirements and customer specifications, or if relevant, guidelines for nominal quantity are met.

5.5.2 A procedure shall exist to define compliance criteria for lot quantity checking.

5.5.3 Checks shall be implemented and recorded, according to a sampling plan which ensures a proper representation of the manufacturing lot.

5.5.4 Results of these checks shall be compliant with defined criteria for all products ready to be delivered.

5.5.5 If relevant, all equipment used for final checking shall be legally approved.

5.6 Product analysis (including quality checks)

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

5.6.2 Analyses, which are relevant for product safety and legality, shall preferably be performed by laboratories having appropriate accredited programs/methods (ISO 17025). If the analyses are performed by a factory internal or a laboratory not having appropriate accredited programs/methods, the company shall be able to demonstrate that the results are reliable.

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

5.6.4 A control plan shall be drawn up for internal and external analysis, based on hazard analysis and assessment of associated risk and based on additional information regarding product quality (e.g. complaints). This plan shall cover raw materials, semi-processed and finished products and shall include the types of tests, their frequency and critical limits, which are linked to the specification limits. The test results shall be documented.

5.6.5 The analytical results shall be reviewed regularly and trends identified. Appropriate measures shall be introduced promptly for any unsatisfactory results, or where such trends indicate unsatisfactory results.

5.6.6 Where internal analysis is undertaken, qualified and trained personnel shall be in place, as well as appropriate equipment and premises.

5.6.7 Results of checks on finished products including rework material shall be reviewed by authorized personnel in order to verify the conformity of the finished and semi-finished products with the acceptance criteria.

5.6.8 Where relevant, for verification of finished product quality, 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 characteristic. The results of these tests shall be documented.

5.6.9 Based on any internal or external information on product risk which may have an impact on product safety and/or quality, the company shall update its control plan and/or take any appropriate measure to control the compliance of the finished products.

5.7 Product quarantine (blocking/hold) and product release

5.7.1 A procedure shall be in place for the quarantine and release of all raw materials including packaging materials, semi-processed and finished products, and processing equipment. The procedure shall ensure that only products and materials conforming to product requirements are processed and dispatched.

5.8 Management of complaints from authorities and customers

5.8.1 A system shall be in place for the management of product complaints and, when relevant, shall take into account specific procedures (e.g. undesirable effects).

5.8.2 All complaints shall be assessed by competent staff. Where it is justified, appropriate actions shall be taken immediately.

5.8.3 Complaints shall be analyzed with a view to implementing preventive and corrective actions which avoid the recurrence of the non-conformity.

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

5.9 Management of incidents, product withdrawal and product recall

5.9.1 A documented procedure shall be defined for management of incidents and of potential emergency situations that impact product safety, legality and quality. This procedure shall be implemented and maintained. This procedure includes as a minimum: the nomination and training of a crisis team, an alert contact list, sources of legal advice (if necessary), contacts availability, customer information, and a communication plan, including information to consumers.

5.9.2 Updated emergency contact details (such as names and phone numbers of suppliers, customers and competent authorities) shall be available. A person of the company, who has the authority to initiate the incident management process, shall be permanently available.

5.9.3 The company shall assign the responsibility(ies) for the external communication (crisis management, authorities and communication with media) to specific personnel.

5.9.4 KO N° 5: There shall be an effective procedure for the withdrawal and recall of all products, which ensures that involved customers are informed, as soon as possible.
This procedure shall include a clear assignment of responsibilities.

5.9.5 The feasibility, effectiveness and timeliness of implementation of the withdrawal procedure shall be subject to regular internal testing, based on hazard analysis and assessment of associated risk, but carried out at least once a year. This shall be carried out in a manner to ensure the effective implementation and operation of the procedure.

5.10 Management of non-conformities and non-conforming products

5.10.1 A procedure shall exist for the management of all non-conforming raw materials including packaging materials, semi-finished and finished products and processing equipment. This procedure shall include always the following criteria, but may include other requirements:

- isolation/quarantine procedures,
- risk assessment,
- identification (e.g. labeling),
- decision about the further use (e.g. release, destruction, rework/post-treatment, blocking, customer information, rejection/disposal).

5.10.2 The responsibilities for the management of non-conforming products shall be clearly identified. The procedure for the management of non-conforming products shall be understood by all relevant employees.

5.10.3 Where non-conformities are present, immediate corrections shall be taken to ensure that product requirements are complied with.

5.10.4 Out of specification finished goods or finished goods that do not meet other legal and/or customer requirements are not allowed to be placed on the market. In case of private labels, exceptions shall be agreed in writing with the contract partners.

5.11 Corrective actions

5.11.1 A procedure shall be in place for the recording and analysis of the non-conformities with the objective to avoid recurrences by the provision of preventive actions and/or corrective actions.

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

5.11.3 The effectiveness of the implemented corrective actions shall be documented and shall be validated.

6 Product Defense (optional chapter)

Note: this chapter is only applicable:

- to companies which produce or export goods in countries, which are subjected to product defense legislation,
- in case of specific customer requirement.

For the other companies, the chapter shall be assessed as not applicable by the auditor (N/A).

6.1 Senior Management responsibility

6.1.1 The company shall have a documented product defense procedure in place to address product defense risk from products and establish, implement and maintain a system to reduce or eliminate the identified risk.

6.1.2 A Product Defense assessment shall be conducted annually or upon changes that affect product integrity.

6.1.3 Responsibilities for Product Defense shall be clearly defined. Those responsible shall be key staff or shall have access to the senior management team.

6.1.4 Senior management shall have an internal communication system to inform and update staff about relevant security issues.

6.2 Site security

6.2.1 Based on the product defense procedure and legal requirements, the senior management should define and communicate the areas in which authorized personnel are allowed to access.

6.3 Visitor and personnel security

6.3.1 Visitor policy shall contain requirements relating to product defense.

6.3.2 Employee hiring and employment termination practices shall consider security aspects as permitted by law.

6.3.3 The company shall incorporate product security awareness, including information on how to prevent, detect and respond to tampering or other malicious, criminal, or terrorist actions or threats, into training programs for staff, including temporary, contract, and volunteer staff.
The training shall regularly take place and shall be documented.

6.4 Documentation requested by legislation

6.4.1 If legislation makes registration or on-site inspections necessary, these shall be carried out and evidence shall be provided.

6.4.2 A documented procedure shall be in place for managing external inspections and regulatory visits (if applicable). Relevant personnel shall be trained to execute the procedure.

ANNEX 1: Glossary

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

Assessor (for accreditation bodies)	Person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a Conformity Assessment Body.
Audit	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.
Based on hazard analysis and assessment of associated risk	There are different types of risk analyses (e.g. Risk Matrix, RPN, FMEA, HACCP, etc). Different processing industries prefer different kinds of tools to evaluate their hazards, however the specified IFS term is commonly used as it reflects the most common type of hazard analysis/risk assessment. It shall be seen as the generic term for this topic and companies may use own systems to evaluate their hazards.
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 within the production process identified by the hazard analysis and risk assessment at which control shall be applied, and which is essential to have it under control, in order to limit or to reduce the harm to the consumer and/or the potential severity of damage to an acceptable level and/or to guarantee a compliant product. Loss of control at this step may increase the likelihood of a health damage of the consumer.
Company	Organisation.
Composition	Quantified list of components/ingredients used to define the semi-finished or the finished product and how these are brought together. (e.g. batch formulation, recipe, etc.).
Consumables	Materials such as cleaning agents and lubricants that are used up during cleaning, sanitization or maintenance operations.
Contamination	Occurrence of any undesirable matter, such as chemical, physical and/or microbiological matter in the product.
Correction	Any action that is taken to eliminate a non-conformity. However, corrections do not address root causes. When applied to products, corrections can include reworking products, reprocessing them, regrading them, assigning them to a different use, or simply destroying them.
Corrective action	Measures that are taken to eliminate the causes of existing non-conformities in order to prevent recurrence. The corrective action process tries to make sure that existing nonconformities and potentially undesirable situations don't happen again.

CP – Control point	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.
Customer	Anyone who receives products or services (outputs)from a supplier. Customers can be either people or organizations and can be either external or internal to the supplier organization. Examples of customers include clients, consumers, users, etc.
Deviation	Non-compliance with a requirement but there is no impact on safety related to products and processes. In the IFS, deviations are requirements scored with a B, C or D and KO requirements scored with a B.
Factory inspection	Factory inspection covers specific subjects and can be carried out by any appropriate person. That means regular visits in any areas, for any purposes, to check the conformity (hygiene, pest control, product control, fabrication, foreign body hazards, surrounding control etc.).
FEFO (first expired-first out)	Common process, in which the first expiring products–relating to the shelf life–are removed from storage first.
FIFO (first in-first out)	Common process, in which the first received products are removed from storage first.
Flow diagram	A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular item.
Final product specification	Written statement (paper or electronic document) encompassing all relevant parameters of the final product (chemical, physical, microbiological, appearance etc.). It takes into account parameters of the entire production process. The specification is used to demonstrate the compliance of the finished product compared to a specification given by the client in case of private label or given by the producer/company in case of branded goods. Deviations from the end product specification need to be agreed on with the customer.
Formula	Exhaustive description of quantity and quality of raw materials to be used to process the products, as required in customer specifications. Formula can also include technological parameters and specific "know-how" on the process.
Good Manufacturing Practices	The good manufacturing practices constitute the practical development of the quality assurance concept through the description of the plant activities that are based on sound scientific and state of the art judgement and risk assessment. This allows a producer to define the activities that enable obtaining a safe product that meets defined characteristics e.g. appropriate equipment and envirnonment as well as safety aspects in the whole process/area. In the IFS HPC Standard the good manufacturing practices/pre-requisites programs are aimed to be implemented prior performing the hazard analysis and risk assessment. In the event of no specified good manufacturing practices in the scope of activity, the company shall develop its own GMP's.

Hazard	A biological, chemical or physical agent with the potential to cause an adverse health effect.
Hazard analysis	The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for product safety and therefore shall be addressed in the risk assessment.
Head office assessment (for accreditation bodies)	Assessment of the Conformity Assessment Body Head Office.
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. These measures are aimed to ensure the quality of the IFS schemes.
Internal audit (versus factory inspection)	General process of audit, for all the activity of the company. Conducted by or on behalf of the company for internal purposes. Internal auditing is an independent, objective assurance and consulting activity designed to add value and improve an organization's operations. It helps an organization accomplishes its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes.
Monitoring	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control.
Non-conformity	Non-fulfilment of a specified requirement. Non-conformity can be given in non-respect of legislation, law, product safety, internal dysfunctions and customer issues. In the IFS, defined non-conformities are Majors and KO's scored with a D.
Pest	Any animal or insect such as birds, rodents, cockroaches, flies, and larvae that may carry pathogens and could contaminate raw materials including packaging and the product.
Procedure	Specified way to carry out an activity or process. Procedures shall be implemented and the elaboration of procedures can be done by documents or process description (e.g. flowchart).
Process waters	According to IFS HPC Standard the process waters are defined as waters used within the facilities (e.g. sanitary facilities, etc. …) and also waters used as an ingredient or used for cleaning activities.
Product	Result of a process or activities transforming inputs into outputs. Products include services. In the context of this Standard a product is to be considered a HPC product (e.g. cosmetics, diapers etc. …)
Product Defense	All the actions taken in order to protect products from deliberate or intentional acts of contamination or tampering. Intentional adulteration may include biological, chemical, physical or radiological agents.

Product development	The creation of products with new or different characteristics that offer new or additional benefits to the customer. Product development may involve modification of an existing product or its presentation, or formulation of an entirely new product that satisfies a newly defined customer who wants a market niche. In the IFS HPC 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 group	Grouping of products due to similar characteristics or legal requirements (e.g. cosmetics, household chemical products, etc.).
Product recall	Any measure to achieve the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor.
Product requirements	Includes: product safety, product quality, product legality, process and customer specification.
Product withdrawal	Any measure to prevent the distribution, display and offer of a product out of specification and/or dangerous to the consumer.
Raw material	Any ingredient, including an ingredient that is a mixture of single components, which is used in the manufacture of semi-finished or a final product for commercial distribution and is supplied to a product manufacturer, packer, or distributor by a raw material manufacturer or supplier.
Raw material specification	A document describing detailed product features, attributes and processing factors that enable the user or the document (i.e. supplier) to produce or supply material that will fulfil its intended use.
Reviewer	Person of the certification body in charge of assessing the IFS audits reports before a certification decision is made. The tasks of the reviewer shall be at least: • to check the overall consistency of the audit reports. • to check if the audit reports are properly completed (e.g. compulsory fields, etc.) • to check if the findings are well described and if the justifications are relevant. • to check if the corrective actions 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 always be documented.
Rework	Reprocessed semi-finished or finished product.
Risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s).

Risk assessment	The purpose of risk assessment is to provide evidence-based information and analysis to make informed decisions on how to treat particular risks and how to select between options. Risk assessment is the overall process of risk identification, risk analysis and risk evaluation: • Risk identification is the process of finding, recognizing and recording risks. • Risk analysis is about developing an understanding of the risk. It provides an input to risk assessment and to decisions about whether risks need to be treated and about the most appropriate treatment strategies and methods. • Risk evaluation involves comparing estimated levels of risk with risk criteria defined when the context was established, in order to determine the significance of the level and type of risk.
Risk management	The process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options. In terms of IFS HPC Standard the risk management includes the hazard analysis and the risk assessment.
Safety	Freedom of unacceptable risk for people & for consumer health, concerning the product.
Safety Data Sheet (SDS)	The safety data sheet information is principally intended for use by professional users and must enable them to take the necessary measures as regards the protection of health, safety and the environment at the place of work.The safety data sheet may be supplied on paper or electronically, provided that the addressee has the necessary means of receiving it.
Senior management	Executive management.
Sign off witnes audit (before gaining IFS HPC auditor approval)	The auditor shall be witnessed during a sign-off witness audit. There are two possibilities: • option 1: the witness audit is performed during an audit covering traceability, risk assessment, product safety, legal compliance of destination countries, GMP's in the relevant industries (2nd party audit or accredited scheme or "managed" scheme), before or after having passed the IFS exams. • option 2: the witness audit is performed during the first IFS HPC certification audit of the auditor (after having passed the IFS exams). The auditor will only be classified as "active" in the database when the evidence of the performed witness audit is approved by IFS.
Site	A unit of the company.
Supplier	A supplier provides products and/or services to a customer.
System	Set of interrelated or interacting elements. System is a planned, sustainable structured course of action. Depending on the complexity, documentation is recommended. System includes: documentation, procedure description, control/monitoring, corrective action, site plan.

Traceability	Ability to trace and follow a product through all stages of production, processing and distribution.
Validation	To demonstrate that the essential operational parameters identified by scientific documentation were met during a set period. Basis of process validation is the collection and evaluation of data, from the process design stage throughout production. Moreover, the aim of process validation is to establish by a scientific evidence that a process is capable of consistently delivering quality products. Re-assessment might be necessary annually or whenever changes occur that affect the process and its results.
Verification	To support that the process is functioning as intended on an ongoing basis by monitoring one or more of the essential operational parameters, which may include testing of the results.
Witness assessment (by accreditation bodies)	Assessment of the Conformity Assessment Body when it is carrying out conformity assessment services within its scope of accreditation.
Witness audit (to be performed every 2 years, for IFS HPC approved auditors)	To be assessed during a HPC scheme accredited on-site witness audit against ISO/IEC 17065 at an interval of once every two (2) years by the certification body, in order to evaluate her/his competence (e.g. auditing techniques, etc.).

ANNEX 2: Cross reference annex IFS HPC versus ISO 22716

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

Cosmetics GMP's shall be audited within the IFS HPC audit. Moreover, IFS would like some transparency on the following requirements:

IFS HPC requirement number	ISO 22716 requirement number
1.2.1	3.2.1.1
1.2.2	3.3.2
1.2.3	3.3.1
1.2.4	3.3.2 b) f)
1.2.6	3.2.1.2 & 3.2.2
1.2.7	3.2.1.3
2.1.1.3	17.3.3 a) e)
2.1.1.4	17.4
2.1.1.5	17.4
2.1.1.6	17.3.3 f)
2.1.2.1	17.3.3 b) c) & 17.5 & 17.5.2
2.1.2.2	17.3.3 b) & 17.3.4 d)
2.1.2.3	17.5.2
2.1.2.4	17.3.3 b)
3.2.1.1	3.5.1.1 & 3.5.1.2 & 3.5.1.4
3.2.1.2	3.5.1.1 & 3.6
3.2.1.4 & 3.2.3.1	3.5.2
3.2.2.2	3.5.1.3 & 3.5.1.5
3.3.1	3.4.2.1 & 3.4.2.2 & 3.4.2.3 & 3.4.4
3.3.2	3.4.3
3.3.3	3.4.4
3.3.4	3.4.2.5
3.4.5 & 3.4.6 & 3.4.7	4.6
4.2.1.2	6.4.4
4.2.1.4	6.6.5

IFS HPC requirement number	ISO 22716 requirement number
4.3.1.2	6.7
4.4.4	6.2 a) & 12.1
4.4.5	6.2 b) c)
4.4.8.2	12.1
4.5.4.1.1	4.1.1
4.5.4.1.2 & 4.5.1.3 & 4.5.1.4 & 4.5.1.5 & 4.5.1.6	4.5
4.5.4.1.8	4.9.2 & 11.1
4.5.4.2.1	4.7.1
4.5.4.2.3	4.8
4.5.4.2.6	4.9.3.c)
4.5.4.3.1	6.8
4.5.4.3.2	6.8.1 & 6.8.2
4.5.4.3.3	6.8
4.6.1	4.10.2 & 4.10.4 & 5.5.1
4.6.4	4.10.3 & 5.5.2
4.7.1	11.2
4.7.3	11.4
4.9.1	4.13.2 & 4.13.3
4.9.6	4.5.2 & 4.13.1
4.9.7	4.13.1
4.10.2	6.6.1 & 6.6.4
4.10.3	7.2.6.2 & 7.6.2.3
4.10.5	9.7.1
4.10.6	6.6.7 & 8.3.5 & 8.3.6
4.10.7	6.6.8
4.11.1	6.3.2
4.12.1	5.6.1
4.12.2	5.6.2
4.13.1	5.2.1 & 5.7
4.13.2	5.3.1 & 5.3.3
4.14.1	7.2.3 & 7.2.4.3 & 7.3.3 & 8.3.4
4.14.6	7.3.4
4.14.7	9.8.1
5.1.1	16.1

IFS HPC requirement number	ISO 22716 requirement number
5.1.2 & 5.1.3	16.2.1
5.1.4	16.2.2
5.1.5	16.3
5.3.3	10.2.1 & 15
5.3.4	10.2.2
5.4.2 & 5.4.3	5.4.1 & 5.4.2
5.6.3	9.2.2
5.6.5	9.4
5.6.7	10.2.3
5.7.1	6.5.1 & 8.2.1 & 9.1.2
5.8.1 & 5.8.2 & 5.8.3 & 5.8.4	14.2
5.9.1 & 5.9.2 & 5.9.4 & 5.9.5	14.3
5.10.1	9.5 & 10
5.11.1 & 5.11.3	13.2
6.2.1	3.3.1.3

PART 3

PART 3
Requirements for accreditation bodies, certification bodies and auditors

0 Introduction

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

1 Requirements for the accreditation bodies

1.1 General requirements

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

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

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

Decisions on accreditation can only be made following a recommendation of an accreditation committee or a competent person.

In general, the accreditation committee engaged in IFS HPC accreditation activity or the competent person shall have sufficient knowledge of the IFS HPC Standard, and related normative documents. Therefore they shall have taken part in an IFS HPC awareness/reviewer course organize by IFS or shall be able to demonstrate equivalent knowledge level as confirmed by IFS.

In case of a committee, the trained person provides the other members of the accreditation committee with the necessary information. This information is based on the main points of the IFS HPC awareness/reviewer course with the main emphasis on Part 1 (IFS HPC Audit Protocol), Part 3 (Requirements for accreditation bodies, certification bodies and auditors) and Part 4 (Reporting, certificate, etc.).

1.3 Competences of the assessor of the accreditation body

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

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

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

Witness assessor(s) shall:

- have taken part in the IFS HPC awareness/reviewer organize by IFS, or shall able to demonstrate an equivalent knowledge level as confirmed by IFS,
- have taken part in a course related to hazard analysis and risk assessment,
- have a minimum of two (2) years of experience in the HPC manufacturing industry.

Head office assessors shall:

- have specific knowledge of the IFS HPC Standard,
- have specific knowledge of the relate normative documents.

1.4 Frequency of the assessment of certification bodies

For initial assessment, a head office assessment (with review of at least one (1) full certification process) and at least one (1) witness assessment shall be performed.

The certification body is allowed to perform a maximum five (5) audits before gaining accreditation. In this case, at least one of the audits shall be assessed by the accreditation body (witness assessment) and all audits (including at least one (1) full certification process) shall be reviewed by the accreditation body during the initial headquarter assessment.

For renewal assessment, a head office assessment (with review of at least one (1) full certification process) and at least one (1) witness assessment shall be performed.

For the surveillance within an accreditation cycle, there shall be:

- a minimum of one (1) head office assessment a year,
- a minimum of one (1) witness assessment every two (2) years shall take place.

Note: in order to be in line with accreditation body own surveillance cycles, a flexibility of three (3) months as a maximum can be allowed for the interval between two (2) assessments.

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

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

For consecutive witness assessment, the accreditation body shall, wherever possible, select two (2) different certification body's IFS HPC auditors with different scopes.

1.5 Accreditation of an international certification body

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

1.6 Conditions for regaining accreditation after withdrawal or suspension

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

1.7 Transfer of certification

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

2 Requirements for the certification bodies

Certification bodies intending to issue IFS HPC certificates shall comply with the following rules.

2.1 ISO/IEC 17065 IFS accreditation process

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

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

2.2 Contract with the IFS Management GmbH

After gaining IFS accreditation to ISO/IEC 17065, in order to be allowed to perform IFS HPC audit, the certification body shall sign a contract with IFS in which it commits to meet all IFS requirements. The certification body is not authorized to issue IFS HPC certificates (except the first witness assessment(s) during the accreditation process) before having signed this contract.

2.3 Certification decision

The persons involved in the different steps within the certification decision process shall meet the requirements described in chart n° 1.

Chart N° 1: function and requirements related to certification decision process

Function	Profile/requirements	Further requirements
Technical report assessment (review)	IFS auditor (for any IFS production scheme) + participation at IFS HPC awareness / reviewer course or IFS reviewer (for any IFS scheme) + participation at IFS HPC awareness / reviewer course + participation each year at the certification body in-house training course on IFS HPC (see also section 3.4) or fulfill the following requirements: • to have an university degree in the chemical industry, pharmacy, or comparable, • to have attended (as auditor or observer) **at five (5) complete audits** (related to product safety and/or quality of HPC products) **in the last five (5) years,** • to have participated at the IFS HPC awareness/reviewer course and • to participate each year at the certification body in-house training course on IFS HPC (see also section 3.4).	This shall not be the person who performed the audit. The review shall be documented.
Recommendation for a certification decision	• by a person: IFS auditor, IFS trainer or IFS reviewer (for any IFS scheme) or • a committee: at least one of the members of the certification committee shall be an IFS auditor, IFS trainer or IFS reviewer (for any IFS scheme)	

Function	Profile/requirements	Further requirements
Certification decision	• the certification body (not a subcontracted certification body)	The certification decision is made following recommendation by a competent person or a certification committee. The decision shall be made by the certification body and there will be no involvement of the person who performed the audit. The decision is taken by the certification body, and not a subcontracted certification body.

2.4 Certification bodies' responsibilities for IFS HPC auditors (including freelancers)

Certification bodies have the following responsibilities:

- to manage witness audits (by accreditation bodies and/or by Integrity Program),
- to ensure that at least one member of their staff is an IFS trainer who has taken part in the IFS HPC awareness/reviewer course. The trainer is responsible for the in-house training of all auditors who intend to become IFS HPC auditors or who are already IFS HPC approved auditors. Persons intending to become IFS HPC trainers shall meet the requirements mentioned in section 2.5,
- to perform a sign-off witness before or after she/he has applied for the IFS HPC examinations, based on the chosen option (more details in section 3.2.1),
- to ensure that the auditor is competent in relation to the scope of the audit and its execution and is able to apply relevant laws and regulations, IFS and internal certification body's requirements,
- to ensure that auditor acts impartially (e.g. acting against IFS rules, acting as a consultant, or having involvement with/or acting on the behalf of the company being audited during the previous two (2) years),
- to ensure that no auditor shall perform more than three (3) consecutive IFS HPC audits of the same production site (only applies for complete audits, whatever the time between them; follow-up and extension audits are not concerned by this rule),
- to ensure that an auditor is employed by only one IFS certification body for performing IFS HPC audits and this for a period of not less than 12 months,
- to sign an audit agreement for each audit, this includes a statement accepting all the above-mentioned requirements,
- to maintain auditor competences (continuous supervision by the certification body) and monitor audit execution of every auditor by on site witness audit at least once every two (2) years (see more details in section 3.4),

- to organize a one (1) day training session for IFS HPC auditors once a year for the purposes of sharing experience, calibration and updating knowledge of relevant legal requirements, etc. (more details in section 3.4). The reviewer–if not an IFS auditor–shall also attend this course,
- to maintain records of auditor competences and
- to be fully cognizant of the examination regulations provided by the IFS offices.

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

2.5 Specific requirements for trainers

IFS HPC trainers shall meet the following requirements:

- IFS auditor (for any IFS production scheme) + participation at the IFS HPC awareness/ reviewer course,

or

- to have an university degree in the chemical industry, pharmacy, or comparable,
- to have attended (as auditor or observer) **at ten (10) complete audits** (related to product safety and/or quality of HPC products) **in the last five (5) years** and
- to have participated at the IFS HPC awareness/reviewer course.

When a new version of the Standard is published, the certification body's trainer and reviewer shall take part in the IFS HPC awareness/reviewer course organized by IFS and carry out in-house training of all IFS HPC approved auditors, before performing audits based on the new version.

3 Requirements for IFS HPC auditors

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

Before applying for IFS examinations, auditors shall have signed a contract with the certification body (see ISO/IEC 17065 Standard), including the requirements described under section 2.4.

During an IFS audit, auditors shall as IFS good auditing practice dictates, use relevant sampling techniques, in order to investigate on-site the auditee's production processes and documentation and to check the fulfilment of IFS requirements. In particular, auditors shall perform, during the audit, a product traceability test.

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

3.1 Conversion of auditors to get the IFS HPC auditor approval

IFS has implemented specific rules for auditors already qualified for specific other schemes, in order to recognize already gained experience.

Therefore, for specific auditor approvals, requirements of chart n° 2 shall apply to an auditor who wishes to become an IFS HPC auditor.

Chart N° 2: requirements for auditors' conversion

Auditor approval	Further requirements	Approval for IFS HPC product scope
IFS PACsecure	Participation at IFS HPC product scope training for scope 3 (including exams)	3
BRC IoP	Participation at IFS HPC awareness/ reviewer course + IFS HPC product scope training for scope 3 (including exams)	3
BRC CP	Participation at IFS HPC awareness/ reviewer course + IFS HPC product scope training for related product scope(s) (including exams)	Related product scope(s)

Note: if the auditors are able to provide further evidences of experience/competence as mentioned under section 3.2, they may be approved for further IFS HPC product scopes.

3.2 Requirements for auditors before applying for the IFS HPC examinations

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

3.2.1 "Common" auditor approval process.

a) Education in the household and personal care sector:

- an **university science degree** in chemistry, pharmacy, microbiology or processing engineering or comparable degree (bachelor's and/or master's degree equivalents) **and two (2) years** professional experience in the household and/or personal care industry in relation to production activities (e.g. quality, production, R&D),

or

- if the candidate has a different education background: **five years (5)** professional experience in the household and/or personal care industry in relation to production activities (quality, production, R&D).

b) General audit experience
A minimum of ten (10) complete audits shall be performed by the auditor in the processing industry during the previous two (2) years. The audits shall have been carried out at different production sites.

c) Training in risk assessment
Evidence of knowledge acquired in relation to risk assessment.

d) Training in auditing techniques based on Quality Management System
Course duration: one (1) week/40 hours or equivalent.

e) Specific and practical knowledge for each applied product scope:

- at least two (2) years professional experience in the household and/or personal care industry in relation to production activities (quality, production, R & D) for each applied product scope,

  or

- at least ten (10) performed product oriented audits (including regulation, traceability, risk assessment, product safety and GMPs) against accredited or managed schemes or 2nd party audits, for each applied product scope.

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

f) Language

Additionally to their mother language, auditors **shall be fluent in English.**

g) Sign off witness audit

Before gaining IFS HPC auditor approval, the auditor shall be witnessed during a sign-off witness audit.

This sign-off audit can be performed according to two different options:

- **option 1:** the witness audit is performed during an audit covering traceability, risk assessment, product safety, legal compliance of destination countries, GMP's in the relevant industries (2nd party audit or accredited scheme or "managed" scheme), before or after having passed the IFS exams.
  The observer shall be an IFS approved auditor (for any production scheme) having taking part at the IFS HPC awareness/reviewer course,
- **option 2:** the witness audit is performed during the first IFS HPC certification audit of the auditor (after having passed the IFS exams).
  The observer/supervisor shall be an approved IFS HPC auditor for the relevant audit scope.

The certification body shall inform IFS offices about the date, the name of the audited company where the sign-off witness audit took place. An English copy of the report of the on-site witness audit shall be provided on request to the IFS offices.

The auditor will only be classified as "active" in the database when the evidence of the performed witness audit is approved by IFS.

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

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

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

3.2.2 Specific adaptation of auditor approval for candidates not completely fulfilling the requirements of the "common" auditor approval process (e.g. Quality Managers and/or similar position (R&D, …) in the household and personal care industry): IFS HPC "auditor in progress" program.

In case the applicant has professional experience in the HPC processing activities (fulfillment of requirements 3.2 a), c) and f)) but does not have enough auditing experience (no fulfillment of 3.2 b), d) and g)), she/he may go through the following process:

- participation in the IFS HPC training and examinations for auditors, organized by IFS, and
- participation in a "witnessing program", as described in chart n° 3.

Chart N° 3: witnessing program

N° of audits	Tasks	Possible audits types
1–3	Candidate shall observe an auditor (shadow observer)	Audit covering traceability, risk assessment, product safety, legal compliance of destination countries, GMP's in the relevant HPC manufacturing industries (2nd party audit or accredited scheme or "managed" scheme),
4–6	Active participation in the audit under supervision of an approved IFS HPC auditor	Audit covering traceability, risk assessment, product safety, legal compliance of destination countries, GMP's in the relevant HPC manufacturing industries (2nd party audit or accredited scheme or "managed" scheme),
7–9	Active participation in the IFS certification audit under supervision of an approved IFS HPC auditor	IFS HPC audit, not necessarily for the related product scope
10–witness audit	Lead auditor during an IFS HPC certification audit, under the supervision of an IFS HPC approved auditor	IFS HPC audit for the related product scope

Note: It may be possible to perform audits from one to three (shadow observer) before participating at the IFS HPC training, but audits from four to ten shall always be performed after the participation in the training and successful completion of the IFS exam.

3.2.2.1 Further rules of the IFS HPC "auditor in progress" program

- The observer, auditor or audit team, shall never be separated during the audit.
- Audits from four to ten, the IFS HPC audit reports shall include the names of the observers.
- Only one "auditor in progress" is allowed to attend these audits.
- The witnessing program shall be completed within two (2) years after the passed IFS exams. For each of these audits where observation is carried out, a report (template provided by IFS) shall be provided (upon request) to IFS. The number of the audit shall be documented in the report.

- Audits from one to nine can apply for scope extensions and can be performed in any IFS HPC product scope.

Finally, if the witness audit has been conducted satisfactory, the certification body shall inform IFS. The complete CV with a list of participated and witnessed audits shall be sent to IFS. If all requirements are fulfilled, the auditor will be activated in the database by IFS.

3.3 IFS HPC training and examinations for auditors

Auditors who comply with the requirements specified in section 3.2 shall take part in two (2) different courses and an examination process:

- a general course on IFS HPC Standard: the auditor can either take part in training course organized by IFS, or an in-house course organized by the certification body,

and

- a scope specific course(s), based on IFS HPC product scope(s) the auditor applies for. These scope specific courses are organized by IFS.

1) IFS HPC awareness/reviewer course
The general course is a two (2) days course and it is yearly organized by IFS.

But if the in-house option for this training is chosen by the certification body, it shall be performed with at least a one (1) day face-to-face meeting, and the remaining time may be organized through other means e.g. webinars. It shall address the following topics:

- Audit protocol
- Reporting
- IFS HPC checklist (overview)
- KO requirements
- Basic information on risk assessment
- Basic information on legislation

Note: the certification body can organize this course in-house (then, it is called "IFS HPC awareness/reviewer in-house"), as long as the following condition is fulfilled:

- to have a reviewer and/or trainer who has previously participated at the IFS HPC awareness/reviewer course provided by IFS.

2) Scope specific course(s), based on IFS HPC product scope(s) the auditor applies to
In accordance to the product scope(s) for which the auditor has applied for, the auditor shall additionally attend a one and a half (1,5) day IFS HPC product scope training course, organized by IFS.

Examinations
The examinations (general part + scope specific part(s)) shall take place during the training period.

Note: detailed examination regulations and schedules are provided by IFS and are available on line on the IFS website.

Upon successful completion of the examinations, the auditor is officially authorized to perform IFS HPC audits for the product scope(s) she/he's approved for.

The auditor is registered on the IFS database and a personal IFS HPC auditor certificate is issued (defining duration of validity, name of the certification body, name of the auditor, languages and approved IFS HPC product scope(s)).
The certificate validity begins when the participant is activated on the IFS database (in most cases the day of passing the examination) and is valid until the end of the second calendar year.

The auditor cannot perform IFS HPC audits when her/his IFS HPC auditor certificate expires. The certification body is responsible for maintaining their auditors' approval.

3.4 Maintenance of auditor's qualification

Auditor's registration shall be re-assessed before end of validity of the auditor certificates.

For maintaining their approval, auditors shall fulfil the following requirements:

- to attended and successfully completed an internal training by the certification body, each year. The certification body shall hold a one (1) day auditor course, for the purpose of sharing experience, calibration and updating knowledge of relevant legal requirements, etc. This training shall be lead (partly or entirely) by the IFS HPC trainer,
- to be assessed during a HPC scheme accredited on-site witness audit against ISO/IEC 17065 at an interval of once every two (2) years by the certification body, in order to evaluate her/his competence.
  This audit can be performed at any time during the year of end of validity of auditor certificate.
  The observer shall not be part of the audit (as a team member).
  If the on-site witness audit is performed during an IFS audit, the certification body shall specify the name of the observer in participants' list of the IFS audit report.

  Note 1: Witness audits performed by accreditation bodies during IFS HPC or IFS PACsecure audits are accepted as a replacement of witness audits performed by an observer from the certification body.

  Note 2: in case of an audit team in which the team can split during the audit (as both auditors have companies' products scopes), it is not possible to perform a witness audit by an observer, as the auditor who is witnessed doesn't perform a complete audit. However, if the team does not split, it is possible to do so for the lead auditor, as it will be possible to witness the auditor during a complete audit.
- to have performed a minimum of ten (10) IFS HPC audits every two (2) years and
- to have attended and successfully completed every two calendar years, a two (2) days IFS HPC calibration course training, organized by IFS (subsequent to passing the initial examinations, the first mandatory calibration training shall be successfully completed in the second calendar year following the date on which the initial examination was successfully completed).

The documented evidence of all above mentioned requirements shall be provided to IFS offices within an updated CV at the time when the auditor requests for registration to the IFS HPC calibration training.

The auditor re-approval shall be managed every two (2) years, based on the same above mentioned rules.

If the above mentioned rules are fulfilled, the auditor certificate is extended to two (2) more years.

If at least one of the above mentioned rules are not fulfilled, the auditor needs to be reactivated within a one year period, through:

- an IFS HPC witness audit (the observer shall be an IFS HPC approved auditor for the relevant audit scope and the auditor shall act as a lead auditor) and
- if the auditor did not attend the calibration training during the last 2nd calendar year, she/he shall attend the next scheduled IFS HPC calibration training course and additionally attend the following course in order to maintain her/his cycle of qualification.

In case of non-compliance within the requested timeframe, the auditor shall lose IFS HPC registration and will need to apply for the initial approval process.

Example of duration of validity of the IFS HPC auditor's certificate:

- Date of passing the initial IFS HPC examinations: 25th of October 2015
- Date of end of validity for IFS HPC auditor certificate (initial approval): 31st of December 2017
- Auditor is authorized to perform IFS HPC audits between 25th of October 2015 and 31st of December 2017.
- In 2017, if the auditor has fulfilled all the above mentioned requirements, the new end of validity of the IFS HPC auditor certificate (re-approval) is: 31st December 2019.

3.5 Scope extension for IFS HPC approved auditors

IFS HPC auditors may, during the validity of their HPC auditor certificate, extend their scopes of registration.

For this scope extension, they shall provide the following evidence to IFS offices:

- same evidences as for the initial approval, based on new experience

or

- ten (10) complete witness audits against IFS HPC performed as observer, in the relevant scope. Audits shall be carried out on different production sites (the information shall be provided in the audit report). The observer shall have participated at all the steps of the audit (on-site audit, assessment and decision processes).

In addition to this evidence, they shall take part to the related IFS HPC scope specific training and exam(s).

3.6 Audit teams

3.6.1 General rules

In general, all members of the audit team shall be IFS HPC approved auditors. In case of auditing in teams, the following regulations apply:

- an IFS HPC audit team shall consist of IFS HPC approved auditors whose product scopes comply with the activities of the audited site,
- a lead auditor shall be always appointed,

- lead and co-auditor(s) shall always be approved for at least one product scope of the audit scope. Two (2) hours of the audit duration are not shareable; this additional time shall be allocated to the team, not to an individual auditor, for common tasks (e.g. opening and closing meeting, discussion about findings, etc.),
- the remaining time can be split as long as the auditor competences for product scopes are not misused during the audit. No "crossing over" is allowed. This means that, if the lead or the co-auditor(s) do not have, individually, all product scopes which are necessary for the audit, they have to assess all parts of the audit related to product scope knowledge together.

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

The minimum audit duration shall anyway be respected.

3.6.2 Specific rules for audit team and auditing three consecutive times

In general, the certification body shall assign a new audit team for the 4th consecutive audit of a production site.

If this is not possible (due to missing approval for product scope of their auditors), IFS may allow, as an exceptional case, the following sequence of auditor planning:

- year 1–3: lead auditor A + co-auditor B
- year 4–6: lead auditor B + co-auditor C
- year 7: lead auditor A or C + co-auditor A or C.

PART 4

PART 4
Reporting

1 Reporting

1.1 Audit overview (Annex 1)

The audit report shall be structured as follows:

- **cover page**

  The cover page of the audit report shall include:

  - the logo of the certification body,
  - the IFS HPC logo,
  - name of the audited company or site,
  - date(s) of audit,
  - name and address of the certification body,
  - the certification body's accreditation details,

- **audit overview**

  It shall contain the most important audit report criteria such as:

  - **audit details:**
    - name of the lead auditor and name of the co-auditor and the trainee, if applicable,
    - audit date(s) (in case of follow-up audit, the date of the follow-up audit shall additionally be specified),
    - duration of the audit,
    - previous audit date,
    - name of the certification body and the auditor who performed the previous audit,
    - name and address of the audited site,
    - name and address of the company (or headquarters),
    - GLN (Global Location Number), if available,
    - COID (IFS identification code number) as defined in the IFS database,
    - version of the standard.
  - **audit scope:**
    - audit scope (mandatory description of processes/products).
  - **audit participants' list**
    - list of key personnel present during the audit.
  - **final audit result**
    - final audit result (in case of follow-up audit, specify that a follow-up audit has taken place and that the Major non-conformity has been resolved).
  - **company profile**
    - company profile description (see next section 1.1.1).

1.1.1 Company profile including compulsory information

The company profile shall contain key information about the company. This information provides a general overview of the company's structure and activities which will allow customers to have a clear understanding of the main aspects related to company structure, organization, production, processes etc. In addition, other compulsory information, specified below shall be provided. If it is believed to be pertinent other additional information can also be provided.

The compulsory information shall be:

- year of construction of the site,
- a summary of key investments made by the company relating to the production with the particular reference to investments concerning product quality and safety (construction changes, machinery, etc.),
- the area of the site (manufacturing plus storage area) in square metres/feet,
- the number of employees listed according to full time (FTE) and part time employees, shift work, etc.,
- product groups and products per scope produced in the company,
- the number of production lines,
- a complete view of the company's processes,
- a description of product exclusions, if applicable,
- a description of outsourcing processes, if applicable,
- if the audited company also trades products, specify these products,
- in case of multi-site certification, if the certification body has decided to decrease audit duration time, provide explanations about the reasons for decreasing,
- the name and contact data (phone, fax, email …) of the contact person in case of emergency (e.g. withdrawal/recall),
- confirmation if the company fulfils the requirements about the use of IFS HPC logo,
- if the site is certified according to other schemes, specify scheme's names,

Below the company profile, name of the person in charge of assessing the report (reviewer).

1.2 IFS Audit report (Annex 2)

The main content of the IFS audit report is structured as follows:

- predetermined tables on evaluation of requirements and scoring and awarding of certificate,
- the result of the audit with level and percentage,
- the date of the renewal audit (follow-up audit, if applicable),
- a general summary in a tabular format for all chapters, listing the number of assessed scores for each chapter,
- observations on KO's and Majors (in case of follow-up audit, additional explanations on the reasons why the Major has been resolved),
- general summary table for all chapters, indicating the average score of each chapter
- overall summary of the audit,
- table of compulsory fields: for specific defined IFS HPC audit requirements, the auditor shall provide minimum explanations, even in case of A scoring (see section 1.2.1),

- comments concerning follow-up of corrective actions implemented from the previous audit,
- a list of all established deviations and non-conformities for each chapter (1 to 5, and 6 if applicable),
- a separate list (including explanations) of all requirements evaluated with N/A (not applicable),
- detailed audit report (checklist).

1.2.1 Table of compulsory fields for specific defined IFS HPC audit requirements

The following compulsory information shall lead to a more significant and descriptive IFS HPC audit report, even if the auditee fulfils nearly all IFS HPC requirements. The additional content will give more precise information about the auditee. This will add value for every user/reader of the IFS audit reports. The auditor is requested to provide, during an audit, and even in the case of an A evaluation, an additional justification and/or further background information of these specific requirements for the audited company.

In every case, the auditor shall provide written supplementary information about the procedures of the audited company, as regards to the 6 KO requirements.

Part of the audit report	Number of IFS HPC requirement	Compulsory remarks to be added
Corporate policy	1.1.4	How the company communicates the information to the employees (minimum description)
Senior Management Responsibility	KO N° 1	Minimum description (e.g. how the Senior Management ensures that the employees know their responsibilities, etc.)
Record keeping	2.1.2.3	Duration of record keeping for "product safety and legality related" records.
Hazard analysis and risk assessment	KO N° 2	List CCPs with associated critical limits. If the company does not have any CCP this shall be specified.
Product specifications	KO N° 3	Minimum description (e.g. what is the evidence that specified recipe/formulation is followed?
Laboratories	4.5.4.1.9	• Which analyses are performed in the own laboratory? • Which analyses are performed by an external laboratory?
Traceability	4.14.4	Summary of the traceability test result. In case of a problem found provide precise information relating to the problem
	KO N° 4	Describe the traceability system from the raw materials to distribution

Part of the audit report	Number of IFS HPC requirement	Compulsory remarks to be added
Legislative framework	4.3.1.5	To list if applicable: • the name of the person responsible for the product safety/quality in the company, • the name(s) of independent assessor(s) working for the company.
Procedure of withdrawal/recall	KO Nº 5	The auditor shall provide the following information: • How many withdrawals and recalls have been occurred since the last audit? • Specify product(s) involved • Specify the cause of the withdrawal and product recall.
Product analysis (including quality checks)	5.6.1	Specify if there is an internal microbiologist
Complaints management	5.8.2	Details concerning complaints raised from consumers, clients (e.g. retailers) and authorities.
Corrective actions	KO Nº 6	Details of the last corrective actions taken.

1.3 Action plan (Annex 3)

The auditor/certification body describes and explains all identified deviations and non-conformities (KOs, Majors) in each chapter in the action plan, which has a specified format.

1.4 Minimum requirements for the IFS HPC certificate (Annex 4)

After a successful completion of the IFS HPC audit, the certification body shall issue a certificate. For the purposes of international recognition, and to be understandable, IFS HPC certificate granted by the certification body shall include the following information:

- the name and address of the certification body, including its logo,
- the logo of the accreditation body or its name and registration number,
- name and address of the audited company,
- COID (IFS identification number) as defined in the IFS database,
- name and number of product scope(s),
- description of product exclusions, if applicable,
- description of the audit scope (with compulsory descriptions of processes/products),
- description of outsourcing process (es), if applicable,
- level achieved,
- audit score in percentage, if required by the customer or by the audited company,
- if the chapter related to Product Defense was assessed, this shall be stated on the certificate (under the audit scope: "Product defense chapter was assessed"),
- date of the audit (last day of the audit),
- date of follow-up audit, if relevant,

- next audit to be performed within the time period (renewal audit),
- certificate issue date,
- the date of expiration of the certificate (the certificate validity shall remain the same each year as described in the Audit Protocol, Part 1),
- name and signature of the certification body's person (s) responsible for the certification decision as described in Part 3 of the Standard,
- place and date of signature,
- the current IFS HPC logo.

2 Software auditXpressX™

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

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

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

Every IFS audit data shall be uploaded to the IFS database by the certification body (uploading shall include the audit report, action plan and certificate).

There are 5 user groups which have access to the IFS database:

- auditors
- certification bodies
- certified companies
- consultants (only Americas)
- retailers and other users.

The different groups' access rights are as follows:

Auditors:

- Manage their own data

- Download the own auditor profile, which includes all information available at the IFS Database about the auditor-standards, scopes, examinations, overview about the performed audits
- Receive IFS newsletter

Certification bodies

- Manage their certified companies and upload IFS audit reports, action plans and certificates.
- Suspend certificates under specific situations.
- Manage all IFS audits dates via the diary function, enabling other IFS users (e.g. retailers, companies, etc.) to have a good overview of the scheduled audits. It is mandatory to upload in the diary function of the IFS database all audits dates, at latest two (2) weeks before the audit.
- Manage their accounts.
- Possibility to compare two consecutive IFS audit reports and action plans, for internal auditor training and calibration purposes.
- Download the IFS logo(s).

Certified companies/suppliers

- Access to their own data.
- Possibility to unlock retailers and other users for their achieved percentage, detailed IFS audit report and action plan.
- Possibility to compare two consecutive IFS audit reports and action plans, for internal auditor training and calibration purposes.
- Download the IFS logo(s).
- Manage their certification bodies.
- Manage company personnel access (create sub-accounts) to the audit data.
- Search for other certified companies.
- Manage their suppliers using a "favourites" option.
  - Access for the headquarters of certified companies.
  - A "headquarter" access for certified companies can be set up which allows a company headquarter to administer all of their certified sites through a single access point.

Consultants (only Americas)

- Manage own data about the standards, scopes, languages etc.
- Visible on the public web site of the IFS – including reviews from their customers

Retailers and other users

- Search for certified companies,
- Manage their certified companies via a "favourites" option,
- Receiving information via e-mail e.g. in case of a certificate suspension of their favorite companies,

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

Security of the database

The security system used for the database is based on international recognized and mostly used security systems. The different access (e.g. retailer and certified companies) provide general information about all certified companies. If no further authorization is granted by the certified companies both user groups will be able to see the following information only:

- the company's name and address,
- the certification body's name and address,
- the auditor's name,
- the scope of the audit,
- the date and duration of the audit,
- IFS certificate's date of issue and its validity.

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

- IFS audit report and action plan.

The IFS users (e.g. certified companies/retailers) automatically receive access to the unlocked data by the certified company after the data has been unlocked. Communication to the IFS users is via a secure web process which guarantees that only authorized IFS users can view specific data of the certified companies/suppliers.

ANNEX 1: Audit overview

Cover page

Logo of the certification body

IFS HPC Version 2

Final Audit Report

Audited company: "Detergent and Co. Ltd"

Date of audit: 04. 11./05. 11. 2016

Name and address of certification body

Accreditation number of the certification body

Audit Overview
IFS HPC
Version 2, April 2016

Audit details

Lead auditor: Jane Doe ***Co-auditor:*** John Doe ***Trainee:*** Mr. Example	***Date/Time of current audit:*** 04. 11. 2016 (09:00–18:00) 05. 11. 2016 (08:30–17:30)	***Date/Time of previous audit:*** 06. 10. 2015 (09:00–18:00) 07. 10. 2015 (08:30–12:30) ***CB and auditor of previous audit:*** TEST GmbH/Frank Sample

Name and address of the company (Headquarters) Detergents and Co. Ltd. 123 Sample Street London, UK		***Name and address of the audited site*** Detergents and Co. Ltd. 1 Example St. S2 1PU, Sheffield, UK	
		EAN Code/UCC Global Location Number COID	
Phone: 0 1 2 3 4 5 6	Fax: 01 23 45 67 89	Phone: 0 1 2 3 4 5 7	Fax: 01 23 45 67 88

Audit Scope

For the certification scope of the audit:
(detailed description of processes/products)

Product scope(s):

Audit participants list

Name	Position	Opening meeting	Documentation review	On-site audit	Closing meeting
Mr. Quality	Quality Manager	X	X	X	X
Mrs. Manager	Senior Manager	X	X		
Mrs. Transport	Transport Manager	X	X	X	

Final audit result

As a result of the audit performed on 04. 11. and 05. 11. 2016, "xyz" found that the processes and activities of **Detergents and Co. Ltd.** for the above mentioned scope of audit comply with the requirements set out in the IFS HPC, version 2, at **Foundation Level,** with a score of xx %.	Next audit between: xx.xx.xx and xx.xx.xx

Company profile
Description about the key investments made by the company relating to the production concerning product quality and safety (construction changes, machinery, etc.) Explanation:
What is the year of construction of the audited site(s)? (mandatory explanation). Explanation:
Area of the site (manufacturing plus storage area) in square metres/feet. Explanation:
Number of employees (FTE) and part time, work shifts. Explanation:
What are the product groups and products per scope produced in the company? (mandatory explanation). Explanation:
Number of production lines (mandatory explanation). Explanation:
Complete view of the company´s processes (mandatory explanation). Explanation:
Description of product exclusions, if applicable (yes/no). If so, provide explanations. Explanation:
Description of outsourcing processes, if applicable (yes/no). If so, provide explanations. Explanation:
Does the audited company trade products? If so specify these products. Explanation:
Is it a multi-site certification? If so, provide explanations in case of decreasing audit duration. Explanation:
Name and contact data (phone, fax, Email …) of the contact person in case of emergency. Explanation:
Does the company fulfil the requirements about the use of IFS HPC logo? If not, please provide explanations. Explanation:
List if the site is certified according to other schemes. Specify scheme's names. Explanation:
Reviewer:

ANNEX 2: IFS Audit report

Explanations regarding the audit report

Evaluation of requirements

Result	Explanation	Points
A	Full compliance	20 points
B (deviation)	Almost full compliance	15 points
KO requirement scored with a B	Almost full compliance	15 points
C (deviation)	Small part of the requirement has been implemented	5 points
D (deviation)	Requirement has not been implemented	–20 points
Major non-conformity	Major non-conformity can be given in non-respect of legislation, internal dysfunctions, customer issues or when the identified non-conformity could lead to a serious health hazard.	15 % of the possible total amount of points is subtracted
KO requirement scored with a D	The KO requirement has not been implemented	50 % of the possible total amount of points is subtracted
N/A	Not applicable Requirement not applicable for a company	N/A requirements will be excluded from the final scoring

Scoring and awarding of certificates

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

IFS HPC
Version 2, April 2016

Audit Report

Result:
The activities of company "Detergents and Co. Ltd" met the requirements of the IFS HPC, Version 2.

The company passed with a score of xx % at:

Foundation (Higher) Level
… %

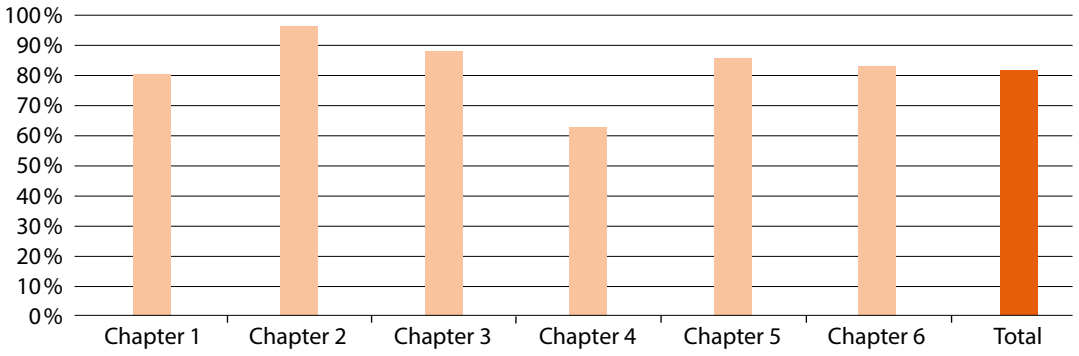
Date of renewal audit: between the DD.MM.YY and DD.MM.YY

Summary:

	Chapter 1	Chapter 2	Chapter 3	Chapter 4	Chapter 5	Chapter 6
	Senior management responsibility	**Quality and product safety management**	**Resource management**	**Planning and production process**	**Measurements, analyses, corrective actions, etc.**	**Product Defense**
KO	0	0	0	0	0	0
Majors	0	0	0	0	0	0
A	0	0	0	0	0	0
B	0	0	0	0	0	0
C	0	0	0	0	0	0
D	0	0	0	0	0	0
N/A	0	0	0	0	0	0

Observations regarding KO's and Majors:

General summary table for all chapters:



Overall summary of the audit

Table of compulsory fields

Part of the audit report	Number of IFS HPC requirement	Compulsory remarks to be added
Corporate policy	1.1	How the company communicates the information to the employees (minimum description)
Senior Management Responsibility	KO N° 1	Minimum description (e.g. how the Senior Management ensures that the employees know their responsibilities, etc.)
Record keeping	2.1.2	Duration of record keeping for "product safety and legality related" records.
Hazard analysis and risk assessment	KO N° 2	List CCPs with associated critical limits. If the company does not have any CCP this shall be specified.
Product specifications	KO N° 3	Minimum description (e.g. what is the evidence that specified recipe/formulation is followed?
Laboratories	4.5.4.1.9	• Which analyses are performed in the own laboratory? • Which analyses are performed by an external laboratory?
Traceability	4.14	Summary of the traceability test result. In case of a problem found provide precise information relating to the problem
	KO N° 4	Describe the traceability system from the raw materials to distribution
Legislative framework	4.3	To list if applicable: • the name of the person responsible for the product safety/quality in the company, • the name(s) of independent assessor(s) working for the company.
Procedure of withdrawal/recall	KO N° 5	The auditor shall provide the following information: • How many withdrawals and recalls have been occurred since the last audit? • Specify product(s) involved • Specify the cause of the withdrawal and product recall.
Product analysis (including quality checks)	5.6	Specify if there is an internal microbiologist
Complaints management	5.8	Details concerning complaints raised from consumers, clients (e.g. retailers) and authorities.
Corrective actions	KO N° 6	Details of the last corrective actions taken.

Description of follow-up on corrective actions from previous audit

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

Chapter 1: Senior management responsibility

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

Summary of all N/A evaluations

N°	Reference	IFS requirement	Evaluation	Explanation
1.				

Detailed audit report

N°	Reference	IFS requirement	Evaluation	Explanation
1.				
2.				

ANNEX 3: Action Plan

Name and address of the audited company

The corrective action plan shall be returned to the certification body before: _____

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

ANNEX 4: Certificate

Certificate

Herewith the certification body

Name of the certification body

(being an accredited certification body for certifications according to IFS and having signed an agreement with the IFS owner) confirms that the product(s) and process(es) of

Name of the audited site
Address
COID
(Headquarters)

For the audit scope:
(detailed description of process(es)/product(s) groups plus, outsourcing process(es) if applicable)
(description of product exclusions, if applicable)
(**"Product defense chapter was assessed",** if applicable)

Meet the requirements set out in the

IFS HPC
Version 2, April 2016

at Foundation/Higher Level

with a score of XX % (if required)

Certificate-Register number

Audit date *(if relevant: Date of the follow-up audit)*

Certificate issue date

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

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

- Date and place
- Name and signature of the responsible person at the certification body
- Address of the certification body

Logo of the accreditation body
or its name and registration number

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

The Standard owner of the present document is:

IFS Management GmbH
Am Weidendamm 1 A
10117 Berlin
Germany

Managing Director: Stephan Tromp
AG Charlottenburg
HRB 136333 B
VAT-N°: DE278799213

Bank: Berliner Sparkasse
IBAN number: DE96 1005 0000 0190 0297 65
BIC-/Swift-Code: BE LA DE BE

The IFS HPC Standard is available online via:
www.ifs-certification.com

Or by mail, fax and email:
IFS Management GmbH
Am Weidendamm 1 A
10117 Berlin
Germany

Phone: +49-(0) 30-72 62 50-74
Fax: +49-(0) 30-72 62 50-79
Email: info@ifs-certification.com

ifs-certification.com