

IFS Global Markets HPC

Development program for assessing household and personal care suppliers in relation to product safety and quality



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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 15 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

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 Technical Support

Pius Gasser

Email: gasser@ifs-certification.com



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Members of the IFS International Technical Committee

Andrea Artoni Conad Soc. Coop., Italy
Fayçal Bellatif Eurofins certification, France
Sébastien Bian Groupe Casino, France

Sabrina Bianchini DNV GL Business Assurance Italia S.r.l., Italy

Cristina Díez Palacios Alimentación, Spain
Andreas Dörr Coop Genossenschaft, Switzerland

Jürgen Eichmann Kaufland Warenhandel GmbH & Co. KG, Germany Frank Ferko Consultant (former on behalf of US Foods), USA

Massimo Ghezzi Carrefour Italia – GS SPA (on behalf of Federdistribuzione), Italy

Cécile Gillard-Kaplan Groupe Carrefour, France

Almudena Hernández AENOR, Spain Luc Horemans Scamark, France

Prof. Dr. Horst Lang Globus SB-Warenhaus Holding GmbH & Co.KG, Germany

Maria Lopez de

Montenegro DIA, Spain

Aline Maysse Europe snacks, on behalf of FEEF (Fédération des Entreprises et

Entrepreneurs de France), France

Joachim Mehnert DQS CFS GmbH, Germany
Dr. Angela Moritz REWE Group, Germany
Alberto Peiró Mercadona, Spain
Ute Pieper METRO AG, Germany

Dr. Jürgen Sommer Freiberger Lebensmittel GmbH & Co. KG, Germany

Gabriele Speri A.I.A. SPA, Italy

Stephen Thome Dawn Food Products, USA

Lucia Tortoreto Coop Italia società cooperativa, Italy
Bert Urlings Vion Food Group, Netherlands

Karin Voss EDEKA ZENTRALE AG & Co. KG, Germany

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- Maria Pia Gianotti, Auchan Italy
- Elisabetta Meneveri, Auchan Italy
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- Ute Pieper, Metro Germany
- Carinne Contremoulin, Scamark France
- Nicoletta Palese, Bureau Veritas Italy
- · Sara Palombella, Bureau Veritas Italy
- Christine Flöter, TÜV Nord, Germany

IFS Team

Helga Barrios IFS HPC Standard Manager

Joao SteinIFS Global Markets Program ManagerChryssa DimitriadisHead of Standard ManagementNevin RühleDirector Business Development

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

Contents

PART 1

Assessment protocol

1	The history of International Featured Standards and IFS HPC Standard	12
1.1	The IFS Global Markets – HPC program	13
1.2	Benefits of the IFS Global Markets – HPC program	13
2	Purpose and contents of the assessment protocol	14
3	Steps within the IFS Global Markets – HPC program	14
4	Types of assessments	15
4.1	Self-assessment	15
4.2	Pre-assessment Pre-assessment	15
4.3	Initial assessment	15
4.4	Re-assessment (after a "not approved" assessment)	15
4.5	Renewal assessment	15
5	Coverage of the assessment	16
5.1	Scope of the assessment.	16
6	The assessment process	17
6.1	Voluntary self-assessment or pre-assessment	17
6.2	Certification body/assessment service provider selection—contractual	
	arrangements	18
6.3	Duration of an assessment	19
6.3.1	Basic level assessment	19
6.3.2	Intermediate level assessment	19
6.4	Drawing up an assessment time schedule	19
6.5	Conducting the assessment	20
6.6	Evaluation of requirements	20
6.7	Scoring system	20
6.7.1	Scoring a requirement as a non-conformity	21
6.7.1.1	Major non-conformity	21
6.8	Scoring a requirement with N/A (not applicable)	22
6.9	Assessment report and letter of confirmation	22
6.10	Format of the assessment report	22
6.11	The different steps for the assessment report	23
6.11.1	Drawing up the report of the assessment and outline of the action plan	23
6.11.2	Company's completion of the corrective action plan	23
6.11.3	Validation of the corrective action plan	24
6.12	Scoring and conditions for issuing an assessment report and a letter of	
	confirmation	24
6.12.1	Basic level	24
6.12.2	Intermediate level	26
6.13	IFS Global Markets assessment timeframe	28

7	Assessment cycle	29
8	Information about conditions of withdrawal of the report and letter of confirmation	30
9	Distribution and storage of the assessment report	30
10	Supplementary action	30
<mark>11</mark> 11.1	Appeal and complaints Certification bodies'/assessment service providers' appeal and complaints	31
	procedure	31
11.2	Quality assurance actions after complaint notification	31
12	Ownership and usage of the IFS Global Markets – HPC logo	32
13	Review of the IFS Global Markets – HPC program	33
Annex 1	Application of checklists	34
Annex 2	Assessment process	35
Annex 3	Product scopes	36
Annex 4	Products excluded from the IFS Global Markets – HPC scope	37

Part 2 List of IFS Global Markets – HPC assessment requirements

1	Senior management responsibility	40
1.1	Corporate structure	40
1.2	Customer focus	41
2	Quality and product safety management system	41
2.1.1	Documentation requirements	41
2.1.2	Record keeping	42
2.2	Product safety management system	42
2.2.1	Risk management system (hazard analysis and risk assessment)	42
2.2.2	Risk management team	43
2.2.3	Hazard analysis and risk assessment	44
3	Resource management	47
3.1	Personnel hygiene management	47
3.1.1	Personnel hygiene	47
3.1.2	Protective clothing for personnel, contractors and visitors	48
3.1.3	Procedures applicable to infectious diseases	49
3.2	Training and instruction	49
3.3	Staff facilities, sanitary facilities and equipment for personnel hygiene	50
4	Planning and production process	51
4.1	Contract agreement	51
4.2	Specifications and formulas	51
4.2.1	Raw Materials (including packaging materials), semi-finished products	
	and rework specifications	51
4.2.2	Finished product specifications	53
4.3	Legislative framework	53
4.4	Purchasing (outsourcing if applicable)	54
4.5	Factory location	55
4.5.1	Site security	55
4.5.2	Factory exterior	55
4.5.3	Plan layout and process flow	56
4.5.4	Buildings and facilities	56
4.5.4.1	Buildings and internal structures	56
4.5.4.2	Lighting, air conditioning/ventilation	57
4.5.4.3	Water quality	57
4.6	Cleaning and disinfection	58
4.7	Waste disposal	59
4.8	Risk of foreign materials	59
4.9	Pest monitoring/pest control	60
4.10	Receipt of goods and storage	61
4.11	Transport	62
4.12	Maintainance and repair	63

4.13	Equipment	63
4.14	Traceability	64
5	Measurements, analyses, corrective actions and management of incidents	65
5.1	Internal audits	65
5.2	Factory inspections	65
5.3	Manufacturing process validation and control	66
5.4	Calibration, adjustment and checking of measuring and monitoring devices	67
5.5	Quantity checking (quantity control/filling quantities)	67
5.6	Product analysis (including quality checks)	68
5.7	Product quarantine (blocking/hold) and product release	69
5.8	Management of complaints from authorities and customers	69
5.9	Management of incidents, product withdrawal and product recall	69
5.10	Management of non-conformities and non-conforming products	70
5.11	Corrective actions	71
Annex 1	Glossary	72

PART 3:

Requirements for certification bodies, assessment service providers and assessors

0	Introduction	78
1	Requirements for certification bodies/assessment service providers	78
1.1	Certification bodies	78
1.2	Assessment service provider	78
1.3	Certification bodies'/assessment service providers' responsibilities	
	for IFS Global Markets – HPC assessors (including freelancers)	79
2	Requirements for IFS Global Markets – HPC assessors	79
2.1	General requirements	79
2.2	Requirements for IFS Global Markets – HPC assessors	80
2.2.1	General requirements on assessors for initial application	80
2.2.2	IFS auditors	80
2.2.3	Scope extension for IFS HPC auditors	81

PART 4:

Reporting, auditXpressX™ and IFS database

0	Introduction	84
1	Reporting	84
1.1	Assessment overview (Annex 1)	84
1.2	Assessment report (Annex 2)	85
1.3	Action plan (Annex 3)	85
2	auditXpressX™	85
3	The IFS database (www.ifs-certification.com)	86
Annex 1	Assessment overview	89
Annex 2	Assessment report	92
Annex 3	Corrective action plan	95
Annex 4	Letter of confirmation	96



PART 1

1	The history of International Featured Standards and IFS HPC Standard	12
2	Purpose and contents of the assessment protocol	14
3	Steps within the IFS Global Markets – HPC program	14
4	Types of assessments	15
5	Coverage of the assessment	16
6	The assessment process	17
7	Assessment cycle	29
8	Information about conditions of withdrawal of the report and letter of confirmation	30
9	Distribution and storage of the assessment report	30
10	Supplementary action	30
11	Appeal and complaints	31
12	Ownership and usage of the IFS Global Markets – HPC logo	32
13	Review of the IFS Global Markets – HPC program	33
An	nex 1: Application of checklists	34
An	nex 2: Assessment process	35
An	nex 3: Product scopes	36
An	nex 4: Products excluded from the IFS Global Markets – HPC scope	37



PART 1 **Assessment protocol**

1 The history of International Featured Standards and IFS HPC Standard

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 service companies. Ever rising demands of consumers, the increasing liabilities of retailers, wholesalers and food service 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 postfarm 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 of the IFS Food Standard was developed by the HDE and launched in 2003.

For the current IFS Food version the International Technical Committee and the national working groups from France, Germany (for the whole German speaking area), Italy, Spain and North America have been actively involved, in addition to retailers, stakeholders and representatives of industry, food services and certification bodies from all over the world. Currently, IFS Food has been developed and supported by food industry from Austria, France, Germany, Italy, Netherland, Spain, Switzerland, USA as well as experts from other European countries, Asia and South America.

Along the years, IFS Management has developed with interested stakeholders different standards to cover all processes and activities within the supply chain e.g. IFS Broker, IFS PACsecure or the IFS HPC standard among others.

In order to prevent HPC companies from being overwhelmed by different requirements, the French, Italian and German retailers developed the first version of the IFS HPC in 2009. The Version 2 was a collaboration of the retail federations from France, Germany and Spain, and the valuable support from industries and certification bodies.

It is the aim of retailers and producers to have transparency over their whole international supply chain, therefore the IFS HPC is necessary to cover this aspect as well was to ensure that producers deliver safe and quality goods.

The fundamental objectives of IFS HPC as well as for other IFS standards are:

- to establish a common standard with a uniform evaluation system,
- to work with accredited certification bodies and qualified IFS approved auditors,
- to ensure comparability and transparency throughout the entire supply chain.

1.1 The IFS Global Markets – HPC program

Having worked with the IFS HPC standard for several years, IFS recognized the need for technical assistance and support for small and/or less developed companies in the development of their quality and product management system.

For these companies that because of their size, lack of technical expertise, economic resources or the nature of their work, encounter difficulties in implementing product safety and quality management systems in their companies, market opportunities often exist within formal supply chains where entry requirements are high. These companies do not necessarily have access to the expertise, technical and financial resources to meet these requirements in terms of quality and product safety.

Following this, it was decided to draw up a standardized and a voluntary step-by-step assessment approach on the basis of the IFS HPC checklist. The initiative is named the IFS Global Markets – HPC program and will provide "small and/or less developed businesses" assistance in the development of safe and high quality products and to give the first steps in implementation of the IFS HPC standard.

The program's objective is to facilitate market access locally, create mutual acceptance along the supply chain and provide a framework for mentoring, developing and assessing small and less developed HPC companies. The program includes a protocol to drive incrementally the continuous improvement process in product safety management systems.

Moreover, it offers a flexible application of the stepwise approach in sense of time, starting level and final level to achieve.

1.2 Benefits of the IFS Global Markets – HPC program

The IFS Global Markets – HPC program combines the checklist with the IFS assessment protocol, basic requirements for certification bodies/assessment service provider and assessors as well as a defined assessment report. In addition, the program guarantees that every assessment report is developed in the same way and uploaded in the IFS database, where all retailers and manufacturers supporting the IFS Global Markets program can find and follow the development of each service provider.

The main advantages of the IFS Global Markets – HPC program are:

- to provide an assessment program for small and less developed companies,
- to offer a systematic risk based approach to achieve the IFS standard over a defined period of time,
- to establish a uniform consistent and differentiated evaluation system,

- · to provide an approach for continuous improvement process within the IFS scoring system,
- to work with qualified certification bodies/assessment service providers and assessors, and
- to ensure comparability and transparency throughout the entire supply chain.

2 Purpose and contents of the assessment protocol

This assessment protocol describes the specific requirements for the organisations involved in IFS Global Markets – HPC program assessments.

It also provides guidance for assessment against the basic and intermediate level requirements to assist with the process of attaining full certification to IFS HPC, if required.

The purpose of the protocol is to define the criteria to be followed by a certification body/assessment service provider performing assessments against the IFS Global Markets – HPC program requirements as a product and process assessment. It also details the procedures to be observed by the companies being assessed and clarifies the rationale of assessing them.

The IFS requirements for certification bodies, assessment service providers and assessors are clearly described in Part 3 of this document.

3 Steps within the IFS Global Markets – HPC program

The protocol should be used as an user guide in relation to the following key phases of the IFS Global Markets – HPC program:

(0) Self or pre-assessment:

A voluntary self- or pre-assessment against the basic or intermediate level checklist is carried out to allow the site/s to decide its entry level to the program. Subject to the outcome of the self- or pre-assessment, the company should pass to either phase 1 (basic level assessment), phase 2 (intermediate level assessment) or phase 3 (IFS HPC certification).

(1) Assessment with certification body/assessment service provider: Basic level

A non accredited assessment of the site/s is carried out against the requirements specified in the basic level checklist. The technical requirements at this level are comprised of approx. 35 % of the key elements of the IFS HPC standard, including quality and product safety management, resource management, specifications, measurements, analyses & improvements.

Depending on the business partner, further requirements can be added to the checklist and be assessed.

(2) Assessment with certification body/assessment service provider: Intermediate level

A non accredited assessment of a site is carried out against the intermediate level checklist, which includes the basic level requirements and approx. a further 20% more of the IFS HPC standard elements, including management responsibility, further requirements in regard to quality and product safety management, resource management, specifications, measurements, analyses and improvements.

Depending on the business partner, further requirements can be added to the checklist and be assessed.

(3) Certification against the IFS HPC standard by a certification body:

An official accredited audit can be carried out against the IFS HPC standard.

Possible options to apply the checklists are stated in Annex 1, Part 1: Application of checklists. As phases 1 and 2 are regarded as transitional, each level-duration should not exceed one (1) year, unless a different individual agreement/requirement with the business partner exists. Generally, a program must be agreed with the assessed company to achieve the requirements of the IFS HPC standard within a maximum of three (3) years.

Product risk assessment and company performance should be considered when exceptions in regard to the timeframe are granted.

4 Types of assessments

4.1 Self-assessment

A voluntary self-assessment is conducted by the site against the basic or intermediate level checklist to decide on an entry level to the program.

4.2 Pre-assessment

A voluntary assessment is conducted with the support of an independent and qualified consultant or a mentoring certification body/assessment service provider against the basic or intermediate level checklist to decide on an entry level to the program.

4.3 Initial assessment

An initial assessment is either a site's first assessment to the IFS Global Markets – HPC against the basic or intermediate level checklist or the assessment after an interruption of the assessment cycle.

4.4 Re-assessment (after a "not approved" assessment)

A non accredited scheduled assessment of the site is carried out against all the requirements of the basic or intermediate level checklist.

4.5 Renewal assessment

A non accredited scheduled assessment of the site is carried out against the basic or intermediate level checklist after an initial assessment within the relevant assessment cycle.

Note: companies and retailers which favour the assessed site in the IFS database will receive a message, if there is repetition of a certain level.

5 Coverage of the assessment

IFS Global Markets – HPC is a program for assessing site/s producing household and personal care products. The following scopes are defined for IFS Global Markets – HPC assessment:

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 precharged 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, classis plasters, compresses – without the sterile condition, cotton wool, incontinence products) etc.

Products excluded from the scope of the IFS Global Markets – HPC are also specified in Annex 4, Part 1.

Furthermore, the IFS Global Markets – HPC shall not apply to any of the activities or products already covered by other IFS standards e.g. trading, logistical activities, food processing etc.

5.1 Scope of the assessment

The next statements shall be taken into consideration for a better performance of the assessment:

- the planned level and the scope of the assessment shall be clearly and unanimously stated in the contract between the assessment body and the assessed company. The attained level and scope of the assessment shall be declared in the assessment report and on the letter of confirmation.
- the assessment scope will also be reviewed by the assessor during the opening meeting of the assessment.
- the scope of the assessment 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 assessment shall take place when products of the defined assessment scope are being processed and/or packed. For example, it is not possible to include in the scope of the IFS Global Markets HPC assessment production lines of the assessed site which are not operating during the assessment, unless those production lines involve the same risk assessment study and the same products and scopes as the lines which are assessed when operating. If, during the assessment, some lines are not operating at the assessed site and involve different risk assessment study(ies), product(s) and scope(s), the assessor can ask the company to run the production line(s) later during the assessment day so that the line(s) is/are assessed later during the assessment.
- the assessment shall be specific to the site where all the processing or packaging of the product(s) is undertaken. Where decentralised processes exist and the assessment of a certain location is insufficient for gaining a complete view of the company's processes, then all other relevant facilities shall also be included in the assessment. Full details shall be documented within the company profile in the assessment report.
- The activities undertaken during the assessment shall be reviewed and agreed at the beginning of the assessment after an initial risk assessment. In addition, these activities can be modified after the risk assessment (for instance, if a further activity interferes with the one concerned by the assessment scope).
- in the case of outsourced processes, the certification body/assessment service provider shall be made fully aware of such arrangements. The scope of assessment shall clearly be described and specified in the report and on the letter of confirmation.
- if, under exceptional circumstances, the company decides to exclude specific product(s) from
 the scope of the assessment, the certification body/assessment service provider may allow it,
 if the contamination risk between included and excluded products is properly controlled (and
 verified by the certification body/assessment service provider/assessor). If documented and
 justified, the exclusion shall always be specified in the letter of confirmation and in the company profile of the assessment report.

The assessment scope shall make reference to the assessed product scopes (see Annex 4).

The company shall inform its certification body/assessment service provider about any change that may affect its ability to conform with the assessment requirements (e.g. recall, alert on products, organization and management, contact address etc.). This information shall be communicated within three (3) working days. Details shall be defined and agreed between both parties.

6 The assessment process

6.1 Voluntary self-assessment or pre-assessment

Before being assessed, the company shall read the current version of requirements of the IFS Global Markets – HPC program in detail. Information on the IFS Global Markets – HPC program and general requirements are available and can be downloaded free of charge from the IFS website.

Additional business specific requirements can be provided by the business partner or via the certification body/assessment service provider.

The self-assessment should be carried out by the site itself. Alternatively, the pre-assessment could be carried out by a certification body/assessment service provider or an independent and qualified consultant.

Self- or pre-assessment of requirements of the basic and intermediate level checklist is a voluntary step. Its intention is to allow the business to carry out its own gap analyses process and develop a corresponding action plan.

6.2 Certification body/assessment service provider selection—contractual arrangements

To ensure the integrity of the IFS Global Markets – HPC program the company going for an assessment against the basic or the intermediate level shall choose a certification body or assessment service provider with the corresponding assessors meeting the criteria of Part 3 of this program.

Certification bodies/assessment service providers can have assessors qualified for one or several scopes. Confirmation of the product scopes and product groups for which the certification body/assessment service provider can perform assessments shall be obtained from the individual certification body/assessment service provider. In general, an assessor (lead and co-assessor) is not allowed to perform more than three (3) consecutive assessments of the same company's site.

In case of a pre-assessment the assessor who performs this assessment shall be different form the assessor who performs the initial assessment.

An individual assessment agreement shall exist between the assessed company and the certification body/assessment service provider detailing the scope of the assessment, the assessment date, duration and further reporting requirements.

The agreement must be in place:

- authorising the certification body/assessment service provider to assess the management systems, facilities, sites and practices of the assessed party,
- authorising the certification body/assessment service provider to upload the assessment report in the IFS database,
- clarifying invoicing of the assessment.

The assessment shall be carried out in the working language of the company and the certification body/assessment service provider shall make every attempt to appoint an assessor whose native language or main working language is the language of the company.

Requirements evaluated with C, D and/or Major shall always be translated into English within the action plan and the assessment report. Exceptions shall be agreed with the business partner.

It is the responsibility of the assessed company to verify that the certification body/assessment service provider is approved to conduct IFS Global Markets – HPC assessment.

6.3 Duration of an assessment

The certification body/assessment service providers have an appropriate system for estimating the minimum time needed for an assessment. An assessment of the complete checklist(s) should typically last four (4)—eight (8) hours. The assessment duration does not include time for assessment preparation and report generation, which shall require two (2) to three (3) hours.

A number of factors, which are detailed in the contract between the certification body/assessment service provider and the assessed company, play a role in determining the time required for a comprehensive assessment.

They include:

- · the size of the company
- the scope of the assessment
- the number of personnel employed at the site
- the number of deviations and non-conformities identified in the previous assessment.

1/3 of the assessment duration shall be spent as a minimum, in the production area of the site.

In the event that not everything related to the defined assessment scope has been assessed during the planned assessment duration, additional time is necessary.

The assessor is encouraged to review documents and records within the production area rather than the office.

6.3.1 Basic level assessment

The assessor will carry out a non accredited assessment against basic level checklist. The duration of the assessment depends on the nature and complexity of the assessed company.

6.3.2 Intermediate level assessment

The assessor will carry out a non accredited assessment against the intermediate level checklist including basic level requirements. The duration of the assessment depends on the nature and complexity of the assessed company.

6.4 Drawing up an assessment time schedule

The certification body/assessment service provider shall provide the assessment time schedule.

The assessment time schedule includes appropriate details concerning the scope covered and the complexity of the assessment. The assessment time schedule shall be sufficiently flexible to respond to any unexpected events which may arise during the site inspection activity as part of the assessment. The assessment time schedule takes into consideration a review of the assessment report and action plan relating to the previous assessment, whatever the date when the previous assessment has been performed. It also specifies which of the company's products or product ranges are to be assessed.

The assessment time schedule shall be sent to the assessed company before the assessment, to ensure availability of responsible persons on the day of the assessment.

The company will assist and co-operate with the assessor during the assessment. The assessor who conducts the assessment will assess all the requirements of IFS Global Markets – HPC program, which are relevant to the company's structure and function. If applicable, individual business partner specific questions and requirements could be assessed.

During the closing meeting, the assessor shall present and discuss with the company deviations and (all) non-conformity (ies) which have been identified. The certification body/assessment service provider shall issue a provisional assessment report and outline a corrective action plan to the company, which shall be used as a basis for drawing up corrective actions for the deviations and non-conformity (ies).

6.5 Conducting the assessment

Assessments can be conducted according to Annex 1: application of checklists.

Certification bodies/assessment service providers shall download the current version of the program from the IFS website. If available, the certification body/assessment service provider shall use the checklist in the local language of the assessed company. Where translation in local language is not available, the English version shall be used.

The assessor shall assess all requirements of the relevant checklist.

If applicable, additional business partner's checklists may be assessed. These will be scored separately.

6.6 Evaluation of requirements

The assessor assesses the nature and significance of any deviation or non-conformity. In order to determine whether compliance with basic or intermediate level requirements of the IFS Global Markets – HPC program have been met, the assessor has to evaluate the requirements of the checklist agreed on. There are different levels to rank the findings.

6.7 Scoring system

For the regular requirements of the IFS Global Markets – HPC program, there are four (4) scoring possibilities:

- A: Full compliance with the requirement specified in the program.
- B: Almost full compliance with the requirement specified in the program, but a small deviation was found.
- C: Only a small part of the requirement in the program has been implemented.
- D: The requirement in the program has not been implemented.

Points are awarded for each requirement as follows:

Chart N° 1: scoring of requirements

Result	Explanation	Points
Α	Full compliance	20
В	Almost full compliance	15
С	Small part of the requirement has been implemented	5
D	Requirement has not been implemented	0

In addition to this scoring, the assessor can decide to give the company a "Major" non-conformity to any requirement of this program. This possibility is explained in the next section.

6.7.1 Scoring a requirement as a non-conformity

In IFS Global Markets-HPC, there is one type of non-conformity known as Major. It will lead to a subtraction of points from the total amount.

6.7.1.1 Major non-conformity

<u>A Major non-conformity can be given to any requirement</u> when there is a substantial failure to meet the requirements of the program. This includes non-respect of legislation, law, product safety, customer issues and/or in case of internal dysfunctions (e.g. completely not regulated and controlled processes).

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

This non-conformity will subtract 10% of the possible total amount of points.

In the event that one (in intermediate level) or several Major non-conformity(ies) is/are issued during the assessment, and there is a current IFS Global Markets report and letter of confirmation in place, these shall be withdrawn in the IFS database by the certification body/assessment service provider as soon as possible and at latest two (2) working days after the assessment date.

In the IFS database, explanation about reasons for withdrawing the current report/letter of confirmation shall be given 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 corrective 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 notification (with explanations about the identified non-conformity(ies)) from the IFS database that the current report/letter of confirmation has been withdrawn.

In the event where more than one Major non-conformity have been identified, a complete new assessment shall be performed if continued compliance with IFS Global Markets HPC is desired.

21

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

Those requirements deemed not applicable to the site shall be identified and/or pre-determined by the business partner, where applicable.

When the assessor agrees that a requirement is not applicable for a site, it has to be scored as:

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

N/A scoring is possible for any requirements of the IFS Global Markets – HPC program checklist, except the requirement 2.2.3.6 about determination of CCP's. Even if the company does not have any identified CCP's, the company shall document a logical approach which needs to be assessed by the assessor.

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

N/A requirements will be excluded from the final scoring.

6.9 Assessment report and letter of confirmation

Following each assessment, a written report shall be prepared in the agreed format (see Part 4). Furthermore, a letter of confirmation shall be issued if the assessment is provisionally approved or approved, only.

The report and the letter of confirmation shall be uploaded into the IFS database after the assessment within the set timeframe (see Part 1, chapter 7.9).

The report gives an overview of the compliance of the company.

The letter of confirmation specifies details of the assessment and the final assessment result.

6.10 Format of the assessment report

The assessment report shall provide transparency and confidence to the reader and will be completed by the assessor. The assessment report can be subdivided into different sections:

- General information about the company.
- · General assessment result.
- General summary in a tabular format for all chapters.
- Summary of the assessment.
- Summary and observations of all established Major non-conformity (ies).
- Description of follow-up of corrective actions from previous assessment.
- Separate list (including explanations) of all requirements evaluated with N/A (not applicable).

All deviations and Majors identified during the assessment, are presented in a separate action plan. Following the allocation of each) deviation or Major, the site has to provide a corrective action plan in order to avoid error's recurrence. In this way, the reader of the report is made aware of the (Major) deviations and also the corrective actions that the site is initiating. If existing, the assessment related to additional business partner specific requirements shall be reported separately.

6.11 The different steps for the assessment report

6.11.1 Drawing up the report of the assessment and outline of the action plan

The assessor shall explain all Major non-conformities and deviations (B, C, D) and all requirements that are found as N/A.

The action plan shall include all the requirements which are not evaluated with A or N/A grade.

The outline action plan shall conform to the auditXpressX™ outline action plan. It shall include the elements of chart N° 2.

The assessor shall complete all of field A in chart N° 2, explaining and justifying the deviations and non-conformities findings before sending the company the outline action plan and the pre-report of the assessment.

The certification body/assessment service provider shall send the company both the pre-report of the assessment and the outline action plan within two (2) weeks after the assessment date.

Chart N° 2: Outline action plan

Number of the require- ment	IFS Global Markets – HPC requirement	Evalua- tion	Explana- tion (by the assessor)	Correction, root cause and correc- tive action (by the company)	Responsibility, date and status of implementation (by the company)	Release by the assessor
			Field A	Field B	Field C	Field D
B 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).	Major				
B 3.1.1.2	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.	С				
B 4.1.2	Changes of existing contractual agreements shall be documented, communicated and updated between the contract partners.	В				

6.11.2 Company's completion of the corrective action plan

The company shall enter the correction, root cause and proposed corrective actions (field B of chart N° 2) for all Major non-conformities and deviations (B, C, D) listed by the assessor.

For all evaluated deviations with score C, D and Major non-conformity, the company shall clearly state the responsibilities and implementation deadlines for corrective actions (chart N° 2, field C).

All corrective actions shall be implemented within three (3) months. If this is not possible, exceeded timeframe need to be agreed. The company shall forward the corrective action plan to the certification body/assessment service provider within two (2) weeks of having received the assessment pre-report and the action plan layout. If this deadline is not respected the company has to undergo a complete new assessment.

Note: variant processes for drawing up the report and outlining the action plan could be agreed with the business partner.

6.11.3 Validation of the corrective action plan

The assessor or a representative of the certification body/assessment service provider shall validate the corrective action plan submitted by the assessed company (field D of chart N° 2). If the corrective actions are not valid or are inadequate, the certification body/assessment service provider shall return the action plan to the company for completion in due time. If deadlines are not respected, the site has to undergo a complete new assessment.

6.12 Scoring and conditions for issuing an assessment report and a letter of confirmation

The general scoring of the different levels is described below.

6.12.1 Basic level

The outcome of the assessment according to basic level can be:

Chart N° 3: assessment results in basic level

Assessment Status result		Action (assessed site)	Report form	Assessment frequency
> 1 Major in basic level and/or total score < 75 %	Not approved	Actions and new assessment to be agreed upon	Report gives status	Re-assessment, if desired
Max. 1 Major in basic level and total score ≥75%	Provisionally approved at basic level as long as further actions taken and validated by the partner or CB/ASP for final approval	 Send corrective action plan within two (2) weeks after receiving the prereport. Implement corrective action for deviation from corrective action plan within three (3) months after assessment. Implement corrective action for Major nonconformity for final validation 	Report including corrective action plan gives status	Twelve (12) months to renewal assessment
	In case no further actions are taken or no validation – not approved at basic level	Actions and new assessment to be agreed upon	Report gives status	Re-assessment, if desired
No Major in basic level and total score ≥ 75 %	Approved at basic level	Send corrective action plan within two (2) weeks after receiving the prereport. Implement corrective action for deviation from corrective action plan within three (3) months after assessment	Report including corrective action plan gives status	Twelve (12) months to renewal assessment

6.12.2 Intermediate level

The outcome of the assessment according to intermediate level can be:

Chart N° 4: assessment results in intermediate level

Assessment result	Status	Action (assessed site)	Report form	Assessment frequency
No Major in intermediate level and no Major in basic level and total score < 75 % for intermediate level checklist	Not approved at intermediate level	Actions and new assessment to be agreed upon	Report gives status	Re-assessment of intermediate level, if desired
≥ 1 Major in inter- mediate level and > 1 Major in basic level	Not approved at basic and intermediate level	Actions and new assessment to be agreed upon	Report gives status	Re-assessment, if desired
≥ 1 Major in intermediate level and max. 1 Major in basic level and total score ≥ 75% of basic level checklist	Provisionally approved at basic level as long as further actions taken and validated by the partner or CB/ASP for final approval	 Send corrective action plan within two (2) weeks after receiving the prereport. Implement corrective action for deviation from corrective action plan within three (3) months after assessment. Implement corrective action for Major non-conformity for final validation 	Report including corrective action plan gives status	Twelve (12) months to renewal assessment
	In case no further actions are taken or no validation – not approved at basic level	Actions and new assessment to be agreed upon	Report gives status	Re-assessment, if desired
	Not approved at intermediate level			

Assessment result	Status	Action (assessed site)	Report form	Assessment frequency
≥ 1 Major in intermediate level and no Major in basic level and total score ≥ 75 % of basic level checklist	Approved at basic level	Send corrective action plan within two (2) weeks after receiving the pre-report. Implement corrective action for deviation from corrective action plan within three (3) months after assessment	Report including corrective action plan gives status	Twelve (12) months to renewal assessment
	Not approved at intermediate level			
No Major in intermediate level and no Major in basic level and total score ≥ 75 % for basic level checklist and total score ≥ 75 % for intermediate level checklist	Approved at intermediate level	Send corrective action plan within two (2) weeks after receiving the prereport. Implement corrective action for deviation from corrective action plan within three (3) months after assessment	Report including corrective action plan gives status	Twelve (12) months to renewal assess- ment or IFS HPC certification

Note: the total score is calculated as following:

Total number of points

- = (total number of relevant IFS Global Markets HPC checklist requirements
 - requirements scored with N/A) \times 20

Final score (in %)

= number of points awarded/total number of points.

Generally, for the IFS Global Markets – HPC program assessments, no certificate is granted, but a letter of confirmation is issued. A template can be found in Part 4 of this document and can be generated via the IFS software auditXpressX™.

The evaluation of the assessment is calculated, following the rules, outlined in the decision tree below and explained in chapter 7.8.1 (basic level) and 7.8.2 (intermediate level).

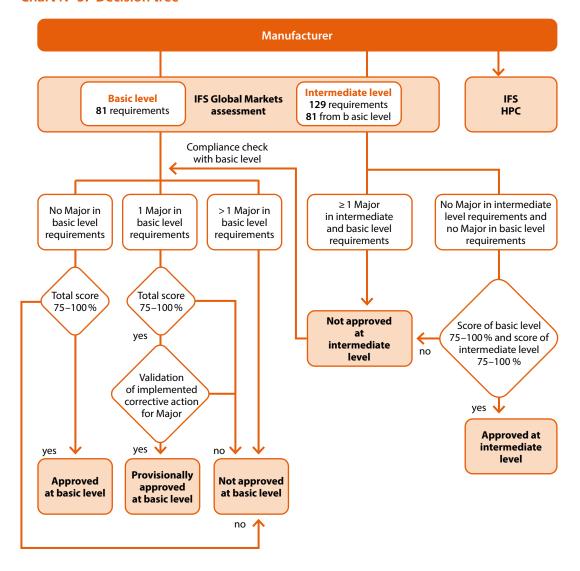


Chart N° 5: Decision tree

6.13 IFS Global Markets assessment timeframe

The assessment shall be valid effectively from the date of issue stated on the formal report and the letter of confirmation itself and shall end after initial assessment date + eight (8) weeks – one (1) day + one (1) year. The date for the following scheduled assessment shall be calculated from the date of the initial assessment, not from the date of issue of the report/letter of confirmation.

If the assessment is not performed in due time, users of the IFS database, which have the assessed company in their favorites list may be informed via the IFS database.

The time between the date of the assessment and the upload of the final report/letter of confirmation is determined as follows:

- two (2) weeks to draw up the pre-report of the assessment
- two (2) weeks for the company/site to respond to the deviations and non-conformity(ies) (draw up the corrective action plan)

two (2) weeks for the assessor to check the proposed corrective actions and upload of the
assessment report, the letter of confirmation and the corrective action plan to the IFS
database.

In total: six (6) weeks between the date of assessment and uploading the assessment report/letter of confirmation to the IFS database:

- Target time: six (6) weeks
- · Maximum time: eight (8) weeks

Note: variant processes for drawing up report/letter of confirmation and outlining action plan could be agreed with the business partner.

7 Assessment cycle

The renewal assessment should be initiated by the business partner or the assessed company.

Note: the assessed company/site receives a reminder from the IFS database three (3) months before the assessment report/letter of confirmation expiration.

Even if the renewal assessment date changes every year and does not completely correspond to the anniversary date, the assessment report/letter of confirmation validity date shall remain the same each year.

This allows to avoid gaps between two (2) consecutive reports/letter of confirmations and to avoid when a company scheduling the assessment earlier loses some months of the report/letter of confirmation validity.

Example:

Initial assessment date:

Date of issue of report/letter of confirmation:

Report/letter of confirmation valid until:

Renewal assessment date:

Report/letter of confirmation valid until:

Report/letter of confirmation valid until:

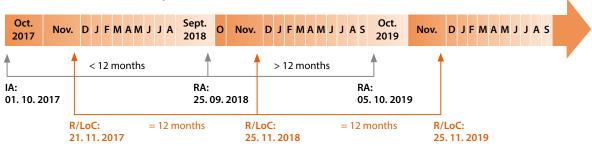
Confirmation valid until:

25. November, 2018

25. November, 2019

(Independently from the renewal assessment date).

Chart N° 6: assessment cycle



IA: initial assessment RA: renewal assessment

 $\textbf{R/LoC:} \ \ assessment \ report/letter \ of \ confirmation \ valid \ until$

The following assessment should be scheduled at earliest eight (8) weeks before and at latest two (2) weeks after the assessment due date (due date is anniversary date of the initial assessment).

Not respecting the mentioned rules in due time will lead to an assessment cycle break.

In case no renewal assessment takes place, the assessed company remains visible a further three (3) months after the validity of report/letter of confirmation expired on the IFS database.

8 Information about conditions of withdrawal of the report and letter of confirmation

Withdrawal of the report and the letter of confirmation by the certification body/assessment service provider is only permitted in the event that any information confirming that the product no longer complies with the requirements of the IFS Global Markets program.

The only exception of this rule may be related to the non-payment of the current assessment by the assessed company.

The contract between certification body/assessment service provider and assessed company shall be in accordance with the assessment cycle (see above chart N° 6).

9 Distribution and storage of the assessment report

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

Access conditions to information about assessment reports are fully detailed in Part 4.

10 Supplementary action

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

11 Appeal and complaints

11.1 Certification bodies'/assessment service providers' appeal and complaints procedure

The certification body/assessment service provider shall have documented procedures for the consideration and resolution of appeals against the results of an assessment.

These procedures shall be independent of the individual assessor and will be considered by senior management of the certification body/assessment service provider.

Appeals shall be finalised within twenty (20) working days of receiving information from the assessed company.

The certification body/assessment service provider shall have documented 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.

11.2 Quality assurance actions after complaint notification

Retailers or any other interested parties have the right to forward any possible complaint to IFS for investigation and management.

The IFS offices collect complaints concerning IFS Global Markets assessments, reports or other circumstances in which the integrity of the IFS brand is in question.

Retailers, certification bodies/assessment service provider, employees assessed according to the IFS Global Markets – HPC or any person can use the complaint form on the IFS website www.ifs-certification.com or can send an email to complaintmanagement@ifs-certification.com to inform IFS about a certain issue.

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 the assessed company, certification body/assessment service provider or the assessors in meeting IFS Global Markets requirements.

Based on this investigation, and if deviations are identified, the certification body/assessment service provider shall implement an appropriate action plan.

IFS GLOBAL MARKETS – HPC VERSION 1

31

12 Ownership and usage of the IFS Global Markets – HPC logo

The copyright of IFS Global Markets – HPC and the registered trademark is fully owned by the IFS Management GmbH. The IFS Global Markets – HPC logo can be downloaded via the secured section of the IFS database.

Furthermore, the terms and conditions stated below shall be checked by the assessor during the assessment and results of this check shall be described in the company profile of the assessment report.

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

Application

These terms and conditions apply for all IFS logos in general.

Form, design and colour of the IFS logo

When used, the IFS Global Markets – 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 Global Markets assessed company may—subject to the provisions mentioned below—use the IFS Global Markets – HPC logo in its documents (for example invoices).

The IFS Global Markets – HPC logo can be used in print, 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 interpretations

When an IFS Global Markets – HPC program assessed company, an IFS training service provider, an IFS consultant or an IFS certification body/assessment service provider publishes documents bearing the IFS Global Markets – HPC logo, comment and interpretations referring to the IFS shall be clearly identifiable as such.

Use of the IFS Global Markets – HPC logo in promotional material

An IFS Global Markets assessed company may use the IFS logo for promotional reasons and publish information about its IFS assessment provided that it is not visible by the end consumer.

The IFS Global Markets – HPC logo and the information about the assessment may be used in correspondence with relevant IFS users, but not in correspondence with the end consumer.

The IFS Global Markets – HPC logo may not be displayed on the products themselves, or any kind of advertising document likely to reach the end consumer (e.g. public exhibitions for end consumers, brochures): The IFS Global Markets-HPC logo may be displayed on any kind of general communications (e.g. exhibitions for business contacts, brochures, generic articles about product safety and quality management in general, vehicles). It must be ensured that all information concerning the IFS Global Markets – HPC assessments shall clearly reference IFS.

The IFS logo may not be used in presentations having no clear connection to IFS.

Further restriction on the use of the IFS Global Markets - HPC logo

The IFS Global Markets – HPC logo shall not be used in a way that could provide the interpretation that the IFS owner is responsible for the assessment decision. Furthermore, the same applies for opinions and interpretations which could be derived from it. In the event of withdrawal of the IFS Global Markets – HPC program assessment decision, the assessed company has to immediately stop the inclusion of the IFS logo on its documents and/or website and stop the communication about IFS.

Communication of the IFS Global Markets - HPC assessment

All the above mentioned rules apply to any communication regarding IFS Global Markets – HPC.

This also means that using the wordmarks "IFS", "International Featured Standards", or "IFS Global Markets – HPC" or similar is not allowed when communicating on finished products, which are available by the end consumer.

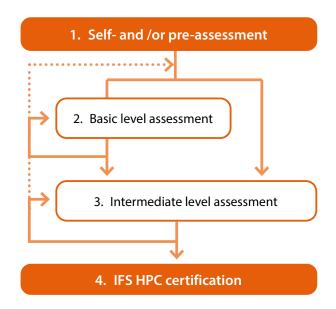
13 Review of the IFS Global Markets – HPC program

The review committee needs to demonstrate control of the quality and content of the program and will regularly review the basic and intermediate level checklists and the protocol to ensure that they are still in compliance with their requirements. The review committee shall be formed with all participants involved in the assessment process: representatives of the retailers, of the industry, of consultants and of certification body/assessment service providers. The objective of the review committee is to share experiences, discuss and decide about the changes to the checklist's requirements of the assessment report and training.

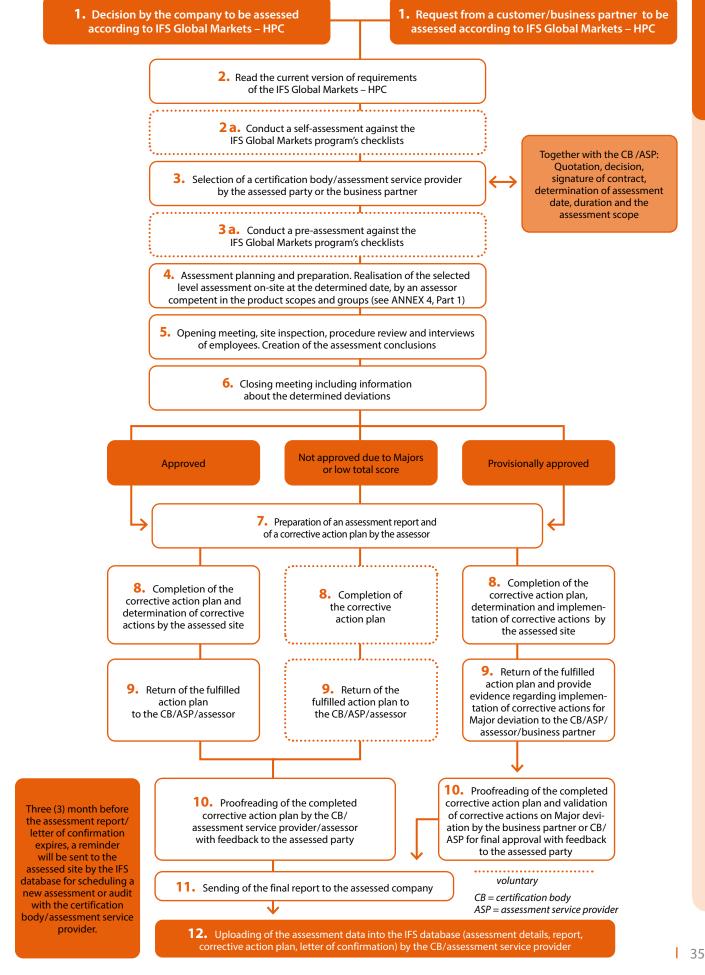
Annex 1: Application of checklists

There are possible variants to apply basic or intermediate level checklists. Typically, the time between passing the assessments is one (1) year and ideally, no fall back should be achieved.

Note: deviating application of checklists and timeframe can be agreed between the business partners.



Annex 2: Assessment process



Annex 3: Product scopes

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.

Annex 4: Products excluded from the IFS Global Markets – HPC scope

This list is by no means exhaustive:

- 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.)

IFS GLOBAL MARKETS – HPC VERSION 1 37



PART 2

Senior management responsibility	40
Quality and product safety management system	41
Resource management	47
Planning and production process	51
Measurements, analyses, corrective actions and management of incidents	65
nnex 1: Glossary	72
	Quality and product safety management system Resource management Planning and production process Measurements, analyses, corrective actions and management of incidents



PART 2 List of IFS Global Markets – HPC assessment requirements

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross refer- ence IFS HPC requirements and ISO 22716
	1	Senior management responsibi	lity	
		The senior management shall be the safety and quality goods and the necessary resources to make between senior management an for quality and product safety management	it possible. Communication d the department responsible	
	1.1	Corporate structure		
В	1.1.1	The senior management shall provide sufficient and relevant resources to meet the product requirements.		1.2.6 and ISO 22716
I	1.1.2		An organization chart shall be available showing the structure of the company.	1.2.1 and ISO 22716
	1.1.3		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.	1.2.3 (KO req. from IFS HPC) and ISO 22716
I	1.1.4		The department responsible for quality and product safety management shall have a direct reporting relationship to the senior management.	1.2.7 and ISO 22716

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
	1.2	Customer focus		
I	1.2.1		A documented process shall be in place to identify fundamental needs and expectations of customers.	1.3.1
	1.3	Management review		
	1.3.1		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.	1.4.1
	2	Quality and product safety man	agement system	
		The risk management system sha ciples and it will be revised every made in the product, process or product requirements.	time when any modification is	
	2.1	Quality management		
	2.1.1	Documentation requirements		
В	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).		2.1.1.1

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross refer- ence IFS HPC requirements and ISO 22716
	2.1.2	Record keeping		
В	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.		2.1.2.1and ISO 22716
В	2.1.2.2	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. These records shall be kept for a minimum of one year after the end of shelf life period and/or in line with customer's requirements.		2.1.2.3and ISO 22716
	2.2	Product safety management sys	stem	
	2.2.1	Risk management system (haza assessment)	rd analysis and risk	
		An effective implementation of gesential to establish a sound for risk assessment.	•	
В	2.2.1.2	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.		2.2.1.1

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
В	2.2.1.3	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.		2.2.1.2
I	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.	2.2.1.4
	2.2.2	Risk management team		
В	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.		2.2.2.1

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
В	2.2.2.2	The risk management team shall have senior management support and shall be well known and established within the company.		2.2.2.3
	2.2.3	Hazard analysis and risk assessi	ment	
		For all products, the following shadescribe the product and product materials, packaging, finished productions for storage and distributed bescribe the intended use of the consumer. Describe all of the steps taken to process flow diagram. Compare the process flow diagrat to ensure it is accurate.	ct category (including raw oduct) and the required oution. Product and identify the target produce the product in a	
В	2.2.3.1	Described the product: Describe the product and product category (including raw materials, packaging, finished product) including composition, chemical parameters, conditions for storage, packaging, labeling, etc.		2.2.3.1 wording slightly different from the IFS HPC
В	2.2.3.2	Identify intended use: Expected use taking into account vulnerable groups of consumers.		2.2.3.2 wording slightly different from the IFS HPC
В	2.2.3.3	Construct flow diagram: Describe all of the steps taken to produce the product in a process flow diagram taking into account products, product categories, raw materials etc. In the event of changes the flow diagram shall be revised.		2.2.3.3 wording slightly different from the IFS HPC
В	2.2.3.4	On-site confirmation of the flow diagram: Compare the process flow diagram with the production process to ensure it is accurate.		2.2.3.4 wording slightly different from the IFS HPC

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
		The production site shall perform facturing process as a minimum sthere are any hazards associated products. The production site could choose to accomplish this assessment. If hazards are identified within the expected that the production site necessary to avoid risks for the country of the production site necessary to avoid risks for the country of the production site necessary to avoid risks for the country of the production site necessary to avoid risks for the country of the production site necessary to avoid risks for the country of the production site necessary to avoid risks for the country of the production site necessary to avoid risks for the country of the production site necessary to avoid risks for the country of the production site necessary to avoid risks for the country of the production site necessary to avoid risks for the country of the production site necessary to avoid risks for the p	step in order to determine if with the production of its e any tool industry recognized the manufacturing process, it is e shall take appropriate actions	
В	2.2.3.5	Conduct a hazard analysis and risk assessment for each step: A hazard analysis shall be available for all physicall, chemical and biological hazards that may be reasonably expected. It shall be conducted for each step from raw materials to the finished product including development and packaging material validation. The assessment shall demonstrate the actions required if a hazard is a risk and the likelihood to harm consumers and severity of the damage. The chosen methodology shall be documented.		2.2.3.5.1 wording slightly different from the IFS HPC
В	2.2.3.6	Determine critical control points: Based on level of acceptability of risk, critical control points shall be identified and documented.		2.2.3.6 wording slightly different from the IFS HPC

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross refer- ence IFS HPC requirements and ISO 22716
В	2.2.3.7	Establish critical limits for each critical control point: For each critical control point identified, the appropriate critical limits shall be defined and validated in order to clearly identify when a process is out of control.		2.2.3.7
В	2.2.3.8	Establish a monitoring system for each critical control point: 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.		2.2.3.8 KO req. from IFS HPC
В	2.2.3.9	Establish corrective actions: For each critical control point, corrective actions shall be established. In case the moni- toring indicates that a particu- lar critical control point is not under control, adequate cor- rective actions shall be taken and documented. Such corrective actions shall also take into account any non-conforming products.		2.2.3.9

Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
В	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.		2.2.3.10
	3	Resource management		
		The company shall provide all ne policies, training, staff facilities et meet hygiene criteria and to pro	tc) to all personnel in order to	
	2.4			
	3.1	Personnel hygiene managemen	ıt	
	3.1.1	Personnel hygiene managemen Personnel hygiene	t	

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
В	3.1.1.2	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.		3.2.1.2
В	3.1.1.3	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.		3.2.1.3
В	3.1.1.4	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 on hazard analysis and assessment of associated risk.		3.2.1.4 and ISO 22716
	3.1.2	Protective clothing for personn	el, contractors and visitors	
В	3.1.2.1	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.		3.2.2.1
В	3.1.2.2	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.		3.2.2.2
В	3.1.2.3	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.		3.2.2.3

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
I	3.1.2.4		Suitable protective clothing and devices to ensure personnel safety shall be available in sufficient quantity for each employee, when required.	3.2.2.4
	3.1.3	Procedures applicable to infect	ious diseases	
В	3.1.3.1	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.		3.2.3.1 and ISO 22716
	3.2	Training and instruction		
В	3.2.1	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.		3.3.1 and ISO 22716
В	3.2.2	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.		3.3.2 and ISO 22716

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
I	3.2.3		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.	3.3.4 and ISO 22716
	3.3	Staff facilities, sanitary facilities hygiene	and equipment for personnel	
В	3.3.1	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.		3.4.2
В	3.3.2	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.		3.4.5
В	3.3.3	Hand washing facilities shall provide as a minimum:water,liquid soap,appropriate equipment for hand drying.		3.4.7

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
I	3.3.4		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.	3.4.4
	4	Planning and production proce	SS	
		Finished product specifications ar tion, any change or modification s Written contracts shall be establis	shall be agreed with the customer.	
	4.1	Contract agreement		
В	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.		4.1.1
В	4.1.2	Changes of existing contractual agreements shall be documented, communicated and updated between the contract partners.		4.1.2
	4.2	Specifications and formulas		
	4.2.1	Raw Materials (including package products and rework specification)		
В	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.		4.2.1.1

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
В	4.2.1.2	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.		4.2.1.5
В	4.2.1.3	When raw materials including packaging materials are repacked, the new label shall contain the relevant information as on the original label.		4.2.1.4 and ISO 22716
В	4.2.1.4	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.		4.2.1.3 and ISO 22716
В	4.2.1.5	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.		4.2.1.2 and ISO 22716

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
	4.2.2	Finished product specifications		
В	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.		4.2.2.1
В	4.2.2.2	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.		4.2.2.2 KO req. from IFS HPC
	4.3	Legislative framework		
В	4.3.1	The company shall comply with the current applicable legislation and shall be able to demonstrate its own role in the supply chain.		4.3.1.1
В	4.3.2	For all relevant raw materials, safety data sheets shall be available in the format required by the destination country and kept up to date.		4.3.1.3
В	4.3.3	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.		4.3.1.7

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
В	4.3.4	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.		4.3.1.4
	4.4	Purchasing (outsourcing if appl	icable)	
В	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 production process that may have an impact on product safety and quality those processes shall be identified, risk assessed and documented withing the product safety and quality management system.		4.4.1 4.4.8.1
В	4.4.2	A contract shall exist between the company and its subcontractor.		4.4.8.2 and ISO 22716
В	4.4.3	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.		4.4.4

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
ı	4.4.4		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.	4.4.5 and ISO 22716
I	4.4.5		Based on hazard analysis and assessment of associated risk, the company shall regularly check the subcontractor in the event of ousourcing, by using an audit checklist covering IFS HPC requirements (e.g. relevant documented risk management system, control plan, traceability system, crisis management, etc.). Documents of such checks shall be available.	4.4.8.3
1	4.4.6		The checks performed at the subcontractor shall be performed by a qualified auditor/inspector.	4.4.8.4
	4.5	Factory location		
	4.5.1	Site security		
l	4.5.1.1		The production and storage areas of the site shall be secured effectively by controlled access in order to prevent unauthorized entry.	4.5.1.2
	4.5.2	Factory exterior		
I	4.5.2.1		The factory exterior shall be sustainable maintained, clean and tidy. The external condition of the premises shall be considered within the internal audit process.	4.5.2.2

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
I	4.5.2.2		All grounds within the site shall be in good condition. Where natural drainage is inadequate, a suitable drainage equipment shall be installed.	4.5.2.3
	4.5.3	Plan layout and process flow		
В	4.5.3.1	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.		4.5.3.2
I	4.5.3.2		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.	4.5.3.3
	4.5.4	Buildings and facilities		
	4.5.4.1	Buildings and internal structure	25	
В	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.		4.5.4.1.1 and ISO 22716

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
l	4.5.4.1.2		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.	4.5.4.1.8 and ISO 22716
I	4.5.4.1.3		 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. 	4.5.4.1.9
	4.5.4.2	Lighting, air conditioning/venti	lation	
В	4.5.4.2.1	All working areas shall have adequate lighting.		4.5.4.2.1 and ISO 22716
В	4.5.4.2.2	Adequate natural and/or artificial ventilation shall exist in all areas.		4.5.4.2.3 and ISO 22716
	4.5.4.3	Water quality		
В	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.		4.5.4.3.1 and ISO 22716

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
I	4.5.4.3.2		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.	4.5.4.3.3 and ISO 22716
	4.6	Cleaning and disinfection		
В	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.		4.6.1 and ISO 22716
В	4.6.2	Cleaning utensils and chemicals shall be clearly identified, used and stored appropriately, to avoid contamination or unintended use.		4.6.6
I	4.6.3		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.	4.6.2

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
I	4.6.4		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.	4.6.5
	4.7	Waste disposal		
В	4.7.1	All current legal requirements for waste disposal shall be met.		4.7.2
I	4.7.2		Waste collection containers and, where existing, compac- tors shall be clearly marked, suitably designed, in good state of repair, easy to clean, and disinfected where necessary.	4.7.3 and ISO 22716
	4.8	Risk of foreign materials		
В	4.8.1	Based on hazard analysis and assessment of associated risk, procedures shall be in place to avoid contamination with foreign material.		4.8.1
В	4.8.2	Potentially contaminated products shall be isolated.		4.8.5 part a
I	4.8.3		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.	4.8.5 part b

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
I	4.8.4		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.	4.8.6
ı	4.8.5		Based on risk assessment metal and/or other foreign material detectors shall be installed to ensure efficiency of detection, in order to avoid subsequent contamination	4.8.3
	4.9	Pest monitoring/pest control		
В	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.		4.9.1 and ISO 22716

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
I	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.	4.9.2
I	4.9.3		Incoming deliveries shall be checked on receipt for the presence of pests. Any infestation shall be documented and control measures taken.	4.9.5
	4.10	Receipt of goods and storage		
В	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.		4.10.1
В	4.10.2	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.		4.10.6 and ISO 22716
В	4.10.3	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.		4.10.4

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
I	4.10.4		Periodic inventory shall be performed to ensure stock reliability. Any significant discrepancy shall be investigated and corrective action taken.	4.10.7 and ISO 22716
В	4.10.5	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.		4.10.2
	4.11	Transport		
В	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 in good conditions.		4.11.1 and ISO 22716
В	4.11.2	In case of transport of danger- ous goods, the company shall ensure that all the relevant legislative requirements are fulfilled.		4.11.2
I	4.11.3		Security of transport vehicles shall be appropriately maintained.	4.11.5

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
	4.12	Maintainance and repair		
В	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.		4.12.1 and ISO 22716
I	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.	4.12.2 and ISO 22716
I	4.12.3		All materials used for maintenance and repair shall be fit for the intended use.	4.12.3
ı	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.	4.12.4
	4.13	Equipment		
В	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.		4.13.1 and ISO 22716
I	4.13.2		Equipment shall be designed and locationed so that cleaning and maintenance operations can be effectively performed.	4.13.2 and ISO 22716

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
	4.14	Traceability		
В	4.14.1	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 the product. The traceability system shall incorporate all relevant processing and distribution records. Traceability shall be assured and documented until delivery to the customer.		4.14.1 KO req. from IFS HPC and ISO 22716
I	4.14.2		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.	4.14.4
I	4.14.3		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.).	4.14.6 and ISO 22716

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
	5	Measurements, analyses, correct of incidents	tive actions and management	
	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 offsite storage locations owned or rented by the company.	5.1.1 and ISO 22716
1	5.1.2		Internal audits shall be carried out at least once a year in all departments	5.1.2 and ISO 22716
I	5.1.3		Audit results shall be communicated to the senior management and to responsible persons of concerned department. Necessary corrective actions and a schedule for implementation shall be determined, documented and communicated to every relevant person.	5.1.4 and ISO 22716
	5.2	Factory inspections		
В	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 house-keeping. Any deviation and the associated corrective actions shall be documented.		5.2.1

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross refer- ence IFS HPC requirements and ISO 22716
	5.3	Manufacturing process validation	on and control	
В	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.		5.3.1
В	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.		5.3.2
В	5.3.3	The company shall ensure that in the event of changes to processing methods, equipment and product formulation (including rework and packaging material), process characteristics are reviewed in order to assure that product requirements are complied with. If relevant, customers shall be informed accordingly.		5.3.4 and ISO 22716

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
1	5.3.4		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.	5.3.3 and ISO 22716
I	5.3.5		There shall be appropriate procedures for prompt notification, recording and monitoring of equipment malfunction and process deviations.	5.3.6
	5.4	Calibration, adjustment and che monitoring devices	ecking of measuring and	
В	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.		5.4.1
	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 and on processes and products shall be carried out.	5.4.2 and ISO 22716
	5.5	Quantity checking (quantity co	ntrol/filling quantities)	
В	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.		5.5.1

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross reference IFS HPC requirements and ISO 22716
I	5.5.2		A procedure shall exist to define compliance criteria for lot quantity checking.	5.5.2
	5.6	Product analysis (including qua	lity checks)	
В	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.		5.6.1
В	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.		5.6.2
В	5.6.3	Where internal analysis is undertaken, qualified and trained personnel shall be in place, as well as appropriate equipment and premises.		5.6.6
I	5.6.4		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.	5.6.7 and ISO 22716

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross refer- ence IFS HPC requirements and ISO 22716
	5.7	Product quarantine (blocking/h	old) and product release	
В	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.		5.7.1 and ISO 22716
	5.8	Management of complaints from	m authorities and customers	
I	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).	5.8.1 and ISO 22716
I	5.8.2		Complaints shall be analyzed with a view to implementing preventive and corrective actions which avoid the recurrence of the non-conformity.	5.8.3 and ISO 22716
	5.9	Management of incidents, prod	uct withdrawal and product	
	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 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.	5.9.1

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross refer- ence IFS HPC requirements and ISO 22716
I	5.9.2		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.	5.9.4 KO req. from IFS HPC
	5.10	Management of non-conformition products	ies and non-conforming	
В	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).		5.10.1 and ISO 22716
В	5.10.2	Where non-conformities are present, immediate corrections shall be taken to ensure that product requirements are complied with.		5.10.3
В	5.10.3	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.		5.10.4

Basic/ Inter- mediate	No	Basic Level Requirement	Intermediate Level Requirement	Cross refer- ence IFS HPC requirements and ISO 22716
	5.11	Corrective actions		
В	5.11.1	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.		5.11.2 KO req. from IFS HPC and ISO 22716
I	5.11.2		The effectiveness of the implemented corrective actions shall be documented and shall be validated.	5.11.3 and ISO 22716

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 definitios apply and shall be respected.

Assessed company	The supplier/processing company to be assessed against the IFS Global Markets-HPC			
Assessment	The judgment of compliance against defined requirements made of an assessed company under the terms of an individual assessment agreement. The judgment of compliance against defined requirements made of an assessed company under the terms of an individual assessment agreement.			
Assessment service provider (ASP)	These are organisations not accredited against ISO 17065 and/or ISO 17021 for the certification of food/product safety scheme(s) but qualified for those. Within the IFS Global Markets – HPC program they are allowed to conduct the assessment, if they comply to the rules mentioned in Part 3 of this document. Assessments shall be performed by an impartial assessor and in an independent way.			
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 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.			
Certification body (CB)	These are organisations accredited against ISO 17065 and/or ISO 17021 for the certification of a food/product safety scheme(s) conducting audits in regard to food/product safety (and quality) with the issue of an accredited certificate, if the audit passes successfully (3rd party audits). Within the scope of the IFS Global Markets – HPC program and under non-accredited procedures, certification bodies can be in charge of the assessment without the issuing of an accredited certificate. Assessments shall be performed by an impartial person and in an independent way.			
Company	General organisation (whereas the site is a unit of the company).			
Consultants	Consultants are independent persons from the assessed company or relevant CB/ASP, who provide professional or expert advice in regard to the IFS Global Markets – HPC Program. They support the assessed party in their practical implementation of the IFS Global Markets – HPC requirements. Within the scope of the IFS Global Markets – HPC program, consultants do not conduct assessments, besides the pre-assessment.			
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.).			

Contamination	Occurrence of any undesirable matter, such as chemical, physical and/or microbiological matter in the product.			
Correction	A correction is 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.			
Customer	A customer is 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.).			
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 "knowhow" 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. In the IFS Global Markets – HPC program the good manufacturing practices are aimed to be implemented prior performing the hazard analysis and risk assessment. In the event that 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.			
Individual assessment agreement	An individual agreement between the certification body/assessment service provider and the assessed company, under which the certification body/assessment service provider shall provide the assessment.			
Letter of confirmation	Final written statement done by the CB/ASP confirming that a company has successfully passed or provisionally passed the assessment. A non-conformity which can be given to any requirement when there is a substantial failure to meet the requirements of the program. This includes the non-respect of legislation, law, food/product safety, customer issues or in case of internal dysfunctions (e.g. completely not regulated and controlled processes). A Major can also be given when the identified non-conformity can lead to a serious health hazard.			
Major non-conformity				
Monitoring	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.			
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).			
Product	Result of a process or activities transforming inputs into outputs. Products include services. In the context of this program a product is to be considered a HPC product (e.g. cosmetics, diapers etc.).			
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	Product requirement 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.			

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 (non-food oriented)	In the IFS Global Markets – HPC the risk management includes: hazard analysisrisk 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.			
Senior management	Executive or Top management.			
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 (initial 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.			



PART 3

0	Introduction	78
1	Requirements for certification bodies/assessment service providers	78
2	Requirements for IFS Global Markets – HPC assessors	79



PART 3:

Requirements for certification bodies, assessment service providers and assessors

0 Introduction

The IFS Global Markets – HPC program includes a product and process assessment. All organizations involved shall comply with the international rules and IFS-specific requirements described in this document. Part 3 of the IFS Global Markets – HPC program mainly deals with certification bodies, assessment service providers and assessors.

1 Requirements for certification bodies/assessment service providers

Certification bodies and assessment service providers intending to perform IFS Global Markets – HPC program assessments shall comply with the following rules.

1.1 Certification bodies

The certification body shall be accredited against ISO 17065 and/or ISO 17021 by an IAF or EA recognized accreditation body. Certification bodies shall have signed a separate IFS Global Markets agreement with the IFS Management GmbH. The agreement includes the acceptance of the IFS Global Markets program and enables access to the IFS database.

1.2 Assessment service provider

Assessment service provider shall provide written evidence about their involvement in the assessment process on behalf of a retailer or buying company.

Assessment service provider shall have signed an IFS Global Markets agreement with the IFS Management GmbH. The agreement includes the acceptance of the IFS Global Markets program and enables access to the IFS database.

1.3 Certification bodies'/assessment service providers' responsibilities for IFS Global Markets – HPC assessors (including freelancers)

Certification bodies/assessment service providers have the following responsibilities:

- To ensure that the assessor:
 - is competent for the scope of the assessment and its execution,
 - is able to access and to apply relevant laws and regulations,
 - has knowledge in product safety and hygiene practices, and the assessment is conducted in an independent way by an impartial assessor.

Note: to ensure impartiality the assessor who performs the assessment shall not have previously provided consultancy to the company they shall assess. Conflict of interests shall be avoided. For further info see glossary.

The certification body/assessment service provider shall maintain these competences (continuous supervision by the certification body/assessment service provider) and shall monitor assessment execution by on-site witness assessment.

To organize a one (1) day training session for IFS Global Markets – HPC program assessors
once a year for the purposes of sharing experience, calibration and updating knowledge of
relevant legal requirements, etc.

Note: only for certification bodies the calibration and updates about Global Markets assessments can be included within the 1 day IFS HPC in house training yearly organized.

• To maintain evidences of assessor competences.

The certification body/assessment service provider is responsible for choosing an assessor with the corresponding scope(s), language, competence(s), etc. for each IFS Global Markets – HPC assessment.

2 Requirements for IFS Global Markets – HPC assessors

During an IFS Global Markets – HPC assessment, assessors shall use relevant samples of products, in order to investigate on-site the assessed sites processes and where applicable documentation and to check the fulfilment of IFS Global Markets – HPC requirements.

2.1 General requirements

IFS Global Markets – HPC assessors shall meet the following requirements:

- They shall have signed a contract with the certification body/assessment service provider,
- They shall have submitted all relevant information about their competence to the certification body/assessment service provider,
- They shall communicate the certification body/assessment service provider clearly, if the necessary impartiality might not be ensured.

Note: The certification body/assessment service provider shall have observed and confirmed the professional qualification and competence of the assessor.

2.2 Requirements for IFS Global Markets – HPC assessors

2.2.1 General requirements on assessors for initial application

Candidates applying for the approval as IFS Global Markets – HPC assessor shall meet the following minimum requirements:

a) Education and minimum experience:

 a science-related university degree and two (2) years professional experience in the HPC sector in relation to household and personal care production activities (quality, production, ...).

or

a science-related university degree and two (2) years audit experience (min. five (5) audits/ year) in the HPC sector in relation to household and personal care production activities (quality, production, ...).

O

- professional education in the HPC industry with technical school or comparable degree and two (2) years professional experience in the HPC sector in relation to household and personal care production activities (quality, production, ...).
- b) Followed as an observer two (2) assessments or audits with regard to HPC product safety at HPC companies, if they do not have assessment and audit experience.
- c) Passed a **risk assessment training** on the basis of the international recognized standards/norms for risk assessment techniques.
- **d)** Have knowledge of local and, if applicable, of the destination country legislation for concerned assessment scopes.
- e) Have profound knowledge of the assessed scope (see Annex 3, Part 1).
- f) Have knowledge of the **local language**If the assessor wishes to perform assessments in language(s) different from their native language they shall be able to provide evidence for speaking fluently this/these other language(s).
- g) Visit the IFS Global Markets HPC assessor course organized by IFS.

Note: If such course is not available in the relevant country or if the business partner has different requirements, other courses can be accepted (and shall be validated by the business partner).

2.2.2 IFS auditors

a) IFS HPC auditors can start conducting IFS Global Markets – HPC assessments without any further qualification in all scopes.

- **b)** IFS Food auditors are allowed to perform IFS Global Markets HPC assessments as long as they fulfill the following requirements:
 - at least 1 year professional experience in the HPC field they shall assess or a minimum of 10 audits in the concerned HPC field (e.g. 2nd party audits, GMPs for cosmetics, BRC Personal Care and Household audits, etc.) and,
 - participation in an IFS Global Markets HPC training course provided by IFS (1 day course).
- c) IFS PACsecure auditors are allowed to perform IFS Global Markets HPC assessments <u>only</u> under scope 3 without any further qualification.

For assessments against other HPC scopes, the IFS PACSecure auditors shall demonstrate:

- at least 1 year working experience in the HPC field they shall assess or a minimum of 10 audits in the concerned HPC field (e.g. 2nd party audits, GMPs for cosmetics, BRC Personal Care and Household audits, etc.) and,
- participation in an IFS GM HPC training course provided by IFS (1 day course).

IFS auditors which do not meet the requirements set up above are not allowed to conduct IFS Global Markets – HPC assessments.

2.2.3 Scope extension for IFS HPC auditors

A minimum of 10 audits as described in the IFS HPC standard or assessments on a <u>determined</u> scope shall count as experience to request a scope extension. In the frame of IFS Global Markets – HPC only intermediate assessments will count to request scope extension.

Once the experience gained is recognized by the IFS office, the IFS HPC auditor shall participate at the IFS HPC scope specific course and it shall take the exam for that scope(s).



PART 4

0 Introduction	84
1 Reporting	84
2 auditXpressX [™]	85
3 The IFS database (www.ifs-certification.com)	86
Annex 1: Assessment overview	89
Annex 2: Assessment report	92
Annex 3: Corrective action plan	95
Annex 4: Letter of confirmation	96



PART 4:

Reporting, auditXpressX™ and IFS database

0 Introduction

After an IFS Global Markets – HPC assessment has been performed, a detailed and well-structured assessment report shall be completed. In general, the language of the report shall be the working language of the company. In special cases, where the native language of the trade partner is different from the language of the company, an English language version of the complete report could also be prepared.

Requirements evaluated with C, D and/or Major shall always be translated into English within the action plan and the assessment report. Exceptions shall be agreed with the business partner.

The IFS Global Markets – HPC assessment report should be prepared according to the following format.

1 Reporting

1.1 Assessment overview (Annex 1)

The first part of the assessment report shall contain the following general information:

Assessment details

The **cover page** of the assessment report shall include:

- · result and level of the assessment,
- · name of the assessed company or site,
- name and address of the certification body/assessment service provider,
- the logo of the certification body/assessment service provider,
- · date of the assessment.

These first pages shall give a summary of the most important assessment report items and shall include:

- name and address of the assessed site,
- name and address of the company (if headquarters,)
- · GLN Global Location Number, if available,
- · COID, as defined in the IFS database,
- assessment date,
- time of the assessment,
- previous assessment date,

- the name of the certification body/assessment service provider and the assessor who performed the previous assessment,
- assessment scope (mandatory detailed descriptions of processes/products),
- · list of key personnel present during assessment,
- name of the assessor(s),
- name of the certification body's/assessment service providers persons(s) responsible for the assessment result decision,
- · result of the assessment,
- company details listed: general information about the company (number of employees, size etc.),
- · company profile,
- · further explanations regarding scoring.

1.2 Assessment report (Annex 2)

The assessment report itself is structured as follows:

- the result of the assessment with level and percentage,
- · general summary table and graphics for all chapters,
- an overall summary of the assessment,
- a list of all established Major non-conformity(ies) and observations of concern
- description of follow-up corrective action from previous assessment (optional, to be agreed on with the business partner),
- a separate list (including explanations) of all requirements evaluated with N/A (not applicable)

1.3 Action plan (Annex 3)

The certification body/assessment service provider/the assessor describes and explains all established deviations and Mayor non-conformity(ies) in each chapter in the corrective action plan, which has a specified format shown in the Annex.

2 auditXpressX™

In order to increase the standardisation of IFS reporting, the auditXpressX™ has been developed.

It offers the following advantages:

- easy collection of assessment data through a user-friendly interface,
- production of quick and error-free IFS assessment reports,
- automatic evaluation of the assessment results by dynamic computation of all relevant items,
- · automatic generation of a standardized assessment report,

- temporary storage of interim assessment data for later completion.
- simple and secure export of completed assessment reports to the IFS database,
- simple exchange of assessment files between the assessors and their competent certification body/assessment service provider,
- · offline working, i.e. no permanent internet connection required,
- an update option provides constant access to the most recent version of the IFS.

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

Every IFS Global Markets assessment report shall be uploaded in the IFS database by the certification body/assessment service provider (uploading of report, action plan, letter of confirmation).

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

- auditors
- certification bodies/assessment service providers
- consultants
- assessed companies
- · retailers and other users.

The different groups' access rights are as follows:

Auditors/assessors:

- manage their own data,
- download the own assessor/auditor profile, which includes all information available at the IFS database about the assessor/auditor—standards, scopes, examinations, overview about the performed audits and assessments,
- receive IFS newsletter,
- access user group specific information.

Certification bodies/assessment service providers:

- manage their assessed companies and upload assessment reports and corrective action plans
- · may withdraw reports in specific situations,
- can manage all IFS assessment dates via the diary function, enabling retailers and companies to have a good overview of the scheduled assessment,
- · manage their accounts,
- have the possibility to compare two consecutive assessment reports and corrective action plans, for internal assessment training and calibration purposes,
- download the IFS logo(s).

Assessed companies:

- have access to their own assessment data,
- have the possibility to unlock retailers and other users for their achieved percentage, detailed assessment report and action plan,
- have the possibility to compare two consecutive assessment reports and action plans, for improvement purposes,
- download the IFS Global Markets HPC logo,
- manage their certification bodies/assessment service providers,
- · manage company personnel access (create sub-accounts) to the assessment data,
- search for other assessed companies,
- manage their suppliers using a "favourites" option.

Access for the headquarters of assessed companies:

A headquarter access for assessed companies can be set up which allows a company headquarter to administer all of their assessed sites through a single access point.

Consultants:

- manage own data about the standards, scopes, languages etc.
- · visible on the public website of the IFS—including reviews from their customers
- access to user group specific information.

Retailers and other users (e.g. Authorities):

- search for assessed companies,
- · manage their assessed companies via a "favourites" option,
- · receive an e-mail notification if a certain assessment level is repeated,
- get information via e-mail in case of a report withdrawal 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 IFS database

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

- the company's name and address,
- the certification body's/assessment service provider's name and address,
- the assessor's name,
- the scope of the assessment,
- the date and duration of the assessment,
- the level achieved at the assessment,
- the IFS Global Markets HPC letter of confirmation's date of issue and its validity.

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

• assessment report, letter of confirmation and corrective action plan.

The retailers and other users/assessed companies automatically receive access to the unlocked data by the assessed company after the data has been unlocked. Communication to retailers and other users is via a secure web process which guarantees that only authorized retailers and other users/assessed companies can view specific data of the assessed companies/suppliers.

Annex 1: Assessment overview

Cover page

Logo of the certification body/ assessment service provider



IFS Global Markets – HPC Version 1, March 2018

Level [approved/provisionally approved/not approved]

Final assessment report

Company/site: [name]

Date of assessment: [dd. mm. yyyy]

Name and address of certification body/ assessment service provider

First page of the assessment report

IFS Global Markets – HPC Level [approved/provisionally approved/not approved] **Assessment details** Date/Duration of assessment: Lead assessor: Date/Duration of the last assessment: Co-assessor: Certification body/assessment service provider; assessor of the Name of the certification body's/ last assessment: assessment service provider's persons(s) responsible for the assessment result decision: Name and address of the company (or head office) Name and address of the assessed site Responsible person: *Name and phone of an emergency contact:* Phone: Fax: Phone: Fax: GLN N°: IFS COID: Local authorization number: Number and kind (full, part) of employees: *Year of construction:* Last structural measures (when and what): Shift patterns: Product's excluded: Size of site: Products manufactured on the site: **Production volume: Number of production lines:** Finished product's storage— Own/third party on site/off site: transportation of products: Outsourced processes/products: Scope Product scope(s) Details regarding the scope Participants of the assessment Name Position Opening Site inspection Procedure Closing meeting review meeting **Company profile**

include here as a minimum:

- does the company fulfill the requirements about the logo use?
- is the site certified according to other schemes? If so, please specify.
- does the company/production site also has traded products? If so, please specify.

Explanations of the assessment report

Evaluation of requirements

Evaluation	Explanation	Points
Α	Full compliance	20 points
В	Almost full compliance	15 points
C	Small part of the requirement is implemented	5 points
D	Requirement has not been implemented	0 points
Major non-conformity	Non-respect of a program's requirement, including legislation, law, product safety, customer issues and/or in case of internal dysfunctions (e.g. completely not regulated and controlled processes). A Major can also be given when the identified non-conformity can lead to a serious health hazard.	10% of the total amount of points possible to reach is substracted
N/A	Not applicable Requirement not applicable for a company	N/A equirements will be excluded from the final scoring

Annex 2: Assessment report

IFS Global Markets – HPC Level [approved/provisionally approved/not approved]

Assessment report

Number of Major non-conformities in basic level checklist:	
Number of Major non-conformities in intermediate level checklist:	
Total score:	%
Level:	
Result:	

Overview of chapters

	Chapter						
		Senior Manage- ment respon- sibility	Product safety and quality manage- ment system	Resource Manage- ment	Planning and produc- tion process	Measure- ments, analyses, corrective actions, and man- agement of incidents	Additional chapter
per-	Basic						
cent	Intermediate						

Overview evaluation

	Basic					
	Intermediate					
	Senior Product Resource Planning Measurements, Addition analyses, chapter production process actions, and management of incidents					
Α						
В						
С						
D						
Major						
N/A						

Summary of the assessment

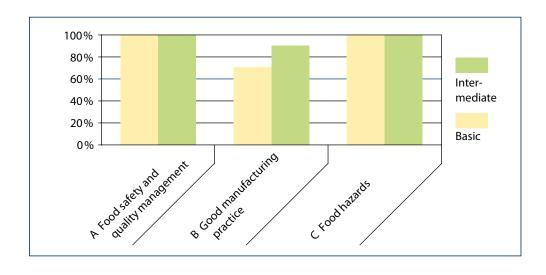
Mention at least:

- Product specifications e.g. which specifications had been checked during the assessment.
- Describe the traceability system and give a summary of the traceability test result.
- The assessor shall provide the following information:
 - How many withdrawals and recalls have been occurred since the last assessment?
 - Specify product(s) involved
 - Specify the cause of the withdrawal and product recall.
- Information about sources and analyses of water used at the site
- Information about pest monitoring/control
- Which allergens are manageged in the site and how?
- List CCPs with associated critical limits.

Observation regarding Major non-conformities
Description of follow-up of corrective action from the previous assessment

Chart

Percent



Summary of the N/A evaluations

No	Reference	IFS Global Markets – HPC requirements	Evaluation	Explanation
1.				

95

Annex 3: Corrective action plan

Name and address of the assessed company/production site

The corrective action plan must be returned to the certification body/assessment service provider before:

Require- ment number	IFS Global Markets – HPC requirement	Evaluation	Explanation (by the assessor)	Correction, root cause, corrective action (by the company)	Responsibility/date/status of implementation (by the company)	Release by the assessor

IFS GLOBAL MARKETS – HPC VERSION 1

Annex 4: Letter of confirmation

Letter of confirmation



Herewith the certification body/assessment service provider

Name of the certification body/assessment service provider

confirms that the activities of

Name of the assessed site Address

COID

(Headquarters)

for the assessment scope:

detailed descriptions of processes/products

got approved/provisionally approved according to the requirements set out in the

IFS Global Markets – HPC Version 1, March 2018

and other associated normative documents

at basic/intermediate level

with a score of XX $\!\%$ (if required)

Assessment date

Date of issue of letter of confirmation

Letter of confirmation valid until

Next assessment to be performed within the time period

(specify soonest and latest assessment date, according to requirements of assessment protocol, Part 1)

- Date and place
- Name and signature of the responsible person at the certification body/assessment service provider
- Address of the certification body/ assessment service provider

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**

DE96 1005 0000 0190 0297 65 IBAN number:

BIC-/Swift-Code: BE LA DE BE

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Or by 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

