Fostering Academia Industry Collaboration
In Food Safety & Quality

FOOD SAFETY MANAGEMENT SYSTEMS

The IFS standard

1. Introduction

Supplier audits have been a permanent feature of retailer's systems and procedures for many years. Until 2003 they were performed by the quality assurance departments of the individual retailers, wholesalers and food services.

The ever-rising demands of consumers, the increasing liabilities of retailers, wholesalers and food services, the increasing 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 involved stakeholders.

The fundamental objectives of IFS Food 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,**
- **to reduce costs and time for both suppliers and retailers.**

In general, when auditing in accordance with IFS, the auditor assesses if the various elements of a company's quality and food safety system are documented, implemented, maintained, and continuously improved.

The auditor shall examine the following elements:

- **organisational structure in relation to responsibility, authority,**
- **qualification and job description,**

- documented procedures and the instructions concerning their implementation,
- inspection and testing: specified requirements and defined acceptance/tolerance criteria,
- the actions to be taken in case of non-conformities,
- investigation of the causes of non-conformities and the implementation of corrective actions,

- **conformity analysis of safety and quality data and review of implementation in practice,**
- **the handling, storage and retrieval of quality and food safety records, such as traceability data, document control.**

2. Types of audits

TYPES OF AUDITS

2.1. Initial audit

2.2. Follow-up audit

2.3. Renewal audit (for recertification)

2.4. Extension audit

2.1. INITIAL AUDIT

An initial audit is a company's first audit to IFS Food. It is performed at a time and date agreed between the company and the selected certification body. During this audit the entire company is audited, both in relation to its documentation and the processes themselves. During the audit, all criteria of the IFS requirements shall be assessed by the auditor.

2.2. FOLLOW-UP AUDIT

A follow-up audit is required in a specific situation when the results of the audit (an initial audit or a renewal audit) have been insufficient to allow the award of the certificate. During the follow-up audit, the auditor focuses on the implementation of the actions taken to correct the Major non-conformity determined during the previous audit.

2.3. RENEWAL AUDIT

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

2.4. EXTENSION AUDIT

In specific situations, such as new products and/or processes to be included in the audit scope or each time the audit scope would need to be updated on the certificate, then, for an IFS Food certified company, it is not necessary to perform a complete new audit, but to organise an on-site extension audit during the validity period of the existing certificate. The certification body is responsible for determining relevant requirements to be audited and relevant audit duration.

3. The certification process

THE CERTIFICATION PROCESS

3.1. Preparation of an audit

3.2. Certification body selection – contractual arrangements

3.3. Duration of an audit

3.4. Drawing up an audit time schedule

3.5. Evaluation of requirements

3.1. PREPARATION OF AN AUDIT

Before being audited, the company shall review all requirements of the IFS Food Standard in detail and, if existing, IFS doctrine and erratum.

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

The expected date for the initial or renewal audit shall be communicated to the IFS offices via the IFS audit portal.

3.2. CERTIFICATION BODY SELECTION

In order to undertake the IFS audit, the company shall appoint a certification body which is approved to perform such audits.

The list of all IFS international approved certification bodies, by country, is available on the website www.ifs-certification.com.

Certification bodies can have auditors qualified for one or several scopes. Confirmation of the product scopes and technology scopes for which the certification body can perform audits shall be obtained from the individual certification body.

IFS audits can be carried out by an audit team, only if all members of the audit team are IFS approved auditors. The audit shall take place when products of the audit scope are being processed.

The audit shall preferably be carried out in the language of the company and the certification body shall make every attempt to appoint an auditor whose native language or main working language is the language of the company.

3.3. DURATION OF AN AUDIT

IFS has implemented a tool to calculate the minimum audit duration based on the following criteria:

- **total number of people (part time workers, shift workers, temporary staff, administrative people, etc.),**
- **number of product scopes,**
- **number of processing steps (“P” steps).**

This tool is available on www.ifs-certification.com .

3.3.1. PRODUCT SCOPES:

1. Red and white meat, poultry and meat products
2. Fish and fish products
3. Egg and egg products
4. Dairy products
5. Fruit and vegetables
6. Grain products, cereals, industrial bakery and pastry, confectionary, snacks

7. Combined products
8. Beverages
9. Oils and fats
10. Dry goods, other ingredients and supplements
11. Pet food

3.3.2. TECHNOLOGY SCOPES / PROCESSING STEP:

IFS tech scope	IFS processing step – including processing/treating/manipulation/storing	
A	P1	Sterilisation (e.g. cans)
B	P2	Thermal pasteurisation, UHT/aseptic filling, hot filling Other pasteurisation techniques e.g. high pressure pasteurisation, microwave
C	P3	Irradiation of food
	P4	Preserving: Salting, marinating, sugaring, acidifying/pickling, curing, smoking, etc. Fermentation, acidification
	P5	Evaporation/dehydration, vacuum filtration, freeze drying, microfiltration (less than 10 µ mesh size)

IFS tech scope	IFS processing step – including processing/treating/manipulation/storing	
D	P6	Freezing (at least –18 °C/0 °F) including storage Quick freezing, cooling, chilling processes and respective cool storing
	P7	Antimicrobial dipping/spraying, fumigation

IFS tech scope	IFS processing step – including processing/treating/manipulation/storing	
E	P8	Packing MAP, packing under vacuum
	P9	Processes to prevent product contamination esp. microbiological contamination, by means of high hygiene control and/or specific infra- structure during handling, treatment and/or processing e.g. clean room technology, „white room“, (controlled working room temperature for food safety purpose, disinfection after cleaning, positive air pressure systems like filtration below 10 µ)
	P10	Specific separation techniques: e.g. filtration like reverse osmoses, use of active charcoal

IFS tech scope	IFS processing step – including processing/treating/manipulation/storing	
F	P11	Cooking, baking, bottling, filling of viscous products, brewing, fermentation (e.g. wine), drying, frying, roasting, extrusion, churning
	P12	Coating, breading, battering, cutting, slicing, dicing, dismembering, mixing/blending, stuffing, slaughtering, sorting, manipulation, packaging Storing under controlled conditions (atmosphere) except temperature
	P13	Distillation, purification, steaming, damping, hydrogenating, milling

3.4. DRAWING UP AN AUDIT TIME SCHEDULE

The audit shall be scheduled based on the following steps:

- **the opening meeting,**
- **the evaluation of existing quality and food safety systems; achieved by checking documentation (HACCP, quality management documentation),**
- **the on-site inspection and interviewing of the personnel,**
- **the final conclusions drawn from the audit,**
- **the closing meeting.**

3.5. EVALUATION OF REQUIREMENTS

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

In IFS Food, there are 4 scoring possibilities:

A: Full compliance with the requirement specified in the Standard

B: Almost full compliance with the requirement specified in the Standard, but a small deviation was found

C: Only a small part of the requirement has been implemented

D: The requirement in the Standard has not been implemented

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

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

The auditor shall explain all scorings with B, C and D in the audit report. In addition to this scoring, the auditor can decide to give the company a “KO” or a “Major” non-conformity that will subtract points from the total amount.

3.5.1. MAJOR non-conformity

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

When there is a substantial failure to meet the requirements of the Standard, which includes food safety and/or the legal requirements of the production and destination countries. A Major can also be given when the identified non-conformity can lead to a serious health hazard.

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

3.5.2. KO (Knock out) non-conformity

In IFS, there are specific requirements which are designated as KO requirements (KO – Knock Out).

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

In IFS Food the following 10 requirements are defined as KO requirements:

1.2.4. Responsibility of the senior management

2.2.3.8.1. Monitoring system of each CCP

3.2.1.2. Personnel hygiene

4.2.1.2. Raw material specifications

4.2.2.1. Recipe compliance

4.12.1. Foreign material management

4.18.1. Traceability system

5.1.1. Internal audits

5.9.2. Procedure for withdrawal and recall

5.11.2. Corrective actions

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

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

3.5.3. N/A (not applicable):

When the auditor decides that a requirement is not applicable for a company, the auditor has to use as scoring N/A - Not applicable - and provide a short explanation in the audit report.

N/A is not possible for KO requirements, except for 2.2.3.8.1 and 4.2.2.1.

4. IFS Requirements

(list of topics and KO's)

1. SENIOR MANAGEMENT RESPONSIBILITY

1.1. Corporate policy/Corporate principles

1.2. Corporate structure

1.3. Customer focus

1.4. Management review

1.2.4. (KO n° 1): The senior management shall ensure that employ- ees are aware of their responsibilities related to food safety and quality and that mechanisms are in place to monitor the effectiveness of their operation. Such mechanisms shall be clearly identified and documented.

2. QUALITY AND FOOD SAFETY MANAGEMENT SYSTEM

2.1. Quality Management

2.1.1. Documentation requirements

2.1.2. Record keeping

2.2. Food Safety Management

2.2.1. HACCP system

2.2.2. HACCP team

2.2.3. HACCP analysis

2.2.3.8. Establish a monitoring system for each CCP (CA Step 9 – Principle 4)

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

3. RESOURCE MANAGEMENT

3.1. Human resources management

3.2. Human resources

3.2.1. Personnel hygiene

3.2.2. Protective clothing for personnel, contractors and visitors

3.2.3. Procedures applicable to infectious diseases

3.3. Training and instruction

3.4. Sanitary facilities, equipment for personnel hygiene and staff facilities

3.2.1.2. (KO N° 3): The requirements for personnel hygiene shall be in place and applied by all relevant personnel, contractors and visitors.

4. PLANNING AND PRODUCTION PROCESS

4.1. Contract agreement

4.2. Specifications and formulas

4.2.1. Specifications

4.2.2. Formula/recipes

4.3. Product development/Product modification/Modification of production processes

4.4. Purchasing

4.5. Product packaging

4.2.1.2. (KO N° 4): Specifications shall be available and in place for all raw materials (raw materials/ ingredients, additives, packaging materials, rework). Specifications shall be up to date, unambiguous and be in compliance with legal requirements and, if existing, with customer requirements.

4.2.2.1. (KO N° 5): Where there are customer agreements in relation to the product formula/recipe and technological requirements, these shall be complied with.

4.6. Factory location

4.7. Factory Exterior

4.8. Plant layout and process flows

4.9. Constructional requirements for production and storage areas

4.9.1. Constructional requirements

4.9.2. Walls

4.9.3. Floors

4.9.4. Ceilings/Overheads

4.9.5. Windows and other openings

4.9.6. Doors and gates

4.9.7. Lighting

4.9.8. Air conditioning/Ventilation

4.9.9. Water supply

4.9.10. Compressed air

4.10. Cleaning and disinfection

4.11. Waste disposal

4.12. Risk of foreign material, metal, broken glass and wood

4.13. Pest monitoring/Pest control

4.14. Receipt of goods and storage

4.15. Transport

4.16. Maintenance and repair

4.17. Equipment

4.18. Traceability (including GMOs and allergens)

4.19. Genetically modified organisms (GMOs)

4.20. Allergens and specific conditions of production

4.21. Food Fraud

4.12.1. (KO N° 6): Based on hazard analysis and assessment of associated risks, procedures shall be in place to avoid contamination with foreign material. Contaminated products shall be treated as non-conforming products.

4.18. Traceability (including GMOs and allergens)

4.18.1 (KO N° 7): 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 food, packaging intended or expected to be in direct contact with food. The traceability system shall incorporate all relevant receiving processing and distribution records. Traceability shall be ensured and documented until delivery to the customer.

5. MEASUREMENTS, ANALYSIS, IMPROVEMENTS

5.1. Internal audits

5.2. Site factory inspections

5.3. Process validation and control

5.4. Calibration, adjustment and checking of measuring and monitoring devices

5.5. Quantity checking (quantity control/filling quantities)

5.1.1. (KO N° 8): Effective internal audits shall be conducted according to a defined agreed audit program and shall cover at least all requirements of the IFS Standard. Scope and frequency of internal audits shall be determined by hazard analysis and assessment of associated risks. This is also applicable for off site storage locations owned or rented by the company.

5.6. Product analysis

5.7. Product quarantine (blocking/hold) and product release

5.8. Management of complaints from authorities and customers

5.9. Management of incidents, product withdrawal, product recall

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

5.11. Corrective actions

5.9.2. (KO N° 9): 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.

5.11.2. (KO N° 10): 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 action shall be clearly defined. The documentation shall be securely stored, and easily accessible.

6. FOOD DEFENSE PLAN AND EXTERNAL INSPECTIONS

6.1. Defense assessment

6.2. Site Security

6.3. Personnel and Visitor Security

6.4. External Inspections

ANNEX

The IFS standard - Requirements

1. SENIOR MANAGEMENT RESPONSIBILITY

1.1. Corporate policy/Corporate principles

1.1.1. The senior management shall draw up and implement a corporate policy. This shall consider as a minimum:

- customer focus

- environmental responsibility

- sustainability

ethics and personnel responsibility

product requirements (includes: product safety, quality, legality, process and specification).

The corporate policy shall be communicated to all employees.

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

1.1.3. From the corporate policy, the quality and food safety objectives shall be communicated to the employees in the respective departments and shall be effectively implemented.

1.1.4. The senior management shall ensure that the achievement of all objectives is regularly reviewed, as a minimum at least once a year.

1.1.5. All relevant information related to food safety and quality shall be communicated effectively and in a timely manner to the relevant personnel.

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1.2. Corporate structure

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

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

1.2.3. Job descriptions with clearly defined responsibilities shall exist and shall be applicable for employees whose work has an effect on product requirements.

1.2.4. (KO n° 1): The senior management shall ensure that employ- ees are aware of their responsibilities related to food safety and quality and that mechanisms are in place to monitor the effectiveness of their operation. Such mechanisms shall be clearly identified and documented.

1.2.5. Employees with influence on product requirements shall be aware of their responsibilities, and shall be able to demonstrate their understanding of their responsibilities.

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

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

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

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

1.2.10. The company shall have a system in place to ensure that it is kept informed of all relevant legislation on food safety and quality issues, scientific and technical developments and industry codes of practice.

1.2.11. The company shall inform its customers, as soon as possible, of any issue related to product specification, in particular of all non-conformity(ies) identified by competent authorities related to products which could have, has or has had a defined impact on safety and/or legality of respective products. This could include, but are not limited to cautionary issues.

1.3. Customer focus

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

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

1.4. Management review

1.4.1. Senior management shall ensure that the quality and food safety management systems are reviewed at least annually or more frequently if changes occur. Such reviews shall contain, at least, results of audits, customer feedbacks, process compliance and product conformity, status of preventive and corrective actions, follow up actions from previous management reviews, changes that could affect the food safety and quality management systems and recommendations for improvement.

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

1.4.3. The company shall identify and review regularly (e.g. by internal audits or on-site inspection) the infrastructure needed to achieve conformity to product requirements. This shall include, as a minimum, the following:

- Buildings - supply systems

- machines and equipment

- transport.

The ults of the review shall be considered, with dcon- sideration to risk, for investment planning.

1.4.4. The company shall identify and review regularly (e.g. by internal audits or on-site inspection) the work environment needed to achieve conformity to product requirements. This shall include, as a minimum the following:

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

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

2. QUALITY AND FOOD SAFETY MANAGEMENT SYSTEM

2.1. Quality Management

2.1.1. Documentation requirements

2.1.1.1. The system for food safety and quality management shall be documented and implemented, and shall be retained in one location (food safety and quality manual or electronic documented system).

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

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

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

2.1.2.5. The reason for any amendments to documents critical for the product requirements shall be recorded.

2.1.2. Record keeping

2.1.2.1. All relevant records necessary for the product requirements shall be complete, detailed and maintained and shall be available on request.

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

2.1.2.3. All records shall be kept in accordance with legal requirements and for a minimum of one year after the shelf life. For products which have no shelf life, the duration of record keeping shall be justified and this justification shall be documented.

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

2.1.2.5. Records shall be securely stored and easily accessible.

2.2. Food Safety Management

2.2.1. HACCP system

2.2.1.1. The basis of the company's food safety control system shall be a fully implemented, systematic and comprehensive HACCP system, based upon the Codex Alimentarius principles. It shall take into account any legal requirements of the production and destination countries which may go beyond such principles. The HACCP system shall be implemented at each production site.

2.2.1.2. The HACCP system shall cover all raw materials, products or product groups as well as every process from goods into dispatch, including product development and product packaging.

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

2.2.1.4. HACCP system shall be reviewed and necessary changes shall be made when any modification is made in the product, process or any step.

2.2.2. HACCP team

2.2.2.1. Assemble HACCP team (CA Step 1)

The HACCP team shall be multidisciplinary and include operational staff. Personnel appointed as HACCP team members shall have specific knowledge of HACCP, product and process knowledge and the associated hazards. Where competent knowledge is not available, external expert advice shall be obtained.

2.2.2.2. Those responsible for the development and maintenance of the HACCP system shall have an internal team leader and shall have received adequate training in the application of the HACCP principles.

2.2.2.3. The HACCP team shall have strong senior management support and shall be well known and established across the whole facility.

2.2.3. HACCP analysis

2.2.3.1. Describe product (CA Step 2)

A full description of the product including all relevant information on product safety exists such as:

- composition

- physical, organoleptic, chemical and microbiological parameters

- legal requirements for the food safety of the product

- methods of treatment

- packaging
- durability (shelf life)
- conditions for storage, method of transport and distribution.

2.2.3.2. Identify intended use (CA Step 3)

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

2.2.3.3. Construct flow diagram (CA Step 4)

A flow diagram shall exist for each product, or product group, and for all variations of the processes and sub-processes (including rework and reprocessing). The flow diagram shall be dated, and clearly identify each CCP with the number assigned to it. In the event of any changes the flow diagram shall be updated.

2.2.3.4. On-site confirmation of the flow diagram (CA Step 5)

The HACCP team shall verify the flow diagram, by on-site checks, at all operation stages. Amendments to the diagram shall be made, where appropriate.

2.2.3.5. Conduct a hazard analysis for each step (CA Step 6 – Principle 1)

2.2.3.5.1. A hazard analysis shall be available for all physical, chemical and biological hazards, including allergens, which may reasonably be expected.

2.2.3.5.2. The hazard analysis shall consider the likely occurrence of hazards and severity of their adverse health effects.

2.2.3.6. Determine critical control points (CA Step 7 – Principle 2)

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

2.2.3.6.2. For all steps which are important for food safety, but which are not CCP's, the company shall implement and document control points (CP's). Appropriate control measures shall be implemented.

2.2.3.7. Establish critical limits for each CCP (CA Step 8 – Principle 3)

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

2.2.3.8. Establish a monitoring system for each CCP (CA Step 9 – Principle 4)

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

2.2.3.8.2. The operative personnel in charge of the monitoring of CCP's shall have received specific training/instruction.

2.2.3.8.3. Records of CCP's monitoring shall be checked.

2.2.3.8.4. The CP's shall be monitored and this monitoring shall be recorded.

2.2.3.9. Establish corrective actions (CA Step 10 – Principle 5)

In the event that the monitoring indicates that a particular CCP or CP is not under control, adequate corrective actions shall be taken and documented. Such corrective actions shall also take into account any non-conforming products.

2.2.3.10. Establish verification procedures (CA Step 11 – Principle 6)

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

- internal audits - analysis -sampling

- Evaluations - complaint by authorities and customers.

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

2.2.3.11. Establish documentation and record keeping (CA Step 12 – Principle 7)

Documentation shall be available covering all processes, procedures, control measures and records. Documentation and record keeping shall be appropriate to the nature and size of the company.

3. RESOURCES MANAGEMENT

3.1. Human resources management

3.1.1. All personnel performing work that affects product safety, legality and quality shall have the required competence by education, work experience and/or training, commensurate with their role, based on hazard analysis and assessment of associated risks.

3.2. Human resources

3.2.1. Personnel hygiene

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

- protective clothing - hand washing and disinfection

- eating and drinking - smoking

- actions to be taken in case of cuts or skin abrasions

- fingernails, jewellery and personal belongings

hair and beards.

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

3.2.1.2. (KO N° 3): The requirements for personnel hygiene shall be in place and applied by all relevant personnel, contractors and visitors.

3.2.1.3. Compliance with personnel hygiene requirements shall be checked regularly.

3.2.1.4. Visible jewellery (incl. piercing) and watches shall not be worn. Any exceptions shall have been comprehensively evaluated by hazard analysis and assessment of associated risks in relation to product and process. This shall be effectively managed.

3.2.1.5. Cuts and skin abrasions shall be covered by a coloured plaster/bandage (different from the product colour) – containing a metal strip, where appropriate – and in case of hand injuries, in addition to a plaster/bandage, a single use glove shall be worn.

3.2.2. Protective clothing for personnel, contractors and visitors

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

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

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

3.2.2.4. Suitable protective clothing shall be available in sufficient quantity for each employee.

3.2.2.5. All protective clothing shall be thoroughly and regularly laundered. Hazard analysis and assessment of associated risks, together with consideration given to the processes and products of the company shall determine if clothing shall be washed by a contract laundry, on site laundry or by the employee.

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

3.2.3. Procedures applicable to infectious diseases

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

3.3. Training and instruction

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

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

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

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

- list of participants (this shall include their signature)

- Date **- duration**

- contents of training **- name of trainer/tutor.**

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

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

3.4. Sanitary facilities, equipment for personnel hygiene and staff facilities

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

3.4.2. The risk of product contamination by foreign material from staff facilities shall be evaluated and minimised. Consideration shall also be given to food brought to work by personnel and personal belongings.

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

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

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

3.4.6. Adequate hand hygiene facilities shall be provided at access points to and within production areas, as well as at staff facilities. Based on hazard analysis and assessment of associated risks, further areas (e.g. packaging area) shall be similarly equipped.

3.4.7. Hand washing facilities shall provide as a minimum:

- running potable water at an appropriate temperature

- liquid soap

- appropriate equipment for hand drying.

3.4.8. Where highly perishable food products are handled, the following additional requirements regarding hand hygiene shall also be provided:

- hand contact-free fittings

- hand disinfection

- adequate hygiene equipments

- signage highlighting hand hygiene requirements

- waste container with hand contact-free opening.

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

3.4.10. Changing rooms shall be situated so that they allow direct access to the areas where food products are handled. Based on hazard analysis and assessment of associated risks, exceptions shall be justified and managed.

3.4.11. Where the hazard analysis and assessment of associated risks show the necessity, cleaning facilities shall be available and used for boots, shoes and further protective clothing.

4. PLANNING AND PRODUCTION PROCESS

4.1. Contract agreement

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

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

4.2. Specifications and formulas

4.2.1. Specifications

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

4.2.1.2. (KO N° 4): Specifications shall be available and in place for all raw materials (raw materials/ ingredients, additives, packaging materials, rework). Specifications shall be up to date, unambiguous and be in compliance with legal requirements and, if existing, with customer requirements.

4.2.1.3. Where required by customers, product specifications shall be formally agreed.

4.2.1.4. Specifications and/or their contents shall be provided in the relevant location and accessible to all relevant personnel.

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

4.2.1.6. The specification control procedure shall include the update of finished product specification in case of any modification:

- of raw material

- of formula/recipe

- of process with influence on the final products

- of packaging with influence on the final products.

4.2.2. Formula/recipes

4.2.2.1. (KO N° 5): Where there are customer agreements in relation to the product formula/recipe and technological requirements, these shall be complied with.

4.3. Product development/Product modification /Modification of production processes

4.3.1. A procedure for product development shall be in place which incorporates the hazard analysis principles, in accordance with the HACCP system.

4.3.2. Product formulation, manufacturing processes, process parameters and the fulfilment of product requirements shall be established and shall have been assured by factory trials and product testing.

4.3.3. Shelf life tests or adequate processes shall be carried out and consideration given to product formulation, packaging, manufacturing and declared conditions; “Use by” or “Best before” dates shall be established accordingly.

4.3.4. When establishing and validating the shelf life of the product (including long shelf life product i.e. labelled with a “best before date”), the results of organoleptic tests shall also be taken into account.

4.3.5. Product development shall consider the results of organoleptic assessments.

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

4.3.7. Recommendations for preparation and/or use of the food products shall be established. Where appropriate, customer requirements shall be included.

4.3.8. The company shall demonstrate through studies and/or perform relevant tests in order to validate nutritional information or claims which are mentioned on labelling. This applies both for a new product and during all its period of sale.

4.3.9. The progress and results of product development shall be properly recorded.

4.3.10. The company shall ensure that in the event of changes to product formulation, including rework and packaging material, process characteristics are reviewed in order to assure that product requirements are complied with.

4.4. Purchasing

4.4.1. The company shall control purchasing processes to ensure that all externally sourced materials and services, which have an impact on food safety and quality, conform to requirements. Where a company chooses to outsource any process that may have an impact on food safety and quality, the company shall ensure control over such processes. Control of such outsourced processes shall be identified and documented within the food safety and quality management system.

4.4.2. There shall be a procedure for approval and monitoring of suppliers (internal and external), outsourced production or part of it.

4.4.3. 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.

4.4.4. The results of suppliers' assessments shall be reviewed regularly and this review shall be based on hazard analysis and assessment of associated risks. There shall be records of the reviews and of the actions taken as a consequence of assessment.

4.4.5. The purchased products shall be checked in accordance with the existing specifications and their authenticity, based on hazard analysis and assessment of associated risks. The schedule of these checks shall, as a minimum, take into account the following criteria; product requirements, supplier status (according to its assessment) and impact of the purchased products on the finished product. The origin shall be additionally checked, if mentioned in the specification.

4.4.6. The purchased services shall be checked in accordance with the existing specifications. The schedule of these checks shall at least take into account the following items: service requirements, supplier status (according to its assessment) and impact of the service on the finished product.

4.5. Product packaging

4.5.1. Based on hazard analysis, assessment of associated risks and intended use, the company shall determine the key parameters for the packaging material.

4.5.2. Detailed specifications shall exist for all packaging materials which comply with the current relevant legislation.

4.5.3. For all packaging material which could have an influence on products, certificates of conformity shall exist which comply with current legal requirements. In the event that no specific legal requirements are applicable, evidence shall be available to demonstrate that packaging material is suitable for use. This applies for packaging material which could have an influence on raw materials, semi-processed and finished products.

4.5.4. Based on hazard analysis and assessment of associated risks, the company shall verify the suitability of the packaging material for each relevant product (e.g. organoleptic tests, storage tests, chemical analysis, migration tests).

4.5.5. The company shall ensure that the packaging used corresponds to the product being packed. The use of correct packaging shall be regularly checked and checks shall be documented.

4.5.6. Labelling information shall be legible, indelible and shall comply with agreed customer product specifications. This shall be regularly checked and checks shall be documented.

4.6. Factory location

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

4.7. Factory Exterior

4.7.1. The factory exterior shall be maintained to be clean and tidy.

4.7.2. All external areas of the factory shall be maintained in good condition. Where natural drainage is inadequate, a suitable drainage system shall be installed.

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

4.8. Plant layout and process flows

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

4.8.2. The process flow, from receipt of goods to dispatch, shall be in place so that contamination of raw materials, packaging, semi-processed and finished products is avoided. The risk of cross-contamination shall be minimised through effective measures.

4.8.3. In case of microbiologically sensitive production areas, these shall be operated and monitored to ensure product safety is not compromised.

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

4.9. Constructional requirements for production and storage areas

4.9.1. Constructional requirements

4.9.1.1 Rooms where food products are prepared, treated, processed and stored shall be designed and constructed so that food safety is ensured.

4.9.2. Walls

4.9.2.1. Walls shall be designed and constructed to prevent the accumulation of dirt, to reduce condensation and mould growth, and to facilitate cleaning.

4.9.2.2. The surfaces of walls shall be in a good condition and easy to clean; they shall be impervious and wear-resistant.

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

4.9.3. Floors

4.9.3.1. Floor covering shall be designed to meet production requirements and shall be in good condition and easy to clean. Surfaces shall be impervious and wear-resistant.

4.9.3.2. The hygienic disposal of waste water shall be ensured. Drainage systems shall be easy to clean and designed to minimise the risk of product contamination (e.g. ingress of pests, etc.).

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

4.9.3.4. In food handling areas, machinery and piping shall be arranged so that waste water, if possible, goes directly into a drain.

4.9.4. Ceilings/Overheads

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

4.9.4.2. Where false ceilings are used, an access to the void shall be provided in order to facilitate cleaning, maintenance and inspections for pest control.

4.9.5. Windows and other openings

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

4.9.5.2. Where there is risk of contamination, windows and roof glazing shall remain closed and fixed during production.

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

4.9.5.4. In areas where unpackaged product is handled, windows shall be protected against breakage.

4.9.6. Doors and gates

4.9.6.1. Doors and gates shall be in good condition (e.g. no splinter-

ing parts, flaking paints or corrosion) and easy to clean.

4.9.6.2. External doors and gates shall be constructed to prevent the ingress of pests; if possible, they shall be self-closing.

4.9.7. Lighting

4.9.7.1. All working areas shall have adequate lighting.

4.9.7.2. All lighting equipment shall be protected by shatter proof covers and installed to minimise the risk of breakage.

4.9.8. Air conditioning/Ventilation

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

4.9.8.2. If ventilation equipments are installed, filters and other components which require cleaning or replacement shall be easily accessible.

4.9.8.3. Air conditioning equipment and artificially generated airflow shall not lead to any product safety or quality risks.

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

4.9.9. Water supply

4.9.9.1. Water which is used as ingredient in the production process, or for cleaning, shall be of potable quality and supplied in sufficient quantity; this also applies to steam and ice used within the production area. A supply of potable water shall be available at all times.

4.9.9.2. 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.

4.9.9.3. The quality of water, steam or ice shall be monitored following a risk based sampling plan.

4.9.9.4. Non-potable water shall be transported in separate, properly marked piping. Such piping shall not be connected to the drinking water system, or allow the possibility of reflux to contaminate potable water sources or the factory environment.

4.9.10. Compressed air

4.9.10.1. The quality of compressed air that comes in direct contact with food or primary packaging material shall be monitored based on hazard analysis and assessment of associated risks.

4.9.10.2. Compressed air shall not pose a risk of contamination.

4.10. Cleaning and desinfection

4.10.1. Based on hazard analysis and assessment of associated risks, 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).**

4.10.2. Cleaning and disinfection schedules shall be implemented and documented.

4.10.3. Only qualified personnel shall be allowed to undertake cleaning and disinfection. The personnel shall be trained and retrained to carry out the cleaning schedules.

4.10.4. The effectiveness and safety of the cleaning and disinfection measures, based on hazard analysis and assessment of associated risks, shall be verified and documented according to a sampling schedule by using appropriate procedures. Resultant corrective actions shall be documented.

4.10.5. Cleaning and disinfection schedules shall be reviewed and modified, if necessary, in the event of a change to product, process or cleaning equipment.

4.10.6. The intended use of cleaning utensils shall be clearly identified. Cleaning utensils shall be used in a way to avoid contamination.

4.10.7. Current data sheets and instructions for use shall be available for chemicals and cleaning agents. Personnel responsible for cleaning shall be able to demonstrate their knowledge of such instructions, which shall be always available on site.

4.10.8. Cleaning chemicals shall be clearly labelled, used and stored appropriately, to avoid contamination.

4.10.9. Cleaning activities shall be carried out in periods of non-pro- duction. If this is not possible, these operations shall be con- trolled as to not affect the product.

4.10.10. Where a company hires a third-party service provider for cleaning and disinfection activities, all requirements specified within section 4.10 shall be clearly defined in the respective contract.

4.11. Waste disposal

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

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

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

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

4.11.5. Waste collection rooms and containers (incl. compactors) shall be designed to be kept clean to minimise pest attraction.

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

4.12. Risk of foreign material, metal, broken glass and wood

4.12.1. (KO N° 6): Based on hazard analysis and assessment of associated risks, procedures shall be in place to avoid contamination with foreign material. Contaminated products shall be treated as non-conforming products.

4.12.2. In all areas, e.g. handling of raw materials, processing, packing and storage, where hazard analysis and assessment of associated risks have identified the potential for product contamination, the use of wood shall be excluded. Where the use of wood cannot be avoided, the risk shall be controlled and the wood shall be in good order and clean.

4.12.3. Where metal- and/or other foreign material detectors are required, they shall be installed to ensure maximum efficiency of detection, in order to avoid subsequent contamination. Detectors shall be subjected to regular maintenance to avoid malfunction.

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

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

4.12.6. In cases where special equipment or methods are used to detect foreign material, these shall be properly validated and maintained.

4.12.7. In all areas, e.g. handling of raw materials, processing, packing and storage, where hazard analysis and assessment of associated risks have identified a potential product contamination, the presence of glass and brittle material shall be excluded. Where the presence of glass or brittle plastic cannot be avoided, appropriate measures shall be in place to protect against breakage.

4.12.8. All stationary objects made of or incorporating glass or brittle material present in areas of handling of raw materials, processing, packing and storage shall be listed in a specific register, including details of their exact location. An assessment of the condition of objects on the register shall be per- formed on a regular basis and recorded. Frequency of this check shall be justified by documents.

4.12.9. Breakages of glass and brittle material shall be recorded. Exceptions shall be justified and documented.

4.12.10. Procedures shall be in place describing the measures to be taken in case of breakage of glass and/or brittle material. Such measures shall include identifying the scope of goods to be isolated, specifying authorised personnel, cleaning the production environment and release of production line for continued production.

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

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

4.13. Pest monitoring/Pest control

4.13.1. The company shall have a pest control system in place which is in compliance with local legal requirements, taking into account, as a minimum:

- 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 risks.

4.13.2. 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.

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

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

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

4.13.6. The effectiveness of the pest control shall be monitored with the help of regular trend analyses.

4.14. Receipt of goods and storage

4.14.1. All incoming goods, including packaging materials and labels, shall be checked for conformity against specifications and to a determined inspection plan. The inspection plan shall be risk based. Test results shall be documented.

4.14.2. The storage conditions of raw materials, semi-processed and finished products as well as packaging shall in each case correspond to product requirements (e.g. refrigeration, protective covers) and shall not be detrimental to other products.

4.14.3. Raw materials, packaging, semi-processed and finished products shall be stored so as to minimise the risk of cross contamination.

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

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

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

4.15. Transport

4.15.1. Before loading transport vehicles, their condition (e.g. absence of strange smells, high dust load, adverse humidity, pests, mould) shall be checked and action taken, if necessary.

4.15.2. Procedures to prevent contamination during transport shall be implemented (food/non-food/different categories of goods).

4.15.3. Where goods must be transported at certain temperatures, before loading, the temperature inside the vehicle shall be checked and documented.

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

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

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

4.15.7. Where a company hires a third-party transport service provider, all the requirements specified within section 4.15 shall be clearly defined in the respective contract or the service provider shall be subject to IFS Logistics requirements.

4.15.8. Security of transport vehicles shall be appropriately maintained.

4.16. Maintenance and repair

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

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

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

4.16.4. Failures of plant and equipment (incl. transport) covered by the maintenance system shall be documented and reviewed with a view to adapting the maintenance system.

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

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

4.17. Equipment

4.17.1. Equipment shall be suitably designed and specified for the intended use. Before commissioning, it shall be verified that the product requirements are complied with.

4.17.2. For all equipment and tools with direct food contact, certificates of conformity shall exist which confirm compliance with current legal requirements. In case no specific legal requirements are applicable, evidence shall be available to demonstrate that all equipment and tools are suitable for use. This applies for all equipment and tools in direct contact with raw materials, semi-processed and finished products.

4.17.3. Equipment shall be designed and located so that cleaning and maintenance operations can be effectively performed.

4.17.4. The company shall ensure that all product equipment is in good condition without any negative influence on food safety.

4.17.5. The company shall ensure that in the event of changes to processing methods and equipment, process characteristics are reviewed in order to assure that product requirements are complied with.

4.18. Traceability (including GMOs and allergens)

4.18.1 (KO N° 7): 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 food, packaging intended or expected to be in direct contact with food. The traceability system shall incorporate all relevant receiving processing and distribution records. Traceability shall be ensured and documented until delivery to the customer.

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

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

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

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

4.18.6. Labelling of semi-finished or finished product lots shall be made at the time when the goods are directly packed to ensure a clear traceability of goods. Where goods are labelled at a later time, the temporarily stored goods shall have been provided with a specific lot labelling. The shelf life (e.g. best before date) of the labelled goods shall be calculated from the original production batch.

4.18.7. If required by customer, identified samples representative for the manufacturing lot shall be stored appropriately and kept until expiration of the “Use by” or “Best before date” of the finished product and if necessary for a determined period beyond this date.

4.19. Genetically modified organisms (GMOs)

4.19.1. For products being delivered to customers and/or countries with GMO requirements, the company shall have in place systems and procedures to allow the identification of products consisting of GMOs, containing GMOs or produced from GMOs, including food ingredients, additives and flavouring(s).

4.19.2. Raw material specifications and delivery documents identifying products consisting of, being made from, or containing GMOs shall be available. The assurances concerning the GMO status of the raw materials shall be agreed by contract with the supplier or the relevant technical documents shall specify the GMO status. The company shall maintain a continuously updated listing of all GMO raw materials used at its premises, which also identifies all blends and formulas to which such GMO raw materials are added.

4.19.3. There shall be adequate procedures to ensure that where products consisting of or containing GMOs are manufactured, contamination of non-GMO products is avoided. Adequate control measures shall be in place to avoid GMO cross contamination. The effectiveness of these procedures shall be monitored by testing.

4.19.4. Finished products containing GMOs or labelled as not containing GMOs shall be declared in accordance with current legal requirements. Delivery documents shall include the corresponding reference to GMOs.

4.19.5. Customer requirements concerning the GMO status of products shall be clearly implemented by the company.

4.20. Allergens and specific conditions of production

4.20.1. Raw material specifications identifying allergens requiring declaration that are relevant to the country of sale of the finished product 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.

4.20.2. Based on hazard analysis and assessment of associated risk, control measures shall be in place from receipt to dispatch, to ensure that cross contamination of products by allergens is minimised. Control measures shall be verified.

4.20.3. Finished products containing allergens requiring declaration shall be declared in accordance with current legal requirements. For the adventitious or unintentional presence, the labelling of legally declared allergens and traces shall be based on hazard analysis and assessment of associated risks.

4.20.4. Where customers specifically require that products are "free from" certain substances or ingredients (e.g. gluten, pork, etc.), or that certain methods of treatment or production are excluded, verifiable procedures shall be in place.

4.21. Food Fraud

4.21.1. A documented food fraud vulnerability assessment shall be undertaken on all raw materials, ingredients, packaging and outsourced processes, to determine the risk of fraudulent activity in relation to substitution, mislabelling, adulteration or counterfeiting. The criteria considered within the vulnerability assessment shall be defined.

4.21.2. A documented food fraud mitigation plan shall be developed, with reference to the vulnerability assessment, and implemented to control any identified risk. The methods of control and monitoring shall be defined and implemented.

4.21.3. In the event of increased risk, food fraud vulnerability assessment shall be reviewed.

Otherwise all vulnerability assessments shall be reviewed at least annually.

Control and monitoring requirements of the food fraud mitigation plan shall be reviewed and amended when applicable.

5. MEASUREMENTS, ANALYSIS, IMPROVEMENTS

5.1. Internal audits

5.1.1. (KO N° 8): Effective internal audits shall be conducted according to a defined agreed audit program and shall cover at least all requirements of the IFS Standard. Scope and frequency of internal audits shall be determined by hazard analysis and assessment of associated risks. This is also applicable for off site storage locations owned or rented by the company.

5.1.2. Internal audits of activities which are critical to food safety and product specifications shall be carried out at least once a year.

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

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

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

5.2. Site factory inspections

5.2.1. Factory inspections shall be planned and carried out (e.g. product control, hygiene, foreign material hazards, personnel hygiene and housekeeping).The frequency of inspections in every area (including outdoor areas) and every single activity shall be based on hazard analysis and assessment of associated risks and on the history of previous experience.

5.3. Process validation and control

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

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

5.4. Calibration, adjustment and checking of measuring and monitoring devices

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

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

5.4.3. All measuring devices shall be used exclusively for their defined purpose. Where the results of measurements indicate a malfunction, the device in question shall be immediately repaired or replaced.

5.4.4. The calibration status of the measuring devices shall be clearly identified (labelling at the machine or on a list of test devices).

5.5. Quantity checking (quantity control/filling quantities)

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

5.5.2. A procedure shall exist to define compliance criteria for lot quantity checking. This procedure shall also, among others, take into consideration the tare, the density and other critical attributes.

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

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

5.5.5. For purchased, already pre-packed products from third parties, there shall be evidence about the compliance with the legal requirements for nominal quantity.

5.5.6. If applicable, all equipment used for final checking shall be legally approved.

5.6. Product analysis

5.6.1. There shall be procedures ensuring that all specified product requirements are met, including legal requirements and specifications. Microbiological, physical and chemical analysis required for that purpose shall be performed internally and/or subcontracted.

5.6.2. Analyses, which are relevant for food safety, shall preferably be performed by laboratories having appropriate accredited programs/methods (ISO 17025). If the analyses are per- formed by a factory internal or a laboratory not having appropriate accredited programs/methods, the results shall be verified on a regular basis by laboratories accredited on these programs/methods (ISO 17025).

5.6.3. Procedures shall exist which ensure the reliability of the internal analysis results on the basis of official recognised analysis methods. This shall be demonstrated by ring tests or other proficiency tests.

5.6.4. A test plan shall be drawn up for internal and external analysis, based on hazard analysis and assessment of associated risks, which covers raw materials, semi-processed and finished products as well as processing equipments and pack- aging materials, and where necessary environmental tests. The test results shall be documented.

5.6.5. Results of analysis shall be evaluated promptly. Appropriate corrective measures shall be introduced for any unsatisfactory results. The analytical results shall be reviewed regularly in order to identify trends. Trends indicating potential unsatisfactory results shall be taken into consideration.

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

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

5.6.8. Based on hazard analysis, assessment of associated risks and on any internal or external information on product risks which may have an impact on food safety and/or quality (incl. adulteration and fraud), the company shall update its control plan and/or take any appropriate measure to control impact on finished products.

5.7.Product quarantine (blocking/hold) and product release

5.7.1. A procedure shall be in place, based on hazard analysis and assessment of associated risks, for the quarantine (blocking/ hold) and release of all raw materials, semi-processed and finished products and packaging materials. The procedure shall ensure that only products and materials conforming to product requirements are processed and dispatched.

5.8. Management of complaints from authorities and customers

5.8.1. A system shall be in place for the management of product complaints.

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

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

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

5.9. Management of incidents, product withdrawal, product recall

5.9.1. A documented procedure shall be defined for management of incidents and of potential emergency situations that impact food 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.

5.9.2. (KO N° 9): 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.

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

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

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

5.10.1. A procedure shall exist for the management of all non-conforming raw materials, semi-finished and finished products, processing equipment and packaging materials. This shall include, as a minimum:

- isolation/quarantine procedures; - hazard analysis and assessment of associated risks; - identification (e.g. labelling)- decision about the further use (e.g. release, rework/post treatment, blocking, quarantine, rejection/disposal).

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

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

5.10.4. Out of specification, final packaged products or packaging materials, both related to private labels, shall not be placed in the market under the label concerned. Exceptions shall be agreed in writing with the contract partners.

5.11. Corrective actions

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

5.11.2. (KO N° 10): 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 action shall be clearly defined. The documentation shall be securely stored, and easily accessible.

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

6. FOOD DEFENSE PLAN AND EXTERNAL INSPECTIONS

6.1. Defense assessment

6.1.1. Responsibilities for food defense shall be clearly defined. Those responsible shall be key staff or shall have access to the top management team. Sufficient knowledge in this area shall be demonstrated.

6.1.2. A food defense hazard analysis and assessment of associated risks shall have been performed and documented. Based on this assessment, and based on the legal requirements, areas critical to security shall be identified.

Food defense hazard analysis and assessment of associated risks shall be conducted annually or upon changes that affect food integrity.

An appropriate alert system shall be defined and periodically tested for effectiveness.

6.1.3. If legislation makes registration or on-site inspections necessary, evidence shall be provided.

6.2. Site Security

6.2.1. Based on a hazard analysis and assessment of associated risks, identified areas critical to security shall be adequately protected to prevent unauthorized access.

Access points shall be controlled.

6.2.2. Procedures shall be in place to prevent tampering and/or allow identification of signs of tampering.

6.3. Personnel and Visitor Security

6.3.1. Visitor policy shall contain aspects of food defense plan. Delivery and loading staff in contact with the product shall be identified and shall respect the access rules of the com- pany. Visitors and external service providers shall be identi- fied in areas with product storage and shall be registered at the time of access. They should be informed about the site policies and their access controlled accordingly.

6.3.2. All employees shall be trained in food defense with respect to the product requirements and the training needs of the employees or when significant program changes occur. The training sessions shall be documented. Employee hiring and employment termination practices shall consider security aspects as permitted by law.

6.4. External Inspections

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