Transition plan of TNV from ISO 22000:2005 to ISO 22000:2018

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1. EXECUTIVE SUMMARY

ISO 22000:2018 is an ISO standard for management systems of Food Safety Management System, published in June 19, 2018. The aim of the ISO 22000 is to harmonize the requirements for food safety management on a global level. The standard contributes to ensure food safety throughout the whole food chain from farm-to table.

The 2018 version of ISO 22000 was published on June 19 2018. With this release, ISO 22000:2005 will be withdrawn. Companies certified to the ISO 22000:2005 standard have to transition their

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certificate to ISO 22000:2018, and there is a 3-year transition period until June 29 2021 according to IAF resolution 2018-15. We recommend to start the transition preparations already now. The aim of the ISO 22000 is to harmonize the requirements for food safety management on a global level. The standard contributes to ensure food safety throughout the whole food chain from farm-to table. The standard does not state specific criteria for Food Safety Performance, nor is it prescriptive about the design of a management system. Until June 19, 2021, i.e. within the 3 years of the date of publication of ISO 22000:2018, certifications issued against both ISO 22000:2018 and ISO 22000:2005 remain valid but transition need to be completed by.June 29, 2021 and beyond June 19 2021 certifications against the latter standard will not be recognized. TNV have planed our activities to permit the migration of certifications to ISO 22000:2018. The expiry date of all the certifications issued against ISO 22000:2005 during the period of migration must be the final one of the period of migration – June 19 2021, consequently the validity of the certificate becomes less than 3 years, leading to increased economic costs to be met by the organizations. In order to discourage the old standards, starting from Jun 20, 2020, (2 years from the date of publication of the standard ISO 22000:2018) TNV shall carry out new audits against the requirements of the new standard and shall not accept any application for ISO 22000:2005.

Certifications to ISO 22000:2018 can be granted to the client with TNV logo but any certificate with accreditation mark shall be only once TNV demonstrate our ability and accreditation is granted to TNV demonstrating the conformity of its system against following standards:

2. **TRANSITION PROCESS:**
   - Auditors & Marketing Team should communicate the transition arrangements to certified clients at the earliest to all active client and suspended client, withdrawal client need not be contacted By Email /By Telephonic Communication / By Sending the Letter/ By Publishing the Transition Information on TNV website.

   - Arrange the Training on ISO 22000:2018 to all the TNV Auditors & Office Staff those who are involve in the certification process (Application Review & Audit File Review) and Evaluate the competence of auditors and other staff as per OSS Evaluation Process for ISO 22000:2018.

   - After the Transition Implementation confirmation from Client Side- TNV will conduct the Clients Management System for Transition Audit of ISO 22000:2018. Additional Man-day will be added for Transition Audit. (In case of Surveillance Audit). In case of Re-Certification Audit – Half Man-day Extra Audit time will be added for Review of Implementation and Effectiveness of Implementation on New Changes

The TNV, in managing the migration to the new standard, shall ensure that, during the evaluation performed at the premises of clients, the following aspects were respected:

   i. The outcomes of the evaluations, the findings raised and the management of them must be documented;
   ii. The evaluation of the conformity of clients to the new standard during the migration process does not affect the continuity of the certification against ISO 22000:2005;
   iii. If evaluation activities have already taken place against the requirements of the Final Draft of ISO 22000, the decision-maker shall undertake a new review of the

certification to ensure that the decision taken complies with all the normative requirements of the final version of ISO 22000:2018;

iv. The decision to issue certification against ISO 22000:2018 must be taken only after examination, acceptance and verification of the closure of the client's plan for the management of any major nonconformities, or after examination and approval of the plan for the management of any minor nonconformities.

It uses the management system standard structure guideline Annex SL to allow for simplified integration with other management system standards, such as ISO 9001 and ISO 14001. IAF have published.

KEY CHANGES IN ISO 22000:2018: These are some of the key changes to consider:
- Changes due to the adoption of HLS
- Business Context and interested parties
- Strengthened emphasis on leadership and management commitment
- Risk Management
- Strengthened focus on objectives as drivers for improvements
- Extended requirements related to communications
- Other changes that are specific to ISO 22000 and food safety management
- The PDCA cycle
- The scope now specifically includes animal food
- Communicating the food safety policy
- Food Safety Management System Objectives
- In addition, there are several key changes in the ISO 22000:2018 compared to ISO 22000:2005
- related to the HACCP systematics.
- These points represent a significant shift in the way Food Safety management is perceived.

Standard Structure - What has changed?
The table below shows the main clauses from ISO 22000:2005 and ISO 22000:2018.

ISO 22000:2005	ISO 22000:2018	PDCA
4. Food safety management system	4. Context of the organization	PLAN
5. Management responsibility	5. Leadership	
6. Resources management	6. Planning	
7. Planning and realization of safe products	7. Support	
8. Validation, verification and improvement of the food safety management system	8. Operation	DO
	9. Performance evaluation of the food safety management system	CHEK
	10. Improvement	ACT

Common Structure for ISO 22000-2018

- The first thing that can be noticed looking at the table is that there is no direct correspondence between the clauses; however, as a general rule:
- The old 4, 5 and 6 clauses correspond to the new clauses 4, 5, 6 and 7
- Clause 8 of the new version corresponds to most of the previous version's clause 7
- 2005's version clause 8 is now addressed in clauses 9 and 10
- In the new version, the different subjects addressed by the standard are organized according with their position in the PLAN/DO/CHECK/ACT cycle, and that explains most of the clauses that changed place, for instance:
- The topic about the competence of food safety team and how it is appointed that was presented inside HACCP clause 7 (2005 version), moved to clause 5.3 (Organizational roles, responsibilities and authorities) and clause 7.3 (Competence), since it is an PLAN activity, not a DO activity.
- Emergency preparedness and response also jumps from clause 5.7 (2005 version) to clause 8 (Operation), that is the DO clause according with the standard.
- Management review leaves the Management Responsibility (clause 5) of the 2005 version to the CHECK step of the cycle (clause 9 of the new version).
- Despite of the fact that in the case of points 2 and 3 presented above the subjects are no longer under a clause that included all the Management responsibilities (in the last version), Top Management is still accountable for these issues in the new version.

3. TRANSITION DOCUMENTS
TNV shall prepare total set of documents which includes following 14 documents for supporting and validating transition:

Sl.	Document Name	Reference	Objective of the Documents
1	Transition Plan	TNV-F-Mt-02	Transition Plan for ISO 22000-2018
2	Competence Criteria for Auditor	TNV-P-03	Selection of Auditor & Technical Expert
3	Competence Criteria for Certification Personal	TNV-P-03	Training and evaluation of the certification personal
4	Competence Evaluation Form	TNV-50-FT	Evaluation form for verifying the knowledge and competence of the Auditor and certification personal
5	Stage 1 Audit Report	TNV-F-14-F	Stage 1 audit for initial certification
6	Stage 2 Audit Report	TNV-F-15-F	Stage 1 audit for initial certification
7	Transition Audit Report	TNV-F-14-FT	Transition Audit Format
8	Revised Certificate issue checklist	TNV-F-037-FT	Revised Checklist for Issuance of the Certificate under ISO 22000-2018
Guidance Document for Certified client			
9	Gap Analysis	TNV F-MTGA	Format of Gap Analysis
10	Self-Assessment Checklist for ISO 22000-2018	TNV F-SelfAC	Self-Assessment Checklist
11	Inquiry / Application Form for transition	TNV F- 001-FT	FSMS Transition Inquiry Form
Guidance Documents for Audit team and Certification Personal			
12	ISO 22004 Q and A	ISO 22004 Q & A	Question and Answer for Reviewing Auditor
13	Auditor Guide	TNV-F-055-Rev-06	Auditor Guide including FSMS Transition Guide
14	Training Documents on recent Changes	TNV-FSMS-PPT	Training Documents as approved by EG

4. TRANSITION APPROACH
TNV shall analyses and understand the requirements of ISO 22000:2018 and commenced identification of differences between the standard and its current management system. TNV shall make a transition plan by determining both the changes required its procedure and competence criteria and client's management system and the time frame required to execute them in order to conform to the standard. TNV shall take permission / approval / consent of the transition plan from our Accreditation Body.

Plan for ISO 22000-2018 transition:

1) Training and verification of competence of auditors and other staff.
2) TNV Shall communicate the transition arrangement; TNV shall publish the transition process and guideline on the website www.isoindia.org and shall send letter by registered post to the client within six months from the date of the publication of the standards in phased manner as per surveillance date due for the client.
3) TNV shall start accepting the transition request by **June 2019**, TNV Plan Single visit approach in normal case, but in case of special request from the Client; staged process may be adopted. Transition may be carried out either by special audit for the transition or with the surveillance audit. Man-days for the transition may be following:
4) TNV shall issue certificate for ISO 22000:2005 with the expiry date of 19 June 2021 and if client fails to complete the transition by three years after the publication of ISO 22000:2018, certificate shall expire its validity. This clause shall not affect the surveillance requirement of the TNV. In case transition is not completed during the validity period of the standards, the whole process of certification shall be required (Stage-1 & Stage-2 Audit to be made necessary for certification to be reinstated).

5. **COMMUNICATION WITH THE CLIENT**
   TNV shall:

   1. *Inform their clients with regard to the migration and share with each of them the management plan of the migration and of the relative certification;*
   2. *Decide whether there shall be just one single audit or a number of audits in various steps/stages;*
   3. *Plan the timeline for audit activities and the issue of the certificate against the standard;*
   4. *Decide the dates of the audits to be performed at the client organizations;*
   5. *Plan the timeline for the decisions concerning certification decisions so as to update the certificates in good time;*
   6. *Encourage organizations still without certification to implement a management system in accordance with the new standard.*

6. **RECOMMENDED STEPS FOR CERTIFIED CLIENT FOR THE TRANSITION**
   6.1. Get to know the content and requirements of ISO 22000:2018. The standard is available for purchase from ISO and possibly from your national standards provider. If you are a current user of ISO 22000:2005 you should focus on the changes in requirements.
   6.2. Conduct the Awareness Training within the Organization on ISO 22000:2018.
   6.3. Ensure that all the Key personnel in your organization are trained and understand the requirements and key changes.
   6.4. Do the Gap Analysis considering the New Requirements of ISO 22000:2018 which need to be addressed to meet the new requirements and establish an implementation plan. Implement actions and update your management system to meet the new requirement.
   6.5. Implementation of New Requirements of ISO 22000:2018 and make the necessary amendments in your Food Safety Management System.
   6.6. Do the Risk Analysis as per Requirements of ISO 22000:2018.
   6.7. Conduct the Internal Audit after New Changes in Food Safety Management System
   6.8. Conduct the Management Review Meeting after new requirements Implementation and Internal Audit.
   6.9. Evaluate the effectiveness of implementation through internal audits and define further actions where needed.

7. Transition Implementation Plans and strategy of the TNV:

Certification of conformity to ISO 22000:2018 and/or national equivalents shall only be issued after official publication of ISO 22000-2018 and after a routine surveillance or re-certification audit against ISO 22000:2018. TNV shall ensure that their auditors & Certification Team are aware of the clarifications introduced in ISO 22000:2018, and their implications, prior to conducting audits to that standard.

Sl.	Criteria	Activities Involved	Evidence	Timeline
1	Competence of the TNV	Training their auditors and verify the results to ensure the relevant level of competence is demonstrated.	Auditor Approval	On-Going
2	Communication	Communicate regularly with relevant parties including national standards bodies, Accreditation board i.e. UAF, CBs, existing Client to co-ordinate information and share guidance on the transition process and arrangements for transition.	Mail to Client	31st Aug 2019
3	Planning	Plan the timing of audit and certification activities for the revised standard.	Audit Plan for Transition	On-Going
4	Viability	Consider the stated transition period and current certification period.	Expiry Date	Done
5	Starting Point	Plan the timing of certification decisions for upgrading certification documents.	Competence for Technical Area	01st July 2019
6	Promotion of new Standards	Encourage current users of ISO 22000:2005 to implement ISO 22000:2018 respectively at an early stage, considering any changes that may occur during the DIS stage.	News Letter and New Application	Done
7	Discourage old standards	Encourage new users to implement ISO 22000:2018. **No application shall be accepted after 30th May 2020 for ISO 22000:2005 certification**, it means no new application shall be accepted for ISO 22000-2005 after 30th May 2020 but existing client may continue using their certification status till the validity of the standards i.e. 19th Jun 2020.	Restricted validity till 19th Jun 2021	Done
8	Transition of existing clients	Arrange audit schedules for existing client organizations	List of upgraded Client	July 2019

Sl.	Criteria	Activities Involved	Evidence	Timeline
9	Audit Method	Where a progressive or staged approach to transition is undertaken, the client audit files shall show the progress made and the evaluation of each requirement within ISO 22000:2018.	Transition Audit / Changed Surveillance Audit report for transition	30-11-18
10	Reporting Method	All issues that require client action for compliance with the new requirements shall be clearly identified and raised as documented findings	NCR for Transition	On-Going Monitoring
11	Recommendation Terms	Only when all identified outstanding issues have been addressed (see point 10) and the effectiveness of the management system demonstrated, auditors can recommend certification to ISO 22000:2018	NCR for transition	On-Going Monitoring
12	Documented Information	Evidence of the documented information (for NC Closure) of the client shall be kept available with the TNV to demonstrate that all prior findings have been evaluated for corrective action and compliance before any recommendation for approval to ISO 22000:2018 can be made.	NCR for transition	On-Going Monitoring
13	Validity of the ISO 22000:2005	The TNV shall ensure that the evaluation of a client's conformance to the new requirements during the transition phase does not interfere with the client's on-going compliance with ISO 22000:2005	Permitted till 29th June 2021	On-Going Monitoring

8. Validity of certifications Issued under old version

ISO 22000:2005 certifications will not be valid after three years from publication of ISO 22000:2018. The expiry date of certifications to ISO 22000:2005 issued during the transition period needs to correspond to the end of the three-year transition period and last date would be 29th June 2021.

Accredited certifications to ISO 22000:2018 shall only be issued once the accreditation board approve to deliver certification to the new standard. The Certification Body should conduct an audit of each client against ISO 22000:2018. Due to agreement of the TNV with the certified client, TNV can conduct transition activities during any of the following:
- *Routine surveillance,*
- *Recertification audit or*
- *A special audit.*

9. Transition Audit and Audit Duration:

Where transition audits are carried out in conjunction with scheduled surveillance or recertification (i.e. progressive or staged approach), additional time shall be required to ensure that all activities are covered for the existing and new standards. Conformity to the new standards ISO 22000:2018 may be given only after the demonstrated conformance to ISO 22000:2018:

   i) TNV shall start accepting the transition request by January 2019, TNV Plan **Single visit** approach in normal case, but in case of special request from the Client; **staged process** may be adopted. Transition may be carried out either by special audit for the transition or with the surveillance audit. Man-days for the transition may be following:

   a. In case of Special audit, 1/3rd of the initial audit man-days subject to minimum 1 man-days.

   b. *In case of transition audit planned with Surveillance audit, duration of the surveillance audit shall be increased by 20% of the required man-days subject to minimum .50 man-days.*

   c. *In case of transition audit planned with Recertification audit, duration of the surveillance audit shall be increased by 20% of the required man-days subject to minimum .50 man-days.*

   ii) Certificate issued under ISO 22000:2005 shall not be affected and shall remain valid till the validity of certificate issued under old version of the standard i.e. (19th Jun. 2021).

   iii)TNV shall issue certificate for ISO 22000-2005 with the expiry date on or before 19th Jun. 2021 and this date can be extended to 29th June 2021. if client fails to complete the transition by three years after the publication of ISO 22000:2018, certificate shall expire its validity. This clause shall not affect the surveillance requirement of the TNV. In case transition is not completed during the validity period of the standards, the whole process of certification shall be required (Stage-1 & Stage-2 Audit to be made necessary for certification to be reinstated).

During the transition, TNV shall include and consider the following:

- All issues that require client action for compliance with the new requirements should be clearly identified and raised as documented findings.
- Only when all identified outstanding issues have been appropriately addressed and the effectiveness of the management system demonstrated, approved auditors can recommend certification to the ISO 22000:2018 standard.
- Records should be available to demonstrate that all prior transition audit findings have been evaluated for corrective action and compliance before any recommendation for approval to ISO 22000:2018 can be made.
- Evaluation of a client's conformance to the new requirements during the transition phase does not interfere with the client's on-going conformance to ISO 22000:2005

All the client need to complete the transition before the expiry date of the old FSMS standards i.e. ISO 22000:2005, this means that Management Systems Certificate issued under ISO 22000:2005 standard may be valid till 29th Jun 2021 only and transition must took place to ISO 22000:2018 before this date.

10. TRANSITION PLAN

**Transition Plan & Team**					
Sl.	**Task**	**Timeline**	**Team**		**Responsibility**
1.	Transition planning Meeting	Dec 2018	MD, QM, AM & TM		TM
2.	GAP Analysis Report	Mar 2019	CEO, TM		CEO
3.	Listing of Task	Mar 2019	CEO		CEO
4.	Assignment of Responsibility	Mar 2019	CEO, QM,AM & TM		CEO
5.	Review deliverables list to determine requirements	Mar 2019	-		CEO
6.	Develop matrix of required resources/skills	June 2019	CEO, QM,		CEO
7.	Conduct skill gap analysis	Mar 2019	CEO, QM, VC		CEO
8.	Translations	NA	-		-
9.	Changes to Processes / Procedure	Nov 18	CEO, QM		CEO
10.	Determine timeline	Nov 18	QM		CEO
11.	Establish transition milestones	Nov 18	CEO, QM, AM		CEO
12.	Assign support staff to the Application	Nov 18	CEO, TM		CEO
13.	Determine actual training needed, based on gap analysis	Nov 18	CEO, QM, TM		CEO
14.	Determine roles and responsibilities (such as collect, review, accept Deliverables, resolve variances etc.)	Dec. 2018	QM, CEO		CEO
15.	Assign evaluator for each transition Deliverable	Dec. 2018	CEO, QM		CEO
16.	**Assessment by AB**	**July – Aug 19**	**CEO**		**CEO, QM**

11. TRANSITION TEAM ORGANIZATION
Key team members for transition shall be as following:

- Board of Director & Committee of TNV.
- Mr. Pragyesh Kumar Singh, CEO & MD
- Mr. Nitin Tripathi, QM & TM
- Archna Singh (AM)
- Mr. YK Bhatnagar, TC
- Requirement of the additional staff / manpower: Trainer / Expert for the training

12. COMPETENCE DEVELOPMENT OF THE TEAM TNV.
Team TNV shall comprises of following:
- Certification Team / Staff
- Auditor / Lead Auditor
- Business Associate for Overseas Operation.
- Member of Impartial Team.
- Certification Decision Team.

- *Certification Team / Staff:* shall be eligible to undertake the task of the ISO 22000:2018 only after attending the Transition training and successfully passing the test of the transition competence.
- *Auditor* of the TNV shall be eligible to conduct the audit of ISO 22000:2018 only after acquiring the required competence to audit the management system and same is evaluated in the evaluation form for the new standards. Auditor competence shall be developed in the following manner:
  - o Train the auditors and verify the results to ensure the relevant level of competence is demonstrated.
  - o Communicate regularly with UAF
  - o Communicate with other CBs to co-ordinate information where possible.
- *Business Associate:* of the TNV for overseas operation shall be considered eligible for starting certification business for ISO 22000:2018 only after attending the transition training and have successfully completed evaluation for the transition. Auditor used in overseas shall be evaluated via an evaluation test remotely and must be witnessed within next 6 months.
- *Member of the Impartial Committee:* All the member of the impartial committee shall be given the copy of the ISO 22000-2018 for training purpose. We shall make sure that person making FSMS representation shall attend FSMS transition training by 2019.
- *Certification Decision Team* of the TNV shall be eligible to impart in the certification decision for new version of the standards only after acquiring the required competence to audit the management system and same is evaluated in the evaluation form for the new standards. Auditor competence shall be developed in the following manner:
  - o One of the members of Certification decision team must have attended transition training for new standards and result of the training is verified by evaluation.

13. **COMMUNICATION WITH THE PARTIES:**
- Communication with Accreditation Board and other agencies which may be sources for information / input for transition process.
- Communicate with other CAB, in informal way.
- Communication with existing clients.

14. **UPGRADATION TIMELINE:**
At TNV; Certification decision timeline for the transition timeline is 30 days latest to the date of the date of the closure of the nonconformities of the assessment or 01st May 2021; but last date to accept the application from the certified client is Plan the timing of certification decisions for upgrading certification documents. All the certificate which could not upgraded to latest version of the MSS, shall be withdrawn on 19th June 2021, this timeline can be extended to 29th June 2021 subject to special request if approved and allowed by Accreditation board and IAF.

15. **CERTIFICATION DECISIONS:**
Timing of certification decisions for upgrading certification will be 30 days from the date of the submission of the closure due date or original submission.

16. PROMOTION OF THE USER FOR ISO 22000:2018

TNV Shall promote the certification under new version of the ISO 22000 i.e. ISO 22000:2018 from August 2019 onwards or after getting approval of the accreditation board for the transition.

17. Auditors / Certification Personal Training

TNV shall training it's all resources and shall complete the evaluation before utilizing for any work related to certification activities. All the TNV Auditors and Certification Person (Application Reviewer / Audit File Reviewer) those who are involve in FSMS Certification activities shall complete their Transition Training of ISO 22000:2018.

18. Evaluation / demonstration of the competence of ISO 22000:2018

All the team member including Auditor, Certification team member (this excludes Technical Expert) and staff shall be evaluated for the competence assessment for skill and understanding of the ISO 22000:2018. Every personal may do the following:

- Submit the Copy Transition Training certificate to TNV
- Get Qualify the TNV Evaluation Process for ISO 22000:2018

19. Control via Internal Audit.

TNV shall maintain control by checking the competence of the auditor, during the internal audit, 50% of the auditor (conducting transition audit) file shall be verified as sample.

20. WORKFORCE TRANSITION

During the transition approval of the accreditation board (UAF); TNV shall prefer not to issue certificate to the client, but assessment may be completed and report may be shared with the client, in case client submit special request, TNV may issue certificate to the client certificate for ISO 22000:2018   but shall not use the logo of the accreditation board without the approval of the accreditation board.

21. GOALS & OBJECTIVE

To ensure the effective compliance; TNV shall prefer to take approval of the accreditation board, before start taking application for transition. TNV shall take into account the requirement of the changes and shall make necessary documents to ensure effective assessment and its result.

22. OVERSEAS OFFICES

TNV shall provide training and evaluation of the overseas offices to ensure the competence to conduct the audit of the ISO 22000:2018.

23. TRAINING / KNOWLEDGE TRANSFER

TNV shall discuss and plan how knowledge will be transferred from the incumbent staff to the new staff (documentation/instruction manuals including as-built documents, formal training classes, one-on-one training/knowledge transfer, etc.).

24. SCHEDULE

TNV shall complete the schedule transition by August 2019 with the UAF (timeline is fixed with the next surveillance audit due).

25. Risk Analysis

Following risk analyzed for the transition:

- Skill availability
- Availability of the internal resources.
- Wide scope of the working.

Annexure 01: Informative Section of the Transition Plan.

A. Common Guideline for transition:

Organizations using ISO 22000:2005 are recommended to take the following actions:

1. *Identify organizational gaps which need to be addressed to meet new requirements. Client may please refer "GAP Analysis of ISO 22000:2018 " Annexure: 01 of this documents.*
2. *Develop an implementation plan.*
3. *Provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organisation.*
4. *Update the existing Food Safety management system (FSMS) to meet the revised requirements and provide verification of effectiveness.*
5. *Liaison with TNV (your Certification Body) for transition arrangements.*

B. Comparative of ISO 22000:2018 & ISO 22000:2005:

Introduction			Introduction
Scope	1	1	Scope
Normative references	2	2	Normative references
Terms and definitions	3	3	Terms and definitions
		4	Context of the organization
		4.1	Understanding the organization and its context
Food safety management system	4		
General requirements	4.1	4.3	Documented information
		4.4	Food safety management system
Documentation requirements	4.2	7.5	Determining the scope of the food safety management system
		7.5.1	General
		7.5.2	Creating and updating
		7.5.3	Control of documented information
Management responsibility	5	5	Leadership
Management commitment	5.1	5.1	Leadership and commitment
Food safety policy	5.2	5.2	Policy
		5.2.1	Establishing the food safety policy
		5.2.2	Communicating the food safety policy

Food safety management system planning	5.3	6.2	Objectives of the food safety management system and planning to achieve them
		6.3	Planning of changes
Responsibility and authority	5.4	5.3	Organizational roles, responsibilities and authorities
Food safety team leader	5.5		
Communication	5.6	7.4	Communication (title only)
		7.4.1	General
		7.4.2	External communication
		7.4.3	Internal communication
Emergency preparedness and response	5.7	8.4	Emergency preparedness and response
		8.4.1	General
		8.4.2	Handling of emergencies and response
Management review	5.8	9.3	Management review
		9.3.1	General
		9.3.2	Management review input
		9.3.3	Management review output

Resource management	6	7.1	Resources
Provision of resource	6.1	7.1.1	General
Human resources	6.2	7.1	Resources
		7.1.1	General
		7.1.2	People
		7.3	Awareness
Infrastructure	6.3	7.1	Resources
		7.1.3	Infrastructure
Work environment	6.4	7.1.4	Work environment
Planning and realization of safe products	7		
General	7.1	8.1	Operational planning and control
Prerequisite programmes (PRPs)	7.2	8.2	Prerequisite programmes (PRPs)
Preliminary steps to enable hazard analysis	7.3	8.5.1	Preliminary steps to enable hazards
Hazard analysis	7.4	8.5	Hazard control
		8.5.1	Preliminary steps to enable hazard analysis
		8.5.2	Hazard analysis
Establishing the prerequisite programmes	7.5		

(PRPs)			
Establishing the HACCP plan	7.6	8.5.4	Hazard control plan (HACCP/OPRP plan)
Updating of preliminary information and documents specifying the PRPs and the HACCP plan	7.7	8.6	Updating the information specifying the PRPs and the hazard control plan
Verification planning	7.8	8.8	Verification related to the PRPs and the hazard control plan
Traceability system	7.9	8.3	Traceability system
Control of nonconformity	7.1	8.9	Control of product and process nonconformities
		8.9.1	General
		8.9.2	Corrections
		8.9.3	Corrective actions
		8.9.4	Handling of potentially unsafe products
		8.9.5	Withdrawal/recall
Validation, verification and improvement of the food safety management system	8	8.8	Verification related to PRPs and the hazard control plan
General	8.1		
Validation of control measure combinations	8.2	8.5.3	Validation of control measure(s) and combination(s) of control measure(s)
Control of monitoring and measuring	8.3	8.7	Control of monitoring and measuring
Food safety management system verification	8.4	9.2	Internal audit
Improvement	8.5	10	Improvement
Continual improvement	8.5.1	10.3	Update of the food safety management system
Updating the food safety management system	8.5.2	10.2	Continual improvement

C. ISO 22000:2018 – CHANGES

The new version contains a large number of minor changes that have been introduced to increase the readability and clarity of the standard. In practice, the large majority of these changes will have little if any repercussions for the actual implementation of the standard. Still, the revision also introduces a number of changes that are more structural in nature:

The new version adopts the so-called High-Level Structure (HLS), the common structure for all new management system standards. The adoption of a common structure throughout all standards facilitates the integration of various management systems. Users of ISO 9001:2015, ISO 14001:2015 and ISO 45001 will already be familiar with this structure. In practice, the change in structure will make it easier for organizations to combine ISO 22000 with other management system standards.

In accordance with the changes in ISO 22000, the new version of ISO 22000 will also be a risk-based standard. The standard will distinguish between risk at the operational level l (through the Hazard

Analysis Critical Control Point approach (HACCP)), as well at the strategic level of the management system and its ability to reach its specified goals as such.

The standard now consistently distinguishes two Plan-Do-Check-Act (PDCA) cycles. The first applies to the management system as a whole, while the second, within it, addresses the operations described in Clause 8, which simultaneously cover the HACCP principles. This is illustrated in the graph below.
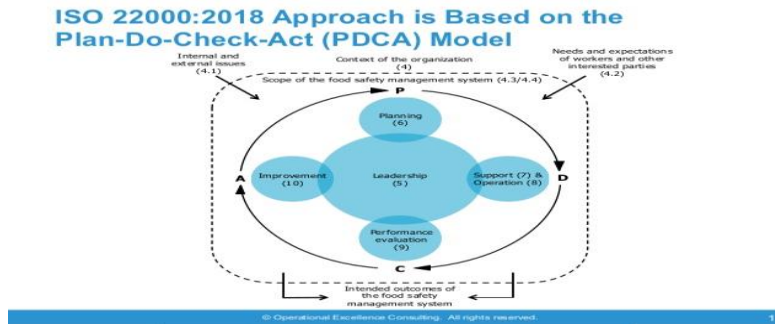
-End-

D. Self-Assessment Checklist for ISO 22000: 2018

Cl.	ISO 22001:2018 clause	ISO 22001:2005 Clause	Guidance	Result C / O / NC
4.1	Understanding the organization and its context	New requirement!	This new concept relates to the factors and conditions affecting organizational operation e.g. regulation, governance and interested parties. What drives the culture and requirements of your organization? Be prepared to discuss with your assessor, how the context of the organization influences the ability to achieve the intended outcomes of your food safety management system.	C
4.2	Understanding the needs and expectations of interested parties	New requirement!	Consider who the interested parties might be and what their relevant interests might be, e.g. workers, customers, regulators, competitors and external providers. Consider the risks and opportunities that are generated for the context. Be prepared to discuss stakeholder interests with your assessor	NC

Cl.	ISO 22001:2018 clause	ISO 22001:2005 Clause	Guidance	Result C / O / NC
4.3	Determining the scope of the environmental management system	Partially covered by 4.1	When determining this scope, the organization shall consider a) the external and internal issues referred to in 4.1; b) the requirements referred to in 4.2. Therefore, the Scope can only be defined when 4.1 - 4.2 have been considered. Do not forget the Scope shall specify the products and services, processes and production sites that are addressed by the FSMS and shall include the activities, processes, products or services that can have an influence on the food safety of the end products.	O
4.4	Food Safety Management System	Partially covered by 4.1	Largely unchanged, only highlight that 2018 version do not longer require a documented FSMS, how to manage the system it is now your decision	
5.1	Leadership and commitment	Partially covered by 5.1, 7.4.3	Top management of the organization are now required to demonstrate leadership and commitment to the FSMS in a number of specified ways: ensuring integration of the FSMS requirements into the organization's business processes, support persons that contribute to the effectiveness of the FSMS, etc.	
5.2	Food safety policy	Partially covered by 5.2	The policy must be now also appropriate to the context, address also internal and external communications and need to ensure competencies related to food safety, provide a framework for setting and reviewing objectives, include commitment to continual improvement among other previously required requisites. The policy shall be also documented and available to relevant interested parties	
5.3	Organizational roles, responsibilities and authorities	Partially covered by 5.4, 5.5, 7.3.2	Apart from communicating responsibilities and authorities, top management shall ensure they are also understood within the organization. New responsibilities and authorities for ensuring that the FSMS conforms to the requirements of the standard and reporting on the performance of the FSMS to top management are to be assigned.	

Cl.	ISO 22001:2018 clause	ISO 22001:2005 Clause	Guidance	Result C / O / NC
6.1	Actions to address risks and opportunities	New requirement!	Consideration needs to be given to its identified internal and external issues (4.1), the needs and expectations of its interested parties (4.2) during planning and determined scope of the FSMS (4.3). A new concept of "risks and opportunities" is introduced. Planning now requires the identification of the risks (defined as the effect of uncertainty) and opportunities related to the performance and effectiveness of the FSMS. Risks and opportunities identified in section 4 become inputs to a comprehensive planning approach.	
6.2	Objectives of the FSMS and planning to achieve them	Partially covered by 5.3	Objectives must be consistent with the food safety policy, follow the SMART criteria, and consider customer, statutory and regulatory requirements. There should be detail of who is responsible, agreed timings and measures in place to establish progress, resources available and whether proposed achievements have been met. Established objectives will be documented information.	
6.3	Planning of changes	Partially covered by 5.3	When determining the need for changes to the FSMS, the organization must be also taken into consideration the purpose of changes, resources and responsibilities apart from ensuring its integrity.	
7.1.1	General	Partially covered by 6.1	The organization shall also consider the capability of and any constraints on existing internal resources and resources required from external sources.	
7.1.2	People	Partially covered by 6.2	Where external experts where used in the development, implementation, operation or assessment of the FSMS, the organization must ensure they retained documented information such as an agreement or contract that defines their relevant competency, responsibility and authority	
7.1.3	Infrastructure	Partially covered by 6.3	Largely unchanged	
7.1.4	Work Environment	Partially covered by 6.4	Largely unchanged, note added highlighting examples of what factors need to be considered within environment	
7.1.5	Externally developed elements of the FSMS	Partially covered by 1	New information regarding externally developed elements of the FSMS to be considered when used	
7.1.6	Control of externally provided processes, products or services	Partially covered by 4.1	New information regarding control of externally provided processes, products or services	
7.2	Competence	Partially covered by 6.2, 7.3.2	External providers are now also considered when determining competence of persons doing work under the organization's control that may affect the FSMS. The term "competent" replaces "trained". The organization shall retained documented information as evidence of competence.	

Cl.	ISO 22001:2018 clause	ISO 22001:2005 Clause	Guidance	Result C / O / NC
7.3	Awareness	Partially covered by 6.2.2	Now personnel must also be aware of the food safety policy, objectives of the FSMS relevant to their tasks, and the benefits of improved food safety performance.	
7.4	Communication	5.6, 6.2.2	Some terms have been replaced to make them more clear (suppliers by external providers and qualifications by competencies)	
7.5	Documented Information	Partially covered by 4.2, 5.6.1	The organization's FSMS must include also documented information and food safety requirements required by statutory, regulatory authorities and customers.	
8.1	Operational Planning and Control	New requirement!	Specific reference is now made to the planning of operations, as well as their control and update. Controls for processes should now be implemented to ensure the realisation of safe products as well as the implementation of defined actions to address risk and opportunities. There are requirements for the control of planned changes and the review of unintended changes. It is now specified that outsourced processes are to be controlled.	
8.2	Prerequisite Programmes (PRPs)	Partially covered by 7.2	Statutory and regulatory requirements shall be taken into consideration when selecting PRPs. Likewise, when establishing the PRPs, the organization must consider also supplier approval, labelling and control of incoming materials, storage, dispatch and distribution.	
8.3	Traceability	Partially covered by 7.9	Further details regarding what to be considered when establishing and implementing the traceability exercise. Documented information must be retained for a defined period, as a minimum, the shelf-life of the product. Its effectiveness shall be also tested.	
8.4	Emergency preparedness and response	Partially covered by 5.7	Documented information is now required to be established and maintained in case of potential emergency situations and incidents. Steps to handle emergencies are now specified.	
8.5.1	Preliminary steps to enable hazard analysis	Partially covered by 7.3, 7.2.4	Source of products is now required to be specified in the documented information concerning raw materials, ingredients and packaging specifications. Documented information regarding characteristics of ends products must include method of distribution and delivery. "Description of processes steps and control measures" has been replaced by "description of processes and process environment" detailing also additional requirements. Processing aids, packaging and utilities are also to be added to the flow diagram/s.	

Cl.	ISO 22001:2018 clause	ISO 22001:2005 Clause	Guidance	Result C / O / NC
8.5.2	Hazard analysis	Partially covered by 7.3.5.2, 7.4, 7.6.2	The identification of hazards shall also be based on internal information and customer requirements. The systematic approach for assessing each control measure, must also consider the viability of establishing measurable critical limits and applying timely corrections in case of failure. Additionally, external requirements that can impact the choice and strictness of control measures shall be documented.	
8.5.3	Validation of control measure(s) and combination(s) of control measure(s)	Partially covered by 8.2	The decision making process and categorization of control measures as well as their validation must be maintained as documented information. It is also mentioned that this validation must be conducted before the implementation of the Hazard control plan.	
8.5.4	Hazard Control Plan	Partially covered by 7.5, 7.6	A Hazard Control Plan includes OPRP plan and monitoring systems for OPRPs as well as a HACCP Plan and monitoring system for CCPs. The organization shall implement, maintain and retained evidence of the hazard control plan as documented information. When critical limits or action criteria are not met the organization shall ensure, among others, that the potentially unsafe products are not released.	
8.6	Updating the information specifying the PRPs and the hazard control plan	Partially covered by 7.7	Once the Hazard Control Plan is established, the information to be updated, if necessary, is listed (process steps and control measures now replaced by descriptions of processes and process environment).	
8.7	Control of monitoring and measuring	Partially covered by 8.3	Included also that software used in monitoring and measuring needs validation prior to use.	
8.8	Verification related to PRPs and the hazard control plan	Partially covered by 7.8, 8.4.2, 8.4.3	Verification activities shall confirm that PRPs and hazard control plan implemented and effective. The organization must ensure that verification activities are not carried out by the same person responsible for monitoring the activity or the control measures.	
8.9	Control of product and Process nonconformities	Partially covered by 7.10	Version 2018 specifies clearly the steps to be followed when action criteria for an OPRP is not met. When reviewing nonconformities identified by consumer complaints and/or regulatory, the organization must ensure there are corrective actions in place. When doing the evaluation for release, conditions apply to all those products that do not comply with the established action criterion for OPRP. Products that are not accepted for release could be also reprocessed, destroyed and/or disposed as waste or redirected for other use as long as food safety in the food chain is not affected. All results of evaluation for release and disposition of nonconforming products shall be retained as documented information.	

Cl.	ISO 22001:2018 clause	ISO 22001:2005 Clause	Guidance	Result C / O / NC
9.1	Monitoring, measurement, analysis and evaluation	Partially covered by 8.4.2, 8.4.3	New clause including mandatory documented information and evaluation of performance and effectiveness with regard to monitoring, measurement, analysis and evaluation methods.	
9.2	Internal audit	Partially covered by 8.4.1	More aspects to consider in the audit programme such as changes in the FSMS, the results of monitoring, measurement and previous audits. The results of the audits must be reported to the food safety team and relevant management. All information must be retained as documented to show evidence of the implementation of the audit programme and audit results. The organization shall determine if the FSMS meets the intent of the food safety policy and objectives set.	
9.3	Management Review	Partially covered by 5.2, 5.8	Several inputs now also to be discussed during the management review meeting (monitoring and measurement results, nonconformities and corrective actions, the adequacy of resources, performance of external providers, etc.).	
10.1	Nonconformity and corrective action	New requirement!	The standard provides all steps to be followed by the organization when a nonconformity occurs.	
10.2	Updating the food safety management system	Partially covered by 8.1, 8.5.1	The importance of improving suitability, adequacy and effectiveness of the FSMS is now highlighted as this was not specified in much detail in 2005 version.	
10.3	Continual improvement	Partially covered by 8.5.2	Largely unchanged	

E. Key Concept of ISO 22000-2018

1. **Context of the Organization:** This is a new requirement to identify the internal and external factors and conditions that affect an organization. Examples of internal issues could include an organization's culture and capabilities, whilst external issues could include the variety of external providers, changes in consumption patterns and the technology advances to name but a few. The organization also needs to identify the interested parties to the FSMS and any requirements they have.
   a. **Guidelines:** The context will influence the type and complexity of management system needed.
2. **Leadership:** There is an explicit requirement for top management to demonstrate leadership and commitment relating to the system. This is an enhanced requirement relating to top management.
   a. **Guidelines:** Top management will need to take accountability for the effectiveness of the FSMS, provide support and resources as necessary and promote continual improvement.
3. **Risk and Opportunities:** This is a new concept introduced in the 'planning' section of the standard. It requires the organization to identify the risks and opportunities that may affect the performance and effectiveness of the FSMS, and take action to address them.
   a. **Guidelines:** "Risk and opportunities" can be thought of as potential adverse deviations from the expected (threats) or potential beneficial deviations from the expected (opportunities).

4. **Hazard Control Plan:** The term of action criteria has been introduced to also clarify what OPRPs are meant for. The Hazard control plan must consider both OPRP and HACCP Plan
   a. **Guidelines:** Review thoroughly your system emphasizing and documenting the how and why for the categorization of control measures managed as OPRPs or CPPs, make a final summary with different plans for each and ensure all established controls were previously validated.
5. **Competence:** Trained has been explicitly replaced by competent personnel in a way to emphasize the importance of considering also aspects such as experience, skills, knowledge, understanding of the task given among others apart from training and/or qualifications alone.
   a. **Guidelines:** Ensure job descriptions, procedures for processes and continuous training are clearly defined and established so you have the right person in the right position.
6. **Performance Evaluation:** There is a new emphasis on the need for evaluation in addition to the current requirements for monitoring, measurement and analysis.
   a. **Guidelines:** Evaluation is the interpretation of results and analysis. This is not new to managers but is made explicit in the standard for the first time. Processes may be well defined and effective, but do they yield optimum results? This may be a new challenge for internal audits.

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