**ISO 22000:2018 CLIENT GAP ANALYSIS TOOL**

**Instructions for Use**

This gap analysis document provides a simple framework for evaluating your food safety management system against the requirements of ISO 22000:2018. It is split into two tables:

* **Part 1: New concepts** – highlighting the new concepts introduced in ISO 22000:2018 and the related clauses, processes and functional activities
* **Part 2: Requirements** – highlighting new and amended clauses between ISO 22000:2005 and ISO 22000:2018

Please complete each table by recording the evidence acquired from one full internal audit against the requirements of ISO 22000:2018.

If you are unable to provide evidence of compliance, you may not be ready to complete the transition to ISO 22000:2018. In this case, please inform NQA that you need additional time to prepare for the transition – we will work with you to select a mutually agreeable date to complete the transition.

**Please ensure that this completed document and internal audit records are available to your auditor at the opening meeting of your transition audit**.

Sections marked as ***(Assessor to Complete)*** will be completed by the assessor during the transition audit.

Client name:

Certificate number:

Date of completion:

**Part 1: New Concepts**

Tip: Ensure that these new concepts have been deployed in a manner that supports the *Process Approach* and *Risk Based Thinking*.

| **New Concepts** | **Phase** | **Clause(s)** | **Activity** | ***(Client to Complete)******Evidence of compliance*** | ***(Assessor to Complete)******Has the Client Demonstrated they have Met the requirements of this clause?*** | ***(Assessor to Complete)******Comments if Required*** |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | ***Yes***  | ***No*** |  |
| **Operational Planning and Strategic Direction**  | **Identify** | 4.1, 4.2 | Have youidentified both internal and external issues and interested parties that are relevant to achieve the intended results of the FSMS in accordance with the food safety policy and strategic direction of your organisation? |  |  |  |  |
| **Assess** | 4.1, 4.2, 5.1, 9.3.2,  | Is the strategic direction being assessed, reviewed and aligned with the food safety policy and objectives by top management? |  |  |  |  |
| **New requirement for the adoption of a Process approach****(where before this was not required)** | **Identify** |  4.4 (0.3), 7.5.1 | Has planning for the food safety management system determined the processes of your organisation, their inputs and outputs and sequence and interaction (using the PDCA cycle at two levels with focus on risk-based thinking)? Is monitoring and measurement of the processes in place? Are processes documented to the extent necessary to support their operation? Is there documented information available to demonstrate that the processes are carried out as planned? |  |  |  |  |
| **Action** | 5.1, 5.2.1 | Is the strategic direction being utilised as an input to the Food Safety Policy/ Objectives/ Risk Management/ Management Review processes? |  |  |  |  |
| **Process Risks** | **Identify** | 6.1, 6.2 | Have risks to achieving process objectives been identified – i.e. what problems or mistakes might occur? |  |  |  |  |
| **Assess** | 4.4,6.3 | Have these risks been considered and addressed when establishing the FSMS and when planning any change to the FSMS – i.e. what controls have you incorporated into your activities to prevent problems or mistakes? |  |  |  |  |
| **Action** | 6.3, 8.1 | Are risks (i.e. potential problems or errors) considered during planning for change, and following unintended change, to ensure requirements continue to be met? |  |  |  |  |
| **Action** | 8.5.4.4, 8.9.3 | Following a corrective action, is there evidence that process risks have been reviewed, i.e. checks made to ensure the problem does not occur again, or new problems (risks) are not introduced? |  |  |  |  |
| **Monitor** | 7.2, 9.1.2,9.3.2, 10.1.1 | Are you analysing the effectiveness of actions taken to address risks? How do you know your processes are effective and efficient? |  |  |  |  |
| **Product Risks** | **Identify** | 6.1, 6.2, 8.2.3, 8.5.1.1, 8.5.1.5.3, 8.5.2.2.1, 8.5.2.2.3 | Have you identified the barriers or risks to achieving product or service compliance? Has product complexity been considered during operational planning? |  |  |  |  |
| **Assess** | 8.1 | Have these barriers/risks been considered as part of your planning of operations? |  |  |  |  |
| **Assess** | 8.2.3, 8.3 | Have these product risks been considered when determining and reviewing your customer requirements? |  |  |  |  |
| **Action** | 8.1, 8.5 | Are the selected organisational and operational controls sensitive to the identified respectively risks and hazards? i.e. appropriate for the likely consequences of failure or unintended changes? |  |  |  |  |
| **Monitor** | 8.5.4 | Are you analysing the effectiveness of the above actions (taken to address product risks)? |  |  |  |  |
| **Risk to the provision of externally provided processes, products and services****(outsourcing)** | **Identify** | 7.1.6 | Have risks associated with externally provided processes, products and services, (outsourcing), been identified? For example, have you applied some form of criticality measure or rating (formal or informal), to your subcontractors? |  |  |  |  |
|  | **Assess** | 7.1.6 | Do identified risks or criticality determine or influence the type and extent of controls or oversight applied to the * selection of external resources or suppliers
* controls or oversight applied to these external resources or suppliers
* degree of information provided to these external resources or suppliers?
 |  |  |  |  |
|  | **Monitor** | 7.1.6 | Are you analysing the effectiveness of actions taken to address risks arising from the use of external resources - subcontractors or suppliers? |  |  |  |  |

**Part 2: ISO 22000:2018 Requirements**

Tip: ensure that you can demonstrate that each requirement of ISO 22000:2018 has been addressed within the QMS.

| **ISO 22000:2018** | **ISO 22000:2005 Cross Reference and the significant changes from the 2005 version** | ***(Client to Complete)******Evidence of compliance*** | ***(Assessor to Complete)******Has the Client Demonstrated they have Met the requirements of this clause?*** | ***(Assessor to Complete)******Comments if Required*** |
| --- | --- | --- | --- | --- |
|  |  |  |  |
| 4.1 Understanding the organisation and its context  | New Requirement: addressed in part 1 above |  |  |  |  |
| 4.2 Understanding the needs and expectations of interested parties | New Requirement: addressed in part 1 above |  |  |  |  |
| 4.3 Determining the scope of the food safety management system  | 4.1 - Have exclusions including justifications been included in the scope?Have external and internal issues and interested parties been considered when determining the scope? Is the scope available, maintained and documented? |  |  |  |  |
| 4.4 Food Safety management system  | 4.1 –Does the maintenance and improvement of the FSMS include also processes and their interactions? A documented FSMS is no longer required  |  |  |  |  |
| 5.1 Leadership and commitment  | 5.1 - Can top management demonstrate their degree of leadership and commitment with respect to the FSMS? |  |  |  |  |
| 5.2 Policy  | 5.2 - Is the policy appropriate to the purpose and context of the organisation? Does it provide a framework for setting and reviewing objectives? Does it address internal and external communications including the need to ensure competencies related to FS? Is it documented and available to relevant interested parties?  |  |  |  |  |
| 5.3 Organizational roles, responsibilities and authorities  | 5.4, 5.5, 7.3.2 – Have the responsibilities for maintaining the FSMS been communicated and understood? Has the responsibility and authority for ensuring that the FSMS conforms to the 2018 requirements and also reporting on the performance to top management been assigned? |  |  |  |  |
| 6.1 Actions to address risks and opportunities | New Requirement |  |  |  |  |
| 6.2 Objectives of the FSMS and planning to achieve them  | 5.3 - Do the objectives support the food safety policy which supports the strategic direction of the organisation?  |  |  |  |  |
| 6.3 Planning of changes  | 5.3 - When changes occur do you consider the purpose and potential consequences of those changes? Are resources for the changes considered and responsibilities and authorities assigned? |  |  |  |  |
| 7.1.1 Resources 7.1.2 People | 6.1, 6.2.1 - Have resource needs been determined, including the capability on existing internal resources and the ones required from external sources? Are documented contracts available for all external experts used for the development or assessment of the FSMS? |  |  |  |  |
| 7.1.3 Infrastructure 7.1.4 Work Environment | 6.3, 6.4 - Has the environment been determined and is being maintained? Have all work environment factors been considered? |  |  |  |  |
| 7.1.5 Externally developed elements of the FSMS | New requirement |  |  |  |  |
| 7.1.6 Control of externally provided processes, products or services | New Requirement |  |  |  |  |
| 7.2 Competence  | 6.2.2, 7.3.2 - Largely unchanged. Is the competence of external providers also considered? Are those responsible for the operation of the hazard plan competent? |  |  |  |  |
| 7.3 Awareness  | 6.2.2 - Unchanged |  |  |  |  |
| 7.4 Communication  | 5.6, 6.2.2 - Unchanged |  |  |  |  |
| 7.5 Documented information  | 4.2, 5.6.1 - Existing procedures for document and record control may meet many of these requirements.Have these been reviewed accordingly? Does the FSMS include documented information and FS requirements required by statutory, regulatory authorities and customers? |  |  |  |  |
| 8.1 Operational planning and control  | New Requirement |  |  |  |  |
| 8.2 Prerequisite programmes (PRPs)  | 7.2 - Are statutory ad regulatory requirements identified when determining PRPs? Are labelling and other processes such as receiving raw materials, storage, dispatch, transportation and handling of products considered when establishing PRPs? |  |  |  |  |
| 8.3 Traceability system  | 7.9 - Does the traceability system consider the relation of lots of received materials, ingredients and intermediate products to the end products and reworking of materials/products? Has documented information been retained for a defined period? Has the effectiveness of the system been verified?  |  |  |  |  |
| 8.4 Emergency preparedness and response  | 5.7 - Has documented information been maintained? Are you responding to emergency situations by establishing internal and external communications, taking actions to reduce consequences, testing the procedure and reviewing and updating the information when needed? |  |  |  |  |
| 8.5.1 Preliminary steps to enable hazard analysis | 7.3 - Is the source of products also included as part of the technical specifications for raw materials, ingredients and packaging?Has method of delivery been included as a characteristic of the end product/s?Are processing aids, packaging and utilities considered as part of the flow/s diagram/s? |  |  |  |  |
| 8.5.2 Hazard Analysis | 7.4 - Have internal information and statutory and regulatory requirements been included for the identification of hazards? Are persons considered when identifying hazards at every step?Does your assessment identify any significant food safety hazards?Does your assessment of control measures include also the feasibility of establishing measuring critical limits and applicability of timely corrections? Are also external requirements considered and documented?  |  |  |  |  |
| 8.5.3 Validation of control measure(s) and combinations of control measures | 8.2, 7.6 - Does your validation cover single and also combination of control measures? Are the validation of control measures, decision-making process and categorization of control measures documented? |  |  |  |  |
| 8.5.4 Hazard control plan (HACCP/OPRP plan) | 7.5, 7.6 - Does your Hazard Control Plan include an OPRP plan and monitoring systems for OPRPs as well as HACCP Plan and monitoring system for CCPs? Is your HACCP Plan documented? |  |  |  |  |
| 8.6 Updating the information specifying the PRPs and the hazard control plan | 7.7 - Are the description of processes and process environment also considered for revision once established the Hazard Control Plan and when required? |  |  |  |  |
| 8.7 Control of monitoring and measuring  | 8.3 - When software is used for monitoring and measuring, has this been validated before use? |  |  |  |  |
| 8.8 Verification related to PRPs and the hazard control plan | 7.8, 8.4.2, 8.4.3 - Are there verification activities in place to confirm the effectiveness of PRPs as well as the Hazard Control Plan? Are the verification and the monitoring of activities or the control measures conducted by different people? |  |  |  |  |
| 8.9 Control of product and process nonconformities | 7.10 - Are corrections and corrective actions in place when action criteria for an OPRP are not met? Are corrective actions addressed when reviewing non-conformities identified by consumer complaints and regulatory inspection reports?Does your evaluation for release of products include those that do not meet the action criterion for OPRPs? Are all results of evaluation for release documented?Has disposition of unsafe products been determined and documented considering also redirection for other use? |  |  |  |  |
| 9.1 Monitoring, measurement, analysis and evaluation  | 8.4.2, 8.4.3 - Is there a flow down from risk identification to what needs to be measured and monitored and then evidence that this data is not just being collected and documented but also performance and effectiveness evaluated? |  |  |  |  |
| 9.2 Internal Audits  | 8.4.1 - Are your internal audit programme and results documented and consider also changes in the FSMS, results of monitoring and measuring and previous audit findings? Are results reported to the FS Team and relevant management? Is your programme able to determine if the FSMS meets the intent of the policy and objectives? |  |  |  |  |
| 9.3 Management review  | 5.2, 5.8 - Are the following inputs also discussed during the MRM? Changes in the business and its context, monitoring and measuring results, non-conformities and corrective actions, performance of external providers, review of risks and opportunities and of the effectiveness of actions taken to address them, extent to which objectives of the FSMS have been met, the adequacy of resources and opportunities for continual improvement among others.Do the outputs include any need for updates and changes to the FSMS? Are results of management reviews documented? |  |  |  |  |
| 10.1 Nonconformity and corrective action | New requirement |  |  |  |  |
| 10.2 Continual Improvement | 8.1, 8.5.1 - Is a process for continual improvement being utilised? How is improvement encouraged and acknowledged? |  |  |  |  |
| 10.3 Update of the food safety management system | 8.5.2 - Unchanged |  |  |  |  |

**Areas for further investigation:**

|  |
| --- |
|  |