**ANNEX B to ToR**

**LOT 2. ISO 22000:2018 Food safety management system (FSMS) implementation**

1. **Key Tasks and Activities**

To fulfil the General goal, the Contractor will seek to ensure the achievement of the following main objective at the level of the mentioned companies by the end of the contract:

* Engaging the companies in applying the principles of ISO 22000:2018, implementing and applying all the documented procedures, and submitting the application for Certificates ISO 22000:2018.
* Conducting a comprehensive gap analysis: Evaluate the current food safety management practices within the companies against the requirements outlined in ISO 22000:2018. Identify areas of non-compliance, weaknesses, and areas for improvement. Developing and implementing documented procedures: Creating a set of documented procedures and processes tailored to each company's operations that align with the requirements of ISO 22000:2018, procedures for hazard analysis, control measures, monitoring, corrective actions, and management review.
* Establishing a Food Safety Team - Forming a dedicated team within each company responsible for overseeing the implementation and maintenance of the FSMS.
* Hazard analysis and risk assessment for each stage of the food production process within the companies. Identify potential hazards, assess risks, and implement appropriate control measures to mitigate risks to an acceptable level.
* Establishing monitoring and control measures to ensure that critical control points are effectively managed and that food safety risks are continuously monitored and controlled throughout the production process.
* Establishing procedures for addressing non-conformities, deviations, and incidents related to food safety, developing corrective action plans to address root causes and prevent recurrence of food safety issues.
* Internal audits and management review - conducting regular internal audits to assess the effectiveness of the FSMS implementation and identify areas for improvement, periodic management reviews to evaluate the overall performance of the FSMS and make necessary adjustments.

The Contractor must fulfil the following tasks:

1. **Process Initiation**

During this stage, the Contractor will launch the assistance activities in each company separately, including:

* Project Kickoff Meeting: Organize a meeting with key stakeholders from the company to introduce the ISO 22000:2018 FSMS implementation project. This meeting will aim to gain buy-in from senior management and establish clear communication channels. (to organize and to carry out the meetings for launching the assistance activity in every company separately);
* Identification and involve relevant stakeholders from different departments or areas within the company who will be impacted by the FSMS implementation. This may include production, quality assurance, procurement, and management teams.
* to submit to and to agree with each company the Initial Audit Plan (GAP Analysis) for the regulatory framework, organization and operation of service provision processes. Identification areas of non-compliance, weaknesses, and opportunities for improvement.;
* to send the lists of documents, questionnaires / forms to request all necessary information in order to fulfill the set tasks;
* to receive documents, questionnaires / forms filled in with all necessary information for fulfilling the set tasks;
* based on these initial data, the consultants of the Company will vary out the preliminary evaluation, necessary upon the initiation of assistance activities;
* to organize discussions and preliminary interviews with the representatives of beneficiary companies, to agree upon the stages and activities to be carried out, and to present all these to the working teams;
* develop a detailed implementation plan outlining the steps, timelines, and milestones for achieving ISO 22000:2018 certification. The plan should include tasks, responsible parties, and deadlines.
* identify potential risks and obstacles that may impact the FSMS implementation process. Develop strategies to mitigate risks and ensure the smooth progress of the project assessment the training needs of employees regarding food safety management and ISO 22000:2018 requirements. Development the training plan to provide necessary knowledge and skills to employees at all levels.
* documentation review - review existing documentation related to food safety management within the company. Identifying gaps and developing plans to update or create necessary documents to align with ISO 22000:2018 requirements
* Working Groups will be stablished in each company to fulfil the set tasks;
* In each of those companies a person will be appointed to be responsible for the implementation of the Food safetyManagement System as Project Coordinator.
1. **Initial Audit (**GAP Analysis**)**

During this stage, the Contractor will carry out the GAP Analysis Initial Audit of the internal organization, regulatory framework and service provision process in each beneficiary company. The objectives to be achieved during the Initial Audit are:

* Identification of the real working system and comparing it with the requirements of the reference ISO 22000:2018 standard;
* Identify non-conformities or discrepancies between current practices and ISO 22000:2018 requirements.
* Assess the potential impact of these non-conformities on food safety and associated risks.
* Identify weaknesses and areas for improvement in food safety management and quality management system.;
* Identification of critical points in activity flow, which may provoke delays, deficiencies, etc. and implicitly additional costs.

The result of this stage will be GAP Analysis report, developed for each company separately.

Documenting the results of the analysis, including identification of non-conformities, weaknesses and areas for improvement. Presenting findings and recommendations in a structured and clear report, highlighting differences between existing practices and ISO 22000:2018 requirements and providing suggestions for corrective and improvement actions.

The structure of the initial audit reports will be coordinated with the EU4Moldova: Focal Regions Programme. The conclusions of the initial audit reports and the audit recommendations shall be endorsed by each company separately.

The Contractor will organize and carry out the meetings for presenting the results of the initial audit in each company.

1. **Design of Food safety management system**

During this stage, the Contractor will develop and suggest to beneficiary companies the projects for implementing the ISO 22000:2018 standard.

The projects will be development based on the conclusions and recommendations of the Initial results of the Gap Analysis 2.

Project documentation will include:

* Food safety management policy;
* Goal and scope of ISO 22000:2018;
* Action directions and specific measures for Food safety management assurance;
* Structure of Food safety Management System to be implemented in each company;
* Reference documentation (list of regulatory documents, instructions, etc.) to be amended, adjusted, completed and/or developed;
* Action Plan for carrying out the activities meant to implement the ISO 22000:2018;
* Necessary methods and means for meeting the management requirements defined in the standards of reference;
* Commitments of companies to implement the ISO 22000:2018.

The structure of project documentation shall be coordinated prior with the EU4Moldova: Focal Regions Programme.

The project documentation shall be approved according to the approval procedures in force by each company. In this respect, the Contractor will organize and carry out meetings to present the initial audit results in each company.

1. **Development of Documentation for ISO 22000:2018**

During this stage, the Contractor will develop and propose to the beneficiary companies the package of documents for implementing the ISO 22000:2018 Food safety management system.

The package of documents will cover, but will not limit itself to the following:

* Food safety management System Manual
* Draft Instructions/process description;
* Risk policy;
* Internal audit procedures and documented Food safety management System;
* Other documents of Food safety management System.

The structure of documentation for the Food safety Management be coordinated with the EU4Moldova: Focal Regions Programme.

The package of documents regarding the implementation of the Food safety management system shall be approved according to the approval procedures in force, by each beneficiary. In this respect, the Contractor will organize and carry out meetings to present the package of documents regarding the implementation of the Food safety management system in each company.

1. **Implementation of Food safety management System**

During this stage, the practical implementation of Food safety management System shall be implemented under the guidance of the consultants of the Contractor. In a practical way, this stage will cover the following activities:

* Internal trainings with the entire personnel, from all the management and execution levels;
* Performing internal audits under the guidance of consultants so as to identify incompliances or emerged implementation problems;
* Workshops for analyzing the incompliances and establishing corrective and preventive measures.

Development of HACCP (Hazard Analysis and Critical Control Points) plans to ensure food safety and prevent risks associated with food contamination. Elaboration of HACCP plans according to basic seven HACCP principles.

* Forming the HACCP team which will include members with knowledge and experience in food safety, food production and other relevant areas.
* Identification of the food or food process for which the HACCP plan will be developed.
* Create a process flow diagram to illustrate all stages of food production and handling, from raw materials to finished product.
* Identify potential hazards associated with each stage of the process, including biological, chemical and physical.
* Determination of critical control points (CCPs) in the food process, where control measures can be applied to prevent or eliminate risks associated with identified hazards.
* Develop monitoring system for each CCP, allowing continuous tracking and control of critical parameters. Definition of monitoring methods, frequency and associated responsibilities.
* Appropriate training and education for personnel who will be involved in the implementation and maintenance of the HACCP plan.
1. **Internal audits and management review and initiating the certification procedure of the Food Safety Management System according to ISO 22000 :2018**

The internal audit of the food safety management system in accordance with ISO 22000:2018 requirements is an essential process for ensuring the effectiveness and compliance of the food safety management system (SMSA).

Audit planning:

Establish audit objectives and areas. Identify the processes and areas to be audited, taking into account the risks and their importance for food safety.

Develop the audit programme including dates, locations and time allocated for each planned audit.

Audit team selection, internal audit team members should be impartial and have adequate knowledge of ISO 22000:2018 and the organization's specific procedures.

Conduct the audit according to the audit plan and ISO 22000:2018 requirements. Verify that processes and practices c meet the requirements of the standard and are implemented effectively. Use audit methods such as interviews, observations, review of documents and records to assess compliance with standards and effectiveness of processes.

Evaluation of findings. During the audit the findings will be documented and any non-conformities or improvements needed in the food safety management system will be identified. The findings will be analyzed to identify the root causes of non-conformities and to recommend appropriate corrective and preventive actions.

Reporting results: documenting audit findings and conclusions in a written internal audit report. The report will include information on the audit scope, methods, findings and recommendations. The audit report will be presented to management and relevant teams to inform on the status of the food safety management system and to request corrective actions or improvements.

Follow-up and verification of corrective actions: monitoring and verification of the implementation of corrective and preventive actions established as a result of internal audit findings. Corrective actions must be effective in addressing identified non-conformities and preventing their recurrence.

Continuous improvement: findings and recommendations from the internal audit report will be used to identify opportunities for continuous improvement of the food safety management system.

The management review of the food safety management system according to the requirements of ISO 22000:2018 involves evaluating the effectiveness and efficiency of the system to ensure that it meets the stated objectives and requirements of the standard.

The management review of the food safety management system (SMSA) according to ISO 22000:2018 requirements will include input information and generate the following outputs:

Input information:

1. Food safety management system (FSMS) documentation: this includes policies, procedures, work instructions, HACCP plans, audit reports, incident records, customer feedback, etc.
2. Internal audit reports: Results of previous FSMS internal audits, which can identify weaknesses, non-conformities and opportunities for improvement.
3. Performance monitoring data: Information on the performance of the food safety management system, such as laboratory test results, non-compliance reports, food safety incidents, customer feedback, etc.

Outputs generated:

1. FSMS Management Review Report is a detailed report documenting the results of the FSMS management review. It will include:
	* The findings and conclusions of the analysis, including identified weaknesses, non-conformances, performance trends and opportunities for improvement.
	* Recommendations for corrective and preventive actions to address non-conformances and improve the effectiveness and efficiency of the FSMS.
	* Assessment of compliance with the requirements of ISO 22000:2018 and identification of potential gaps in the food safety management system.
2. Action Plan: Action Plan: A detailed plan setting out specific actions to be taken to address identified weaknesses and improve the FSMS. It will include responsibilities, deadlines and resources required to implement corrective and preventive actions.
3. Updates to FSMS documentation: Updates to policies, procedures, work instructions, etc. to reflect necessary changes identified in the management review.

The structure of the Internal Audit and Management Review Reports shall be coordinated with the EU4Moldova: Focal Regions Programme.

The Reports on identified incompliances and Reports of final recommendations to eliminate the incompliances and improve certain processes for them to comply with the requirements of ISO standards shall be approved according to the approval procedures in force by each beneficiary.

During this stage, the Contractor will inform and recommend practical modalities and steps to be followed in the certification procedure by a certification body. At the same time, the Contractor will establish the modalities of assistance in negotiating and signing the certification contract and assistance at the certification audit stage (if agreed with the beneficiary companies).

The Contractor will submit a Report describing the contributions provided in guiding the companies regarding the certification procedure by a certification body and assistance in negotiating the certification conditions and provided support.

7. **Finalizing Activities**

The Contractor will summarize all implemented activities and obtained results and will submit a final Activity Report, describing, as well, the contribution provided in implementing activities, obtained results, lessons learned, good practices and recommendations for the Programme.

1. **Key deliverables and indicative timeframe**

The Company shall deliver to EU4Moldova: Focal Regions Programme the following Deliverables, in accordance with the schedule set forth in Section below.

| **Deliverables** | **Expected Period** |
| --- | --- |
| **Deliverable 1: Progress Report 1. Initiating the Process**The Contractor shall submit the Progress Report including:* The GAP Analysis Plan endorsed by each company separately;
* List of received documentation necessary to carry out the Initial Audit.
 | **4 weeks since the contract signature** |
| **Deliverable 2: Progress Report 2.** GAP Analysis Report The Contractor shall carry out the GAP Analysis , present the Report of the GAP Analysis, submit the Progress Report on these activities and attaches: * Initial GAP Analysis organization, regulatory framework and service provision processed in each company, separately;
* Meetings Agenda for presenting the results of GAP Analysis and Lists of participants;
* Information materials used during the meetings for presenting the results of GAP Analysis (word version and ppts, photo, video records);
* Decisions for endorsing the GAP Analysis by each company, separately.

The Company shall submit the draft reports and presentations to the Programme for review and approval prior to the events.  | **2 months since submission of Deliverable 1** |
| **Deliverable 3: Progress Report 3, Design of Food safety Management System**The Contractor shall submit the Progress Report including:* Projects for implementing the Food safety Management in each company, according to the requirements of Terms of Reference;
* Meetings Agendas to present the projects for implementation and Lists of participants;
* Information materials used during the meetings to present the implementation projects for Food safety Management System (word versions and PPPs);
* Decisions for endorsing the projects for implementing the Food safety Management by each company separately;
* Commitment of the company to implement the Food safety management.

The draft documents will be completed in Romanian, presented in electronic version and endorsed by the Programme prior to submission to companies. | **1 month since submission of Deliverable 2** |
| **Deliverable 4: Progress Report 4. Development of the Documentation of Food safety Management System**The Contractor shall develop the packages of documents for implementing the Food safety Management System in each company, according to the Terms of Reference and present the Progress Report including the following that shall be attached: * Packages of documents for implementing the Food safetySystem, according to the list of documents and Terms of Reference requirements;
* Agenda of meetings for presenting the projects to implement the Food safety Management System;
* Information materials used during the meetings to present the packages of documents for implementing the Food safety Management System (word version and PPPs);
* Decisions to approve the packages of documents to implement the Food safety Management System by each company separately.
 | **2 months since submission of Deliverable 3** |
| **Deliverable 5: Progress Report 5. Implementation of Designed Food safety Management System**The Progress Report shall include the description of contributions provided in the process of Implementing the requirements of designed management systems. The following shall be annexed under the Report: * Internal audit reports for identifying incompliances or emerged implementation problems;
* Agendas of workshops/ trainings sessions and Lists of participants;
* Confirmation photo, video and audio materials;
* Results of workshops /training sessions;
* Information materials (word versions and PPPs) used during the workshops / meetings;
* Decisions to endorse the Reports on implemented requirements of designed Food safety Management System, separately by each company.
* Elaboration of HACCP plans
 | **3 months since submission of Deliverable 4** |
| **Deliverable 6: Progress Report 6. Internal audits and management review and initiating the certification procedure of the Food Safety Management System according to ISO 22000:2018** The Progress Report will include the description of performed Internal audits of the Food safety Management System for identifying the compliance of organization, regulatory framework and processes in the companies with documented systems, and the following annexes:* Reports of identified incompliances;
* Management Review Report
* Reports of final recommendations on elimination of incompliances and improvement of certain processes to be compliant with the requirements of ISO standard;
* Agendas of workshops and Lists of participants;
* Confirmation photo and video materials;
* Information materials used during the workshops;
* Decisions for approving the Report of identified incompliances and Report with final recommendations for each company;
* Description of information activities and assistance for initiating certification procedures by the certification body.
 | **2 months since the submission of Deliverable 5** |
| **Deliverable 7: Final report. Finalization of Activities**The Contractor shall submit a Final report, presenting the results of the consultancy, containing an executive summary, a detailed outline of actions and achieved results with lessons learned, good practices and recommendations for the Programme. The Final Report will include the revised documents and annexes with all deliverables produced under this assignment. | **1 week since submission of Deliverable 6** |

**Note:** *The indicated tentative timeframe has been estimated as being sufficient/feasible for the envisaged volume of work to be completed successfully and is proposed as a guideline for the duration of the assignment. It cannot be and will not be used as a single criterion for contract/assignment fulfillment. The submission of envisaged deliverables approved by EU4Moldova: Focal Regions Programme will be the only criterion regarding the activity fulfilment by the Contractor and its eligibility for payment.*