

## **FSM Pacific Regional Oceanscape Program – Economic Resilience (PROPER) Project**

### **Terms of Reference for National Laboratory Feasibility Study**

#### **FEDERATED STATES OF MICRONESIA**

##### **A. BACKGROUND:**

The National Government of the Federated States of Micronesia (FSM) in collaboration with the states and various government departments is implementing a new project as part of its development activities within the FSM.

The FSM Pacific Regional Oceanscape Program – Economic Resilience (PROPER) Project is a government-led fisheries initiative aimed at enhancing the shared management of selected Pacific Island oceanic and coastal fisheries, along with the critical habitats upon which they depend, for economic recovery and resilience. The project consists of three key components: Oceanic Fisheries, Coastal Fisheries, and Marine Habitats and Waste. Each component focuses on specific activities and interventions aimed at addressing the unique challenges faced in their respective areas. The National Oceanic Resource Management Authority (NORMA) and FSM Department of Health & Social Affairs (DHSA) are responsible for implementing the Oceanic Fisheries Component of the PROPER Project.

NORMA, the FSM Government agency responsible for managing the valuable tuna resources, generates significant revenue for both the national and state governments through the sale of fishing rights within the FSM exclusive economic zone. In recent years, FSM has been working to establish its Competent Authority (CA) to gain approval for exporting fish and fishery products to the European Union (EU). The FSM DHSA issues health certificates for exporting fishery products from FSM and is responsible for setting up systems required by the EU for the inspection and certification of all fish products imported from FSM. The CA must ensure regular inspections of FSM fishing vessels, catches, and transshipment activities, alongside a fish sampling program.

All processes must be rigorously documented by the CA to ensure fish exports can be traced back to the origin in the FSM ensuring compliance with the EU's Catch Documentation/Certification Scheme (Import Control Scheme) under the IUU regulation (The EU regulation to prevent, deter and eliminate illegal, unreported and unregulated fishing). The establishment of the CA is crucial for FSM oceanic fisheries development, as the opportunity to export to the EU is likely to increase income for the sector.

Although the CA has been established, its proper functioning in line with EU requirements needs further development through training and capacity-building activities under the PROPER Project. Additionally, the FSM aims to establish a national laboratory to support its CA role as it currently relies on overseas reference laboratories for most of its fish samples testing.

NORMA and DHSA are seeking the services of an individual Consultant with relevant experience in undertaking a feasibility study (including cost/benefit analysis and lab accreditation process) for the establishment of a national laboratory to facilitate trade in fish products, among other national export goods.

##### **B. OBJECTIVE OF THE ASSIGNMENT**

The primary goal of this assignment is to evaluate the feasibility and sustainability of establishing and operating a national laboratory in the Federated States of Micronesia (FSM) to support its function as a Competent Authority (CA) for accessing the European Union (EU) market. The Consultant will comprehensively assess the viability of establishing a national testing laboratory under the FSM Department of Health & Social Affairs (DHSA), which may involve the following tasks:

- **Evaluating Practicality:** Assess the feasibility of setting up a testing lab, considering available resources, infrastructure needs, staffing requirements, technological capacity, operating costs, and projected revenues.
- **Identifying Critical Factors:** Analyze internal and external factors essential for the successful establishment and sustainable operation of the lab, including infrastructure, equipment, human resources, training needs, regulatory requirements, market demand within the Pacific or Micronesia subregion, private sector needs, and potential challenges.
- **Assessing Financial Viability:** Conduct a cost/benefit analysis, explore funding options, and develop a self-sustaining operational model.
- **Mapping Laboratory Landscape:** Examine the current laboratory capabilities in both the public and private sectors, identify gaps compared to international best practices, and assess the specific conformity testing needs of the fish and other relevant product export sectors requiring support.
- **Recommending a Roadmap:** Provide a detailed plan for establishing the laboratory, including design and construction phases, sequential activities, reasonable timeframes, and key implementation milestones aligned with the PROPER project objectives and timelines.
- **Managing Risks and Opportunities:** Suggest measures to mitigate risks and capitalize on opportunities related to effective operationalization of the lab, quality assurance, regulatory compliance, and stakeholder engagement.
- **Facilitating Participation and Income Realization:** Evaluate how the new laboratory could enhance FSM and its partners' participation in the fisheries and other product export value chains, contributing to higher income aligned with the FSM Government's strategic objectives.
- **Ensuring Compliance and Alignment:** Ensure the testing facilities and services meet FSM's requirements, international standards, and private sector demands, while recommending strategies for continued alignment with evolving needs.
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## C. SCOPE OF WORK

To achieve the objectives of the assignments, the Consultant will report directly to the Program Manager for the Environment Health & Food Safety Program of the FSM DHSA in collaboration with the FSM NORMA and undertaking the following phases:

### *Inception Phase*

In the Inception Phase of the feasibility study, the Consultant is tasked with outlining a methodology for the study starting with conducting a comprehensive situational analysis. This phase involves a review of FSM's current quality infrastructure, including any existing

laboratory facilities in the region, related policies, and the needs of the FSM export market, aligning with the broader objectives of the PROPER Project. The Consultant will evaluate international best practices in quality infrastructure and laboratory management, particularly in the context of developing economies in the region, and adapt these insights to the FSM context. The analysis will also incorporate a climate perspective, recognizing the interplay between quality infrastructure, FSM oceanic fishery, and climate resilience. This initial phase sets the stage for a detailed understanding of the requirements and challenges in establishing the laboratory, ensuring that the feasibility study is grounded in current realities and geared towards sustainable, climate-smart solutions in consultation with viable and potential partners in the region and relevant industries.

#### *Technical, Situational, and Needs Analysis for Establishing National Test Lab*

This stage will involve a detailed evaluation of existing laboratory capabilities within FSM and the region, focusing on both public and private sectors, especially as they pertain to the nation's trade in the fisheries sector and related industries. It includes an in-depth analysis of the current state of laboratory services, identifying gaps, and determining specific needs for testing capabilities, equipment, personnel, and technology. The analysis will also cover the existing regulatory framework, exploring how it supports or hinders the development of laboratory infrastructure. This part also evaluates the infrastructure, technology, equipment, and human resources required for establishing and successfully operating a national laboratory.

Moreover, this phase will also examine the market demand for laboratory services, delving into aspects like conformity assessment necessary for trade facilitation. By understanding the technical needs and market dynamics, this phase aims to establish a solid foundation for developing a laboratory, aligning them with FSM's trade objectives and economic development goals. This comprehensive approach ensures that the proposed laboratory is technically feasible, meets and able to adapt to market needs, and aligns with the broader objectives of enhancing FSM's quality infrastructure for sustainable economic growth.

In the subsequent part of the analysis, the focus will be on the technical requirements essential for the establishment of the laboratories. This will encompass a detailed assessment of the specific types of tests, analyses, and associated technologies required, with special attention to those relevant to FSM's key exports like fish products. A critical deliverable from this phase will be a detailed list of equipment, technology, systems, and their precise specifications that are necessary for setting up the lab. Additionally, the study will specify the technical skills and training needs of staff required to proficiently operate the lab, ensuring it meet international testing standards and the demands of modern laboratory operations. This comprehensive approach guarantees that the laboratory is equipped with the most suitable and advanced resources for its intended functions. The evaluation extends to understanding how these technical requirements align with the existing and potential market needs. It should involve identifying the types of tests that are in high demand by the industry and required for compliance with international trade standards. This understanding is crucial for ensuring that the laboratory services are not only technically sound but also relevant and beneficial to FSM's and potential key clients' trade and economic sectors.

#### *Financial Viability and Sustainability Analysis*

This stage involves conducting a detailed financial feasibility study for the establishment and operation of the national test lab. The analysis will start with a thorough estimation of the costs associated with setting up the laboratory, including expenses for design, construction, procurement of equipment and technology, hiring and training of personnel, and ongoing

operational costs. The estimated costs involved in setting up and operating the laboratory should include the initial capital investment, operational expenses, and potential revenue sources (e.g., government funding, fees for services).

Alongside the cost estimation, a comprehensive financial model will be developed to ensure the sustainable operation of the laboratory. This model will include projections of operating costs, revenue streams, and financial performance indicators. It will also evaluate the economic impact of the laboratory on the local and national economy, particularly in terms of job creation, trade enhancement, and contribution to the GDP. The goal of this financial analysis is to establish a viable and sustainable financial framework that supports the long-term success and impact of the laboratory in enhancing FSM's quality infrastructure and trade capabilities.

#### *Regulatory Framework Review and Accreditation Requirements*

This stage involves a thorough review and analysis of the national and international regulatory frameworks that are pertinent to laboratory operations. The primary goal is to ensure that the proposed national test lab complies with international quality and safety standards. This includes examining existing FSM regulations and global standards, such as those set by ISO, WTO, WHO, and others. The review will also consider regulations related to trade, environment, and health to ensure comprehensive compliance. The outcome will be a detailed report outlining the regulatory requirements and recommendations for aligning the proposed laboratory with these standards, thus facilitating their recognition and efficacy in international trade.

#### *Risk Assessment and Mitigation Planning*

This critical stage focuses on identifying and assessing potential risks associated with establishing and operating the national test lab. The assessment will cover various aspects, including technical, operational, financial, and environmental risks. This comprehensive risk profiling will help in understanding the challenges and vulnerabilities of the project. Based on this assessment, the task will involve formulating robust mitigation strategies and contingency plans. These strategies will aim to minimize the identified risks, ensuring the resilience and sustainable operation of the laboratory. This planning is crucial for maintaining the integrity and reliability of the laboratory services and for safeguarding the investment against foreseen risks and unforeseen challenges.

#### *Recommendations Formulation and Stakeholder Buy-in:*

The Consultant will provide actionable recommendations on the establishment, design, and operation of the national laboratory. This includes proposing sustainable models for the governance, management, and funding of the laboratory, along with partnership opportunities with governmental, academic, and international organizations. The consultation process should be clearly outlined not only as a means to collect information but also to assess the stakeholders and industry buy-in for the need for a laboratory.

### **FINAL REPORT**

The final report should present:

- a thorough assessment of the strengths, weaknesses, opportunities and challenges of the overall food safety and national quality infrastructure before considering any major investment in a laboratory.
- Identify appropriate initial actions necessary to effect institutional and regulatory reforms so that the laboratory will have a clear mandate and responsibilities, as well as a process for setting priorities that takes into account all relevant factors.

- Include in the report that decisions on any significant investment in laboratories include plans for regular funding of operational, maintenance, and upgrade costs.
- Present a cost/benefit and risk analysis, supported by financial and economic analysis, and this analysis should be used as the basis for priority setting in the formulation of the laboratory investment plan.
- Present a business plan for the new investment in the national laboratory based on the assessment of capacities, and assessment of demand under various policy and investment alternatives. The business plan should include the following topics;
  - general and specific policies and regulations
  - description of the existing laboratory facilities and their quality
  - assessment of the laboratory for which investment is proposed, including its capacities and operational performance
  - assessment of trends in demand for laboratory services
  - design of the investment proposal, including proposals for changes in policies, governance and administration, quality management
  - prioritization and financial and economic feasibility of the investment
  - making the case for investment including options
  - monitoring and evaluation (how the laboratory will be assessed)

In addition, the Consultant could also include actionable recommendations.

#### **D. DELIVERABLES**

The Consultant will be responsible for the following deliverables.

#	Deliverable Title	Description	Months from Contract signing
1.	Inception Report	A report outlining the initial findings, proposed methodology and work plan for the feasibility study.	1 month
2.	Situational Analysis and Technical Needs Report including market analysis report	Detailed analysis of current laboratory capabilities and technical needs for the proposed lab.	4 months
3.	Technical, Financial Feasibility and Compliance Report	A detailed report covering financial feasibility, regulatory framework compliance, cost/benefit analysis, risk assessment and mitigation strategies for the lab. This includes accreditation processes, such as ISO certification. A detailed budget, including capital expenditure, operating costs, and revenue projections with identification of existing and potential funding sources, including government, Grants, international donors, and private sector contributions.	5 months

6.	Draft Feasibility Study and Implementation Roadmap	Initial draft of the feasibility study, including recommendations and an implementation roadmap for the laboratory including sustainable governance structures to ensure long- term operational viability.	7 months
7.	Validation Workshop	Present, discuss, and validate the findings with stakeholders.	8 months
8.	Final Feasibility Study Report	The final comprehensive feasibility study report, incorporating feedback and revisions.	9 months

## **E. EVALUATION/ SELECTION CRITERIA**

Consultants will be selected on qualifications and experience.

### Mandatory Requirements

Eligible individual consultants must have:

- Post graduate qualifications in Laboratory Sciences, Biochemistry, Microbiology, Industrial Engineering, Chemical Engineering, Biomedical Engineering or related field with a minimum of 10 years post qualification experience.
- Extensive relevant experience in operations and establishment of national testing labs including undertaking laboratory feasibility studies.
- Experience in engagements with developing country governments and development partners relating to trade and market access.
- Proven track records of relevant publications, reports, or similar work in English.

### Desirable requirements

- Working knowledge of national lab operations in the Pacific region or in the fisheries products CA operations.

### **Duration of the Consultancy**

The consultancy will be for a period of 9 months commencing in June 2025 or as soon as possible following PROPER Project effectiveness.

### **Working Arrangement**

For effective delivery of the assignment, the consultant may work with a local counterpart (via sub-consulting).