Export-ready seafood: Understanding regulations and optimising in-plant microbiology testing

The following article is a part of FIFP webinars conducted on 31st January, 2026 on the topic "Export-ready seafood: Understanding regulations and optimising in-plant microbiology testing".

Note from the Chief Editor:

Export-ready seafood: Understanding regulations and optimising In-Plant Microbiology testing was the topic of FIFP webinar conducted on 31st January 2026. A strong Quality Management System (QMS) under QS 9020:2022 forms the foundation of effective laboratory operations. The QMS is an integrated framework that combines Quality assurance policies and Quality control techniques to ensure that analytical processes are valid, regulatory requirements are met, and customer expectations are fulfilled. Ms Vidya Lekshmi's presentation covered key components of Quality Management System framework. Quality is a shared responsibility across all levels of the organisation. She spelt out clearly the responsibilities of management, Quality Assurance Officer and staff in ensuring efficient operation of the Quality Management System Framework. She provided details of inter and intra laboratory quality control practices, the critical role of in-plant microbiology testing, advanced methods of microbial detection, and the international accreditation framework that underpins export-ready seafood operations. Compliance with global standards is essential not only for protecting public health but also for maintaining competitiveness and credibility in international markets. Ms Vidya Lekshmi highlighted the importance of establishing a robust Quality Management System guided by QS 9020 and ISO/IEC 17025:2017 while deploying advanced microbial detection technologies.

Introduction

The seafood export industry operates under strict regulatory frameworks to ensure product safety, quality, and global trade compliance. At the heart of this system lies a robust Quality Management System (QMS) governed by the revised QS 9020:2022 standard which integrates Quality Assurance (QA) policies and Quality Control (QC) techniques. Together, these pillars substantiate the validity of analytical processes, ensure regulatory compliance, fulfil customer objectives, and adhere to applicable international standards.

The Quality Management System (QMS) Framework

A well-functioning QMS for seafood laboratories is built on clearly defined responsibilities across management, quality assurance officers, and staff. The QS 9020 revised standard lays out a structured approach to ensure consistent, reliable outputs.

Management Responsibilities

Senior management plays a critical role in quality systems by recognising the need for a Quality System, involving staff in its development, committing financial and personnel resources, ensuring meeting of laboratory safety requirements, systematically reviewing laboratory functions and assuming leadership in evaluating risks associated with errors.

Quality Assurance (QA) Officer Responsibilities

The QA Officer or Quality Manager must hold relevant coursework, training, and practical laboratory experience; be familiar with QA programs and QC practices; provide technical support to the team; sign off on all Standard Operating Procedures (SOPs); routinely update documentation and conduct frequent audits and report periodically to management.

Staff Responsibilities

Laboratory staff are integral to quality implementation and they must assist management in planning the QA program; help prepare SOPs; incorporate QA and QC activities into daily tasks and clearly understand their individual expectations and roles.

Elements of a Quality System Manual

The Quality System Manual is the cornerstone document of any accredited laboratory. It includes a clearly defined quality policy, organisational structure, personnel qualifications and responsibilities, and detailed equipment requirements. It also covers sampling procedures, analytical methods, validation protocols, analytical quality control practices, documentation control, internal audits, proficiency testing, and corrective and preventive actions. These elements together create a structured and traceable system that guides all laboratory processes and ensures consistency and reliability in operations.

Intra laboratory Quality Control Practices (QS 9020B)

Quality control practices are essential to maintain the accuracy and credibility of laboratory results. Intra laboratory activities such as monitoring air quality, validating autoclave performance, recording incubator temperatures, checking culture media quality, and calibrating equipment are critical routine practices. These are not merely procedural requirements but fundamental to ensuring dependable results.

Daily, monthly, and periodic quality control checks are vital to maintaining laboratory integrity. Key intra laboratory QC practices include:

1. Air Quality Monitoring — Bacterial density monitored monthly
2. Autoclave — Monthly bioindicator check; heat indicator tape used at each use
3. Balances — Daily zero-check; monthly accuracy check with reference weights
4. Biosafety Cabinet — Inspected for airflow each use; certified annually
5. Freezers/Refrigerators — Temperature checked daily, defrosted annually
6. Incubators — Temperature monitored twice daily during use
7. Glassware — Inspected for cleanliness, chips, and etching at each use
8. Hot-Air Sterilising Oven — Temperature verified with heat indicator tape and monthly bioindicator
9. Microscope — Optics cleaned and alignment checked each use
10. Culture Media — Sterility, pH, and appearance verified per batch; performance confirmed with positive and negative culture controls
11. Micro pipettors — Volume accuracy checked quarterly, calibrated annually
12. pH Meter — Standardised with at least two buffer solutions each use
13. UV Lamps — Bulb use monitored; performance tested quarterly
14. Plate Counts — Duplicate analyses and repeat counts performed monthly

Interlaboratory Quality Control Practices (QS 9020C)

Interlaboratory QC ensures data comparability across testing facilities. It is built on three core elements: Uniform criteria for laboratory operations, External review of the program and External Proficiency Testing (PT)

Certification and accreditation programs play a key role. Certification programs (e.g., AFNOR NF Validation) involve third-party certification governed by defined rules. Accreditation programs (e.g., NABL) are administered by specialised accreditation bodies that set standards and assess laboratory competence.

The International Standard for Testing Laboratories (ISO/IEC 17025:2017)

ISO/IEC 17025:2017 is the globally recognised standard for the competence of testing and calibration laboratories. It enables laboratories to demonstrate that they operate competently and generate valid, internationally accepted results. The standard is built on three general requirements: Competence, Impartiality, and Consistency.

Key Sections

Section 4 — General Requirements: Addresses impartiality and confidentiality. Laboratories must keep results private and resist commercial or financial pressures that could compromise quality.

Section 5 — Structural Requirements: Defines the organisational components, management responsibilities, personnel authority, and resources needed.

Section 6 — Resource Requirements: Six clauses covering personnel, facilities, equipment, and support systems.

Section 7 — Process Requirements: Eleven core processes including method validation, sampling, proficiency testing, complaint handling, and results reporting.

Section 8 — Management System Requirements: Two options — Option A for independent laboratories (must comply with Sec 8 in full), and Option B for labs operating within a larger organisation with an ISO 9001:2015-aligned QMS.

Advantages of ISO 17025 Accreditation

i) Increases customer confidence through consistent, traceable, and valid results

ii)Promotes a proactive, risk-based business and quality culture

iii)Enhances laboratory credibility through independent third-party assessment

iv)Builds professionalism and organisational pride

v)Drives cost-effective operations through evidence-based decision making

Advanced methods of microbial enumeration and detection

Traditional culture methods are labour-intensive, involve complex manual handling steps, and are no longer the preferred approach in high-volume export environments. Automation when validated and globally accepted offers significant advantages such as saving of time and cost; reduced potential for human error; more consistent, reliable, and accurate results; results delivered within stipulated timeframes; and easier tracking and storage of results. However, high initial equipment investment, requirement of skilled personnel to operate equipment and difficulty in recruiting adequately trained staff are some of the challenges.

Advanced microbiology testing methods

Advancements in microbiology testing have led to a shift from traditional culture-based methods to automated systems that offer greater speed, accuracy, and traceability. Technologies such as TEMPO, VIDAS, and VITEK provide efficient detection and identification of microorganisms using advanced biochemical, enzymatic, and immunological techniques. These systems reduce manual errors and improve turnaround time. However, all analytical methods must be rigorously validated to ensure their suitability, accuracy, repeatability, and robustness. Key parameters such as sensitivity, specificity, inclusivity, and exclusivity are essential to confirm reliable performance.

TEMPO System (Culture-media based)

TEMPO is a fully quantitative, highly traceable MPN (Most Probable Number) method. It uses chromogenic or fluorogenic substrates for the detection of specific enzyme activities. Each test consists of a culture medium vial and a card specific to the test. The plastic card contains 3 sets of 16 wells (S, M & L) with a one-log volume difference (2.25 µl, 22.5 µl, 225 µl). Based on the pattern of positive wells across the three log dilution ranges, TEMPO automatically calculates the contamination level in the original sample.

VIDAS (Immunological method)

VIDAS, developed by bioMérieux, detects microorganisms from food, environmental, and chemical samples with turnaround times of same-day, next-day, or 48 hours. Its reliability is based on specific antigen-antibody reactions coupled with Enzyme Linked Fluorescent Assay (ELFA) technology, monitored by a calorimeter. Each test strip contains all ready-to-use reagents, washing solution, a specific bacterial protein conjugated with alkaline phosphatase, and a substrate. Results are expressed as Relative Fluorescence Value (RFV), and all steps are performed automatically.

VITEK (Biochemical Identification)

VITEK provides automatic rapid organism identification within 2 to 18 hours using biochemical identification from pure cultures. Available in three formats with increasing levels of capacity and automation, the system uses calorimeter reagent cards (450 nm) that are incubated and interpreted automatically.

Criteria for Selecting Analytical Methods

Analytical methods must be evaluated for fitness for purpose; validation for the specific application; limit of detection; repeatability and reproducibility; robustness; inclusivity and exclusivity.

Laboratory Design and Infrastructure

Laboratory infrastructure plays a critical role in supporting accurate microbiological analysis. An effective microbiology laboratory requires a well-designed floor plan with dedicated zones for media preparation, sterilisation, inoculation, incubation, and waste disposal, along with appropriate biosafety provisions to prevent cross-contamination and maintain operational efficiency.

Requirements of key areas include:

Media Preparation Room — Air-conditioned at 21±2°C with humidity below 60%

Sterilisation Room — Equipped with an exhaust fan

Inoculation Room — Air-conditioned, with smooth, easily cleanable floors and covered corners

Incubation Room — Maintains controlled temperature and humidity conditions

Biosafety Cabinet — For safe handling of microbiological samples

Discarding Room — Demarcated area with an autoclave for decontamination of used materials, glassware cleaning, and waste removal facilities

ELISA Lab — Air-conditioned at 21±2°C with humidity below 60%

Conclusion

Achieving export-ready status in the seafood industry demands a comprehensive, multi-layered approach to quality and safety. From establishing a robust Quality Management System guided by QS 9020 and ISO/IEC 17025:2017, to deploying advanced microbial detection technologies such as TEMPO, VIDAS, and VITEK, seafood processors must invest in both systems and people.

A well-designed laboratory infrastructure, strict adherence to intra laboratory and interlaboratory QC practices, and pursuit of internationally recognised accreditation are not merely regulatory requirements, they are strategic assets that build customer trust, ensure market access, and elevate the credibility of the seafood export enterprise on the global stage.

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