Capacity Building

Improving Seafood Toxicology and
Safety Measures in Selected Fisheries

INFOPESCA

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Content

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Acronyms

AOAC	*Association of Official Agricultural Chemists*
CA	*Competent Authority*
BIP	*Border Inspection Post*
CVED	*Common Veterinary Entry Document*
DG SANTE	*Directorate-General for Health and Food Safety*
EFSA	*European Food Safety Authority*
EU	*European Union*
FAO	*Food and Agriculture Organization of the United Nations*
GMOs	*Genetically Modified Organism*
HACCP	*Hazard Analysis (and) Critical Control Points*
IZS	*Istituto Zooprofilattico Sperimentale Lazio e Toscana*
MOU	*Memorandum Of Understanding*
MRA	*Mutual Recognition Agreement*
MRL	*Maximum Residue Level*
NGO	*Non-Governmental Organization*
RASFF	*Rapid Alert System for Food and Feed (EU)*
SPS	*Sanitary and Phytosanitary*
TRACES	*Trade Control and Expert System (EU)*
WCO	*World Customs Organization*

Introduction

The State of Kiribati has a population of 128 000 with 33 major islands, recognizes a coastal fishing which is primarily carried out for subsistence purposes and for sales in local markets(FAO). In addition, there are some coastal fisheries that are export oriented Kiribati State has in its economic structure of the fishing sector an important agreement with China and one of lesser importance in terms of dimensions with South Korea.

The most important species in terms of quantity and export are yellowfin and bigeye tuna (of less interest is skipjack tuna). Yellowfin tuna is mostly caught with purse seine vessels. The high season for tuna catch runs from April to August. The KIFL fleet consists of 48 vessels, 21 purse seine and 27 longlines. Processing tuna plant is located in Betio and about 150 employees work there. Tuna is exported only frozen whole (a small quantity) and mostly in loins.

Local Market: The fish that supplies the local market is caught daily on small boats (5-6 meters) with nets and lines. The most common species in the two markets are: snapper, bonefish, grouper, skipjack, coral rainbow etc. Snapper and other reef fish can represent a risk of ciguatera to the population. The third capacity building course is dedicated to this type of activity.

Capacity Building Programme

The following capacity building programme has two pillars: the first pillar centres on in house training in the laboratory of Kiribati and for the Government staff, the second pillar is a training programme in a foreign country.

The total budget needed to carry out the capacity building as presented in this programme is USD 250 000. All five capacity building courses will give a complete picture of the modern way of running a reference laboratory for exports to the EU market. In addition, the ciguatera training will also improve the food safety in the country.

Pillar 1: In house training

First Capacity Building Programme for Technicians and Competent Authority in Tarawa

This training program is designed to empower technicians at the new Laboratory

in Tarawa to become self-sufficient in conducting analytical tests on key parameters that are critical for both the export and domestic markets of fish products. The initiative aims to ensure that all procedures and methodologies are not only rigorously adhered to but are also aligned with internationally recognized standards. Through this upskilling, the laboratory technicians will be adept at delivering results that meet the stringent quality and safety expectations required for the successful trade of seafood goods. All the procedures of sampling activities start with the practical work of the Inspector on the field.

Main study points and objectives for this training are:

-Correct execution of sampling in accordance with European legislation. EU Reg.2073/2005.
-Composition of the sample matrices and review analysis.
-The ISO 17025:2018 standard
-Weight of the sample matrices.
-Respect for the cold chain.
-Sample collection and sample execution times.
-Risk of perishability of sample matrices and consequences
-Legal aspects of official sampling
-International litigation
-Risk of Detention and rejection in fish trade
-Study of practical cases

This training module will be given by an International Consultant with at least 10 years of experience in inspection of fishery products with strong skills in European legislation including food control.

This training module is planned to be carried out one month after the opening of the Laboratory. The total cost of this capacity building course is USD 14 900, as shown in table 1 below.

Table 1: Budget of First Capacity Building Course

	unit cost	number	total
Flight	3500	1	3500
DSA	10	250	2500
Meals for trainees	20	30	600
Consultant	12	450	5400
Study room	500	5	2500
Course material	400	1	400
Total			**14900**

Second Capacity Building Programme for Laboratory Technicians

The second section of the training is aimed at the specific training of laboratory technicians and involves a period of 6 days in which the staff will be supported by a specialized technical facilitator and possibly by a representative of the company supplying the equipment, for some tasks could be necessary the support of the international Consultant. The participants in the capacity building will be a group of 4 participants from the Kiribati Laboratory

This training program is designed to empower laboratory technicians at the New Laboratory in Tarawa to become self-sufficient in conducting analytical tests on key parameters that are critical for both the export and domestic markets of fish products. The initiative aims to ensure that all procedures and methodologies are not only rigorously adhered to but are also aligned with internationally recognized standards. Through this upskilling, the laboratory technicians will be adept at delivering results that meet the stringent quality and safety expectations required for the successful trade of seafood goods. The training program has been carefully designed to provide staff members of the Laboratory and of the CA with state-of-the-art techniques and procedures that are necessary to organize a better system chain for the sampling and analysis to promote a safe export activity. The laboratory personnel will receive thorough training that will equip them with the skills needed to monitor, identify, and

address any health concerns to fish.

Main study points and objectives for this training are:

-Equipment setup and calibration (quality assurance data)
-Repeated execution of tests and verification of results
-Periodic Official equipment calibration
-Notes on equipment maintenance
-Planning for the purchase of disposable material
-Internal organizational procedures of the laboratory
-Data compliance
-Correct reporting of the data
-Health documentary supplies necessary to support an international shipment

The fundamental points of data quality assurance

The internship is aimed at making technicians aware of the value of data, understood, among other things, as a legal value. The activities connected with the export performance are connected with analysis tests that the technicians will follow during the internship period are certified, and the values obtained are discussed with the laboratory staff with the aim of increasing sensitivity to the veracity of the final data.

The methodology employed to analyse various fish matrices

One of the most important components of the analytical process is the sample preparation method. Proper planning makes the test easier to administer and ensures that the outcome cannot be changed. At the conclusion of the practical training phase, the technicians must be able to adhere to strict weight and purity criteria for the fabrication of fisheries product samples.

Analytical protocols for chemical determinations required by sector standards

This internship module aims to clarify the legislative context in which the analysis is carried out. With particular reference to European legislation, the problems connected with carrying out the tests in legal compliance with the right number of matrices and aliquots of the sample to be analysed will be considered.

It will be important to familiarize technicians with the health analysis certification for export to the European community. All documentary supplies accompanying the fish products during transport to the destination ports and airports must be clarified.

Analytical protocols for microbiological determinations required by sector standards

During the internship period in the microbiological sector, the technicians will come into contact with problems related to the microbiological safety of fish products. With particular reference to EU Reg. 2073/05, they will be trained in the calculation and estimated count of pathogenic bacterial colonies in order to arrive at the final analysis report. In this session, matrices belonging to live bivalve mollusks and fish will be analyzed.

Carrying out the main maintenance activities on analytical instrumentation

During the training, the technicians will be supported at certain times by the unit of equipment maintenance technicians to carry out normal, ordinary, and extraordinary backups. Georgia has major problems with the new supplies of equipment without technical assistance; emphasis will be placed on improving maintenance skills. In this sense, the technicians will create a list of the major maintenance materials necessary to address the longest period of autonomy with respect to needs. In this regard, the support of this unit will be essential in the purchase plan for use and repair materials.

Interpretation of results

One of the objectives of the training is to equip participants with an analytical awareness of the interpretation of results. In particular, after having actively participated in the execution of many analysis tests, they will have developed decision-making autonomy with the possibility of repeating the tests. The truthfulness of a test is linked to multiple factors, and it is important that those carrying out such tests take into consideration any possibility of deviance. Often, the tests must be repeated several times and corrected in internal procedures as many times as possible.

Validation of a test method

As part of the training course, the main certification and accreditation methods conforming to EU standards will be considered. In particular, during the period of training, it will be described to the candidate technicians how accreditation is

obtained and what steps are necessary to obtain and maintain it.

An always-basic element to take into consideration is that accreditation and training are not definitive processes but are continually evolving. In particular, the technicians who work in the laboratory, the companies providing services and maintenance, and the certifying bodies that outline this process participate in this process.

Calibration of measurement equipment

The analysis response with the related numerical result is an element not acquired as such but follows validation.

The first validation process is linked to the periodic calibration of the instruments in use in the laboratory. In demonstrating a quality process, each laboratory must demonstrate that it calibrates the instruments supplied with precise deadlines. The company responsible for these checks will have to demonstrate that it follows rigid, reliable, and well-described measurement protocols. The technicians will follow these procedures explained by each manager present in the chemical and microbiological departments of the Recognized Laboratory.

Identify the analyses necessary for the different seafood matrices

An element that is important for the execution and exact response of the analyses is the choice of the fish product matrices. In the context of bony fish, it will be explained how to take samples from whole fish and how to take them from a bivalve mollusc. The representativeness of the sample will be indicated following the European reference regulations and, in general, through the guidelines mentioned by the Codex Alimentarius. Acknowledging this knowledge means providing a universally valid result. It is not uncommon for mistakes to be made in this regard, and having awareness and knowledge in this regard means, among other things, protecting shipments from health barriers linked to erroneous interpretations.

How the world of accredited laboratories works

All of the issues regarding the worldwide organization of recognized laboratories will be presented as part of the training curriculum. The explanation of the communication mechanisms will be focused on test reporting and how to communicate in the event of a global dispute. The ability to gradually bring the

laboratory into compliance with worldwide technological and communication standards will be required of candidates. A description of the behavior and functioning of the laboratory itself is often necessary when responding to the same product that was tested because the results are frequently unclear. These components serve as the cornerstone for the laboratory's global contextualization. Furthermore, the laboratories periodically adhere to an ongoing training and certification program run by internationally recognized certifying agencies and businesses.

How to manage requests from a customer who needs to perform an analysis

As part of the work routine of a laboratory, manage requests for analytical performance. In this regard, it will be the laboratory's responsibility during the sample acceptance phase to verify the actual processing capabilities of the laboratory itself, avoiding accepting tests that are considered incapable of proceeding.

How to read the analytical results to make a judgment on the analyzed materials

Developing a critical sense of the tests performed is another essential element for the good management of a laboratory. Too-obvious discrepancies in the results may be the result of errors in the management of the equipment. These problems will be addressed during the internship by training the participants in terms of awareness of the problem.

Topics of internships at the Recognized Laboratory

It is necessary to emphasize that staff members in charge of maintaining the analysis equipment will support the trainee technicians among other people.

The most important elements of the training period thus are

- The ISO 17025:2018 standard: Competences of Testing Laboratories: The candidates will get in touch with the standard, which specifies that laboratories must comply with certain procedures to ensure that their measurement results are reliable and comparable to avoid problems at the BIPs. WCO recognized a scheme of response to entry at the border.
- Calibration of thermometers
- Calibration of analytical and technical balances
- Checks on refrigerators, stoves, and pipettes
- Consideration about limit values for waste water and soil, notes on Regulation 1357/2014: the attribution of the hazardous characteristics of waste

- HPLC technology: maintenance activities and setting of instrumental parameters
- Regulation 1881/2006: Spectrophotometric Tests for the Detection of Heavy Metals
- Microbiological analysis/ Diagnosis of infectious diseases: During the time spent in the microbiological sector, the candidates will follow activities related to the research of the major causes of disease in fish (bacteria, viruses, parasites, etc.). In particular, they will have the opportunity to follow the sowing, growth, and reading phases of the plates and bacterial culture media.
- Calculation of contributions to measurement uncertainty
- Validation of a chemical method
- Validation of a microbiological method
- Verification of the performance of an analytical method
- Instrumental controls and process controls: control charts and trend lines
- Hints from chemical nutritional analyses
- Analysis of Histamine by HPLC and Antibiotic Residues
- Analytical methods for determining the main parameters of water intended for human consumption
- The test report: what it must contain and how it must be structured
- Internal organization of a testing laboratory: from acceptance of the sample to sending the test report
- Constant support in the field with laboratory technicians from the selected EU Recognized Labs.

Table 2: Budget of Second Capacity Building Course (in USD)

	unit cost	number	total
Flight	1500	1	1500
DSA	8	250	2000
Meals for trainees	20	30	600
Consultant	12	300	3600
Study room	500	5	2500
Course material	500	1	500
Total			**10700**

Third Capacity Building on toxic Dinoflagellate

Kiribati is well known for its vast ocean and highly dispersed islands. Similar to other small Pacific Island countries, the country relies heavily on seafood as the main source of protein and the main source of livelihood. While deep sea tuna rakes in the main revenue for the country, the local population most of whom live in the outer islands consume more reef fish which is the main type of fish associated with Ciguatera Fish Poisoning (CFP). More in-depth information and training is needed in this area to be able to assist the general public make informed choices.

The proposed programme aims at national capacities strengthening to identify and address the risk of ciguatera poisoning. The programme is intended for Government staff.

The capacity building programme has the following themes:

- General Introduction to Harmful algal blooms, its characteristics, causes, impacts, associated costs involved, solutions and discussion of key studies around the Pacific
- Organize and conduct an online and or face to face capacity building training for participants from Ministry of Fisheries, Ministry of Health and stakeholders on:
  (i) Surveillance and detection of microalgae *Gambierdiscus* in the marine environment; and
  (ii) Epidemiological diagnosis and recording of CP cases.

- Organize and conduct in-country trainings on ciguatera environmental surveillance and epidemiological monitoring and reporting.

Training to be customised to also include:

- sampling methods for the microalgae in the field,
- identification of benthic microalgal species under the microscope in the laboratory,
- sharing of epidemiological information, and
- using the online incidence case form, database, and species mapping.

Practical training to include:

- Window Screen Deployment,
- sample collection and collection of other
- sample filteration onsite
- Sample preservations and storage
- Sample microscopic
- Analysis and morphology discussions
- Final identification of gambierdiscuss and other toxic dinoflagellates

The span of the training is over 6 months, with training sessions of three afternoons per theme. The capacity building is intended for all Government Staff involved in field work with fishing communities. About 30 persons will be trained, in sessions of 10 trainees per session.

In addition to the budget for the capacity building ciguatera toolkits are needed as specified in table 4.

Table 3: Budget of Second Capacity Building Course (in USD)

	unit cost	number	total
Flight	3500	2	7000
DSA	280	20	5600
accommodation	80	20	1600
Tutor	350	40	14000
Training logistics	1000	3	3000
Total			**31,200**

Table 4: Budget for Ciguatera Toolkit

Type of lab equipment/item needed	Estimated Total cost /Item type(USD)
1.Snorkelling	**3000**
2.Storage	**2000**
3.Lab Equipment	**5400**
4.Microobservation	**6000**
5.Fixatives	**7000**
6.Geolocation	**5000**
7.Miscellineous (i) 2 Compound Microscope (i) 2 Dissecting Microscope (ii) Optix Camera for microscope camera iv)Grid Slides x 150 pcs v)Droper x 20 pieces vi)electronic scale (can read milligram or microgram) vii) Inspiron 24 5000 Touch All-In-One (Dell all in one)	**8000**
TOTAL	**28400**

Pillar 2: in foreign country training

Italy

The proposed programme is designed for a total training of n. 3 laboratory technicians and specifically n.2 technicians and n.1 technician technical coordinator. The purpose of this training period is to make Kiribati technicians autonomous in carrying out analysis tests for the main parameters necessary for the export and internal market of fish products. This programme supports the creation of a reference laboratory currently being created in the capital South Tarawa. The proposed internship programme is based on a period of 40 days in which candidates will be able to attend the most important sections of the Istituto Zooprofilattico Sperimentale Lazio e Toscana(IZS) of Rome-Italy. During the training period, the three candidates will be supported by a tutor who will follow the activities, always trying to evaluate learning level. The training period for a total of six weeks will be divided as follows: 2 weeks in the microbiology laboratory and subsequently 4 weeks in the chemical laboratory.

The Istituto Zooprofilattico Sperimentale del Lazio e Toscana (IZSLT) is a public health control institution with a technical, administrative and managerial autonomy. It operates as a technical and scientific instrument within the National Public Health Service for the Latium and Tuscany Regions (Central Italy) as well as for the Italian State. The headquarters is located in Rome (RM), in conjunction with the local departments in Arezzo (AR), Florence (FI), Grosseto (GR), Pisa (PI), Siena (SI) in the Tuscany Region; Latina (LT), Frosinione (FR) Viterbo (VT) and Rieti (RI) in the Latium Region.

IZSLT mission is:

- control and improve animal health
- protection animal welfare
- control the animal breeding to guarantee the animal productions quality
- control the food of animal origin and feedstuffs safety in order to protect the consumers' health

This mission is carried out through the following activities:

- animal diseases and zoonoses diagnostic services;
- laboratory test to determine the clinical and welfare status of animals;
- food and feedstuffs control by means microbiological, chemical physical and organolectic examinations;
- technical and scientific support to the action on veterinary drug-monitoring;
- experimental research in the field of animal health and welfare, food safety and hygiene of farming and livestock products;
- studies on animal welfare and development and application of alternatives to the use of animal experimental models;
- studies, experiments and production technologies and techniques needed to monitor the safety of food of animal origin and animal feed;
- scientific and technological cooperation at national and international levels;
- epidemiological surveillance on animal health and food safety, on health of livestock and livestock products, including the environmental factors;
- risks analysis linked to the animals and animal products;
- the production of culture media, autovaccines;
- support, technical assistance, training and hygiene information to breeders and manufacturers of food of animal origin;

- training of veterinarians and other operators of the National Health Service and of other countries.

Food safety is guaranteed through an accurate production chain control to check the compliance with the food health and hygiene standards.
Food safety is regulated by National law and UE rules covering the whole production chain, from food production to processing, marketing and consumption.
The Regulation (EC) n. 178/2002 is identified as a reference standard outlining the principles and requirements of food legislation, thus establishing the European Food Safety Agency – EFSA and prescribing food safety procedures.

Food safety represents one of the main competencies of the Istituti Zooproflattici Sperimentali and is pursued through the following activities:

- food and animal feeding stuffs laboratory examinations to detect microbial, viral and mycotic agents; parasites and biotoxins; chemical contaminants; additives, GMOs; allergens; radio-nuclides;
- technical and scientific support to the implementation of surveillance and monitoring plans, emergencies as well as to food alerts;
- experimental research in the field of food safety and livestock production hygiene;
- research, investigation and implementation of methods and technologies focused on the safety of animal origin food and animal feeding stuffs;
- epidemiological surveillance on food safety and hygiene livestock productions and farms;
- food health risk assessment;
- training and documentation targeted to veterinarians, health staff and food producers:
- development and accreting laboratory tests;
- technical-scientific cooperation and collaboration with UE Members and Third Countries as national and international Research Boards

<u>The policy of quality and accrediting</u>

The Istituto Zooprofilattico Sperimentale Lazio e Toscana has implemented the customer-oriented Quality Policy in compliance with the ISO 9000 and UNI CEI ISO/IEC 17025 standards.
This is to grant qualified laboratory results and services, officially acknowledged by EU and by third countries.

IZSLT is a multisites laboratory accredited in 1998 (SINAL n. 201 accreditation) according to the UNI CEI EN 45001 directive, and now by Accredia (the Italian accreditation body) according to the UNI CEI ISO/IEC 17025 standard, “General requirements for the competence of testing and calibration laboratories”.

The documents of the Quality System

The system is regulated by the following documents:

- *Quality Manual*: it describes the organization, tasks and activities of the Institute;
- *Organizational document*: it describes the organization, tasks and activities of each institution unit;
- *Management procedures*: they describe the operating methods and responsibilities related to the management activities of the institute;
- *Standard Operating Procedures*: they describe the operating methods and responsibilities of laboratory tests and support activities.

The quality system of training activities

The training activities have been certified since 2004 by Kiwa Cermet according to the ISO 9001 standard.

Objectives of internships and courses for Recognized Laboratory technicians

1. The fundamental points of data quality assurance

The internship is aimed at making technicians aware of the value of data understood among other things as a legal value. The analysis tests that the technicians will follow during the internship period are certified and the values obtained are discussed with the laboratory staff with the aim of achieving increasing sensitivity to the veracity of the final data.

2. How analyses are carried out on different food matrices

The sample preparation technique is one of the essential elements of the analysis activity. Correct preparation prepares the test for easier execution and allows the final result not to be altered. Specifically, for the preparation of

samples of fishery products, there must be precise weight and purity standards that the technicians must be able to respect at the end of the practical training period.

3. Analytical protocols for chemical determinations required by sector standards

This internship module aims to clarify the legislative context with which the analysis is carried out. With particular reference to European legislation, the problems connected with carrying out the tests in legal compliance with the right number of matrices and aliquots of the sample to be analysed will be considered. It will be important to familiarize technicians with the health analysis certification for export to the European community. All documentary supplies accompanying the fish products during transport to the destination ports and airports must be clarified.

4. Analytical protocols for microbiological determinations required by sector standards

During the internship period at the microbiological sector of the Zooprofilattico Institute of Rome, the technicians will come into contact with the problems related to the microbiological safety of fish products. With particular reference to EU Reg.2073/05, they will be trained in the calculation and estimated count of pathogenic bacterial colonies in order to arrive at the final analysis report. In this session, matrices belonging to live bivalve fish and molluscs will be analyzed.

5. Carrying out the main maintenance activities on analytical instrumentation

During the training the technicians will be supported at certain times by the Unit of the equipment maintenance technicians to carry out normal, ordinary and extraordinary backups.
Kiribati has major problems with the supply of materials given its geographical location and during the training period, emphasis will be placed on improving maintenance skills. In this sense, the technicians will create a list of the major maintenance materials necessary to address the longest period of autonomy with respect to needs. In this regard, the support of this Unit will be essential in the purchase plan for use and repair materials.

6. Interpretation of results

One of the objectives of the training is to equip participants with an analytical awareness on the interpretation of results. In particular, after having actively participated in the execution of many analysis tests, they will have developed decision-making autonomy in the possibility of repeating the tests. The truthfulness of a test is linked to multiple factors and it is important that those carrying out such tests take into consideration any possibility of deviance. Often the tests must be repeated several times and corrected in internal procedures as many times.

7. Validation of a test method

As part of the training course, the main certification and accreditation methods that the IZS laboratory uses will be considered. In particular, during the period of training in Italy, it will be described to the candidate technicians how accreditation is obtained and what steps are necessary to obtain and maintain it.
An always basic element to take into consideration is that accreditation and training are not definitive processes but continually evolving. In particular, the technicians who work in the laboratory, the companies providing services and maintenance, and the certifying bodies that outline this process participate in this process

8. Calibration of measurement equipment

The analysis response with the related numerical result is an element not acquired as such but follows validation.
The first validation process is linked to the periodic calibration of the instruments in use in the laboratory. In demonstrating a quality process, each laboratory must demonstrate that it calibrates the instruments supplied with precise deadlines. The company responsible for these checks will have to demonstrate that it follows rigid, reliable and well-described measurement protocols. The technicians will follow these procedures explained by each manager present in the chemical and microbiological department of the IZS

Institute.

9. Identify the analyzes necessary for the different seafood matrices

An element that is important for the execution and exact response of the analyses is the choice of the fish product matrices. In the context of bony fish, it will be explained how to take samples from whole fish and how to take them from a bivalve mollusc. The representativeness of the sample will be indicated following the European reference regulations and in general through the guidelines mentioned by the Codex Alimentarius. Acknowledging this knowledge means providing a universally valid result. It is not uncommon for mistakes to be made in this regard and having awareness and knowledge in this regard, means among other things, protecting shipments from health barriers linked to erroneous interpretations.

10. How the world of accredited laboratories works

As part of the training programme, all the arguments relating to the international organization of accredited laboratories will be covered. The communication mechanisms will be explained with specific reference to the reporting of tests and their communication in the event of an international dispute. Candidates will have to learn how to make the laboratory increasingly compliant with international technical and communication standards. Particular importance will be given to this part of the training given the geographical location of Kiribati. It is important to remember that the tests conducted on the frozen product departing from Kiribati will often be repeated at destination. Often the response for the same product tested is not unambiguous and requires an explanation on the conduct and operation of the laboratory itself. These elements are the basis of the international contextualization of the laboratory. In addition to this, there is a continuous training and certification programme that the laboratories follow periodically using internationally accredited certifying bodies and companies.

11. How to manage requests from a customer who needs to perform an analysis

As part of the work routine of a laboratory, manage requests for analytical

performance. In this regard, it will be the laboratory's responsibility during the sample acceptance phase to verify the actual processing capabilities of the laboratory itself, avoiding accepting tests which are considered incapable of proceeding.

12. How to read the analytical results to make a judgment on the analyzed materials

Developing a critical sense of the tests performed is another essential element for the good management of a laboratory.
Too obvious discrepancies in the results may be the result of errors in the management of the equipment. These problems will be addressed during the internship by training the participants in terms of awareness of the problem.

Topics of internships at the Recognized Laboratory

It is necessary to reiterate that the trainee technicians will be supported, among others, by personnel responsible for maintaining the analysis equipment.
The most important elements of the training period are analyzed and summarized below:

1. The ISO 17025:2018 standard: Competences of Testing Laboratories.
   The candidates will get in touch with standard specifies that laboratories must comply with certain procedures to ensure that their measurement results are reliable and comparable to avoid problems at the BIPs. WCO recognized to a scheme of response to entry at the border.

2. Calibration of thermometers

3. Calibration of analytical and technical balances

4. Checks on refrigerators, stoves, pipettes

5. Consideration about limit values for waste water and soil, notes on the Regulation 1357/2014: the attribution of the hazardous characteristics of waste

6. HPLC technology: maintenance activities and setting of instrumental parameters

7. Regulation 1881/2006 and Regulation 1169/2011- Spectrophotometric test for the detection of Heavy metals

8. Microbiological analysis/ Ciguatera Tests

   During the two weeks spent in the microbiological sector, the candidates will follow activities related to the research of enteropathogenic bacteria and viruses. In particular they will have the opportunity to follow the sowing, growth and reading phases of the plates and bacterial culture media. The most common rapid tests for ciguatotoxic biotoxins will also be used.

9. Calculation of contributions to measurement uncertainty

10. Validation of a chemical method

11. Validation of a microbiological method

13. Verification of the performance of an analytical method

14. Instrumental controls and process controls: control charts and trend lines
15. Hints of Chemical nutritional analyses

16. Analysis of Histamine by HPLC

17. Analytical methods for determining the main parameters of water intended for human consumption

18. The Test Report: what it must contain and how it must be structured

19. Internal organization of a testing laboratory: from acceptance of the sample to sending the test report

20. Constant Support in the field with laboratory technicians of IZS in Rome

Main tests of interest for Chemical Section Trainings

HPLC for Histamine research

Below are the characteristics described for the analysis tests that will be carried out during the training. A high-performance liquid chromatography method is described for quantitative determination and validation of histamine in fish and fishery product samples. Histamine is extracted from fish/fishery products by homogenizing with tri-chloro acetic acid, separated with Amberlite CG-50 resin and C18-ODS Hypersil reversed phase column at ambient temperature (25°C). Linear standard curves with high correlation coefficients were obtained. An isocratic elution programme was used; the total elution time was 10 min. The method was validated by assessing the following aspects; specificity, repeatability, reproducibility, linearity, recovery, limits of detection, limit of quantification and uncertainty. The validated parameters are in good agreement with method and it is a useful tool for determining histamine in fish and fishery products. Generally the diagnosis is made on the skin flushing, rash, gastrointestinal complaints and throbbing headache, etc. There for analysis of histamine content in the fish is very much important and High Performance Liquid Chromatography method (HPLC) is more sensitive and accurate method used to quantify the histamine content under the EU regulations. The minimum detection limit is 1 mg/kg and it has to range in-between 1 and 200 mg/kg. Validation of this method should be very essential for enhancing the method sensitivity, linearity, accuracy, precision, recovery, repeatability and reproducibility. The European Union has established that the average content of histamine in fish should not exceed 100 mg/kg and no sample may contain more than 200 mg/kg and fishery products should not exceed 200 mg/kg and no sample may contain more than 400 mg/kg out of nine samples. Mishandling coupled with high temperature abuse are common practices in handling fish in the tropic and subtropics, which significantly enhance histamine formation.

Apparatus

The HPLC model Shimadzu, SIL 20A (Kyoto, Japan) equipped with LC solution software, quaternary pump and online degasser model LC20AD and injection valve with a loop capacity of 20 µL was used. The detector used was a programmemable fluorescence detector model RF10AXL with a 350-nm excitation, 450-nm emission. The histamine compound was determined on

reverse-phase ODS Hypersil (150 × 4.6 mm), C18 column.

Sample preparation and extraction

Cut whole sample into small pieces and mashed mechanically. Mixed mass well and weighed a 10-g sample into 100-mL beaker and added 20 mL of 10% tri-chloro acetic acid (TCA) and 20 mL of distilled water. Homogenized sample in 2 min using homogenizer (Heidolph-Q1) and transferred the sample into 100-mL volumetric flask, made up using distilled water and stood 10 min. Then, the sample was filtered through Whatman No. 1 filter paper and pipetted out 10 mL of filtrate to 50-mL beaker and adjusted the pH to 4.6 (Hanna, pH 211, USA) and passed through the column filled by Amberlite CG-50 resin. The 8 mL of eluted samples were taken into 25-mL beaker and adjusted the pH to 7 and made up to 10 mL with distilled water.

Derivatization of sample extracts and standard

Pipetted out 5.0 mL of the column chromatography elute into a 10.0-mL volumetric flask and added 1.00 mL of 1.0 M NaOH and mixed. Then added 0.50 mL of 0.1% OPT and mixed. After that, added 1.50 mL of 1 M H_2SO_4 just after 4 min and mixed. Made up to the mark with distilled water and mixed thoroughly.

Chromatographic separation

Set up the HPLC system and follow at least 30 min to stabilize. The HPLC conditions were maintained as follows; column; ODS Hypersil (150 × 4.6 mm), mobile phase; NaCl:Methanol (20:80), adjust to pH 3.1, flow rate; 0.5 mL/min, detection; excitation 350 nm, emission 450 nm.

Calculation

Histamine content (mg/kg) is calculated using the area under the peaks of standard histamine solution chromatograms.
= [Measured concentration of histamine in extract (mg/L)/Sample weigh (g)] × 100

Method validation

Standard quality control materials (canned fish) T-2742 from FAPAS (Food

Analysis Performance Assessment Scheme, the Food and Environment Agency, Sand Hutton, York, UK) were used for quality control in the study. The method validation procedures were followed according to IUPAC technical report, harmonized guidelines for single laboratory validation of methods of analysis and EURACHEM/CITAC guide CG 4, quantifying uncertainty in analytical measurement. In the method validation following parameters were calculated, i.e. specificity, selectivity, precision, accuracy, linearity and range, LOD, LOQ, robustness/ruggedness and uncertainty. The precision of the method was assayed by 6 replicate extraction of pure analytical standard, which contained histamine in low, medium and high concentrations within the shortest possible time period in the same instrument.

Accuracy and reproducibility values in sample

The LOD was established with six independent sample blanks fortified at a lowest acceptable concentration of histamine (1.00 mg/kg) and measured once each. LOD was calculated using analyte concentration corresponding to a mean blank value +3s. According to that, the LOD was 0.2 mg/kg histamine and LOQ was calculated as LOD × 5 and it was 1 mg/kg of histamine. The dilution factor was 10, hence the working range of this method is calculated as 1.0–250.0 mg/kg, with 0.99 or more correlation coefficient.

Identify variable/interferences which could have a significant effect on method performance. Set up experiments (using reference materials or histamine standards) in order to monitor the effect of each changed condition on the mean value (percentage of validation). Rank the variables in order of significant effect on method performance. Maintain quality control data in order to control the effect of critical variables. Interfering compounds in the analysis of histamine are cadeverine and putrescine (having a similar chemical structure of histamine) and the effect of those studied. The mixture of histamine, cadeverine and putrescine was analysed by HPLC. Separate three peaks were observed for histamine, cadeverine and putrescine. That means, this method is effective to separate histamine from other similar amine compounds.

The pH of mobile phase and the ambient temperature were identified as critical variables. According to the method, the pH of the mobile phase and ambient temperature are 3.1 and 25°C, respectively. Six histamine standards (100.0 mg/kg) were analysed under normal and change conditions (pH of mobile phase 3.4 and ambient temperature 30°C). The percentage of variation in between replicates was calculated and variation of mobile phase pH and ambient temperature were 2.7 and 4.1%, respectively.

The efficiency of OPT derivatives extraction calculated from the unfortified and fortified fish samples, yellowfin tuna (fortified 50.0 mg/kg, histamine standard solution) at different time periods were found and the results are given in Table 3. Average recoveries for fortified samples were 86.3% and that is between the AOAC recommended ranges (75–120%). The main component of uncertainty calculation was associated with the recovery (3.97%) and the uncertainty associated with precision was 0.022%. The expanded uncertainty value of this method was calculated as 11.0% ($k = 2$).After validation the method, the analytical chemistry laboratory, national aquatic resources research and development agency (NARA),This method and that results also confirmed that the method is suitable for the determination histamine in fish and fishery products (*z*-score −1.4 was obtained at an assigned value of 212 mg/kg, *z*-score 0.0 was obtained at an assigned value of 26.8 mg/kg in the Food Analysis Performance Assessment Scheme. Considering the results of method validation criteria such as specificity, selectivity, precision, accuracy, linearity and range, LOD, LOQ and uncertainty, this method is suitable for the determination of histamine in fish and fishery product samples. The method was also validated and results comply with ISO 17025 laboratory accreditation criteria. Below an example of a selected HPLC liquid made in China with German components of production made. The chromatograph proposed and considered below is an example of space-saving instrumentation with sufficient operating characteristics for the future Kiribati laboratory.

LC3600 Series UHPLC

Innovative Ultra High Performance Liquid Chromatograph

- Ultra-high pressure linear motor pump with 150MPa pressure resistance
- Needle-in-loop sampler for lossless injection and minimal cross-contamination
- Liquid-core waveguide flow cell technology for lossless optical energy transmission and ultra-high detection rate
- Fast detection speed, high sensitivity and high separation.
- Flexible configuration of Wayeal's DAD, FLD, ELSD, RID and other detectors to meet the needs of different customers
- PCT international patent

P3600 Binary Pump

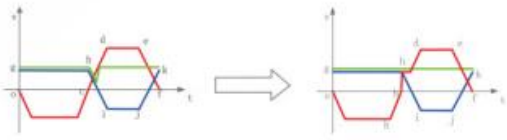
- Ultra-high-pressure linear motor pump with a maximum pressure of 150 MPa and a flow rate range of 0-2 mL/min, covering the use of sub-micrometer columns.
- Dynamic Compression Compensation Technology: Highly accurate real-time pressure-following technology for "zero fluctuation" and extremely high flow stability.
- Equipped with four-way solvent switching device, electric venting valve, six-way in-line degassing, and liquid leak detection, it is free from manual operation.

Technical Parameters

Pump	Linear Motor Pump	Flow Rate Stability	≤0.09% RSD
Gradient Mode	Quasi-quadruplex pumps (2 pumps)	Gradient Stability	< 0.2% RSD
Flow Rate Range	0.0001-2.0000mL/min	Check Valve	Active Check Valve
Maximum Pressure	150MPa	Degassing	6-way Inline Degasser
Flow Rate Error	±1.1%	Flow Rate Increment	0.001mL/min

High Pressure Pump

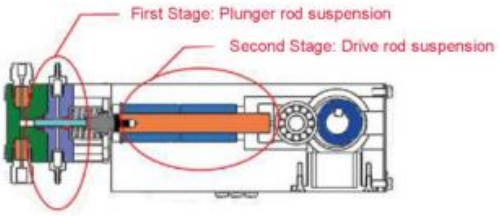
- Customized high-precision gradient valves ensure extremely high gradient repeatability.
- Two-stage suspension technology high-pressure constant-flow pump, which improves system service life, reduces the wear and tear of seals, and reduces cost of use for customers.
- Built-in degasser to meet both high-pressure pump and sampler cleaning fluid degassing.



New cam curve and electronic pulsation suppression

- **Two-stage suspension Drive Technology**
  (Patent No.:201210266733.0).

Compared with the traditional hard connection method, the high-pressure pump adopts drive suspension technology, combined with the suspension plunger rod design of the imported pump head, significantly extending the service life of the seal and reducing the user's cost of use.



- **Methane-resistant Check Valve:**

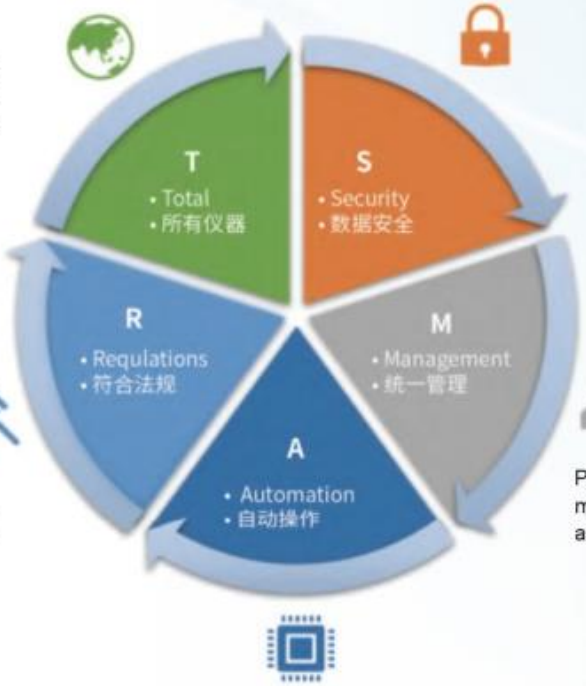
The new check valve greatly reduces the probability of possible check valve failure when using pure methane-based systems.

wayeal 皖仪
Spark

Management of all instruments and third party equipment through one software package

A variety of data backup and storage solutions to ensure data integrity.

A detailed audit trail system ensures optimal data integrity and traceability



Provides unified permission management with data storage and access.

The software provides intelligent operation to automate the whole process of running samples, processing data and printing reports, so that the process can be carried out without human involvement.

Columns

Wayeal self-developed C18 general-purpose coolumn uses uniform size silica microspheres combined with advanced and stable bonding phase modification technology, which can separate different hydrophobic analytes and is widely used and cost-effective.

UV Detector

- Imported light source: German imported deuterium lamp and tungsten lamp;
- Flow cell: The new flow cell, polished optical path and extremely low post-column dead volume design improve system column efficiency;
- Dual wavelength detection: 2 wavelengths can be detected simultaneously;
- Wavelength scan: absorption spectrum can be scanned in the full range of light sources;
- Leakage detection: used for misoperation, overpressure and other situations resulting in the leakage of liquid alarm;
- Dual lamp position design: to meet the 188-900nm wavelength range of spectral options;
- Spectral calibration can be performed automatically, and the spectral calibration algorithm is designed according to the grating spectroscopy theory model and the characteristic spectral line of deuterium lamp. Simple structure and accurate results.

Technical Parameters

Baseline Noise	≤2.0×10^{-6}Au	Wavelength Error	≤±0.1 nm
Baseline Drift	≤1×10^{-5}Au/h	Wavelength Repeatability	≤ ± 0.1 nm
Spectral Range	188 ~ 740nm (900,tungsten lamp)	Linearity Range	≥ 10^{3} (general parameters)
Minimum Detection Concentration		≤3.0×10^{-9}g/mL (naphthalene / methanol)	

DAD Detector

Diode array detector, a highly efficient and powerful general-purpose detector for high performance liquid chromatography systems. Its imported core components and integrated optical structure design provides stable and reliable performance. And it enables simultaneous detection of all wavelengths in the range of 190nm-80nm, with 1024 times more information than the UV detector. Based on the chromatographic functions, it provides a variety of unique functions such as spectrogram and matching calculation, maximum value graph, 3D view, contour line graph, peak purity calculation and spectral library management.

Technical Parameters

Baseline Noise	≤4×10^{-5} Au	Spectral Range	190-800 nm
Baseline Drift	≤3×10^{-5} Au/h	Wavelength Error	≤ ± 0.1 nm
Min Detection Concentration	≤2×10^{-8} g/mL	Wavelength Repeatability	≤ ± 0.1 nm
Linearity Range	≥ 10^{4}	Leak Detection	Standard Leak Detection Module

Basic Configuration

LC3200 Series System Configuration	
System	**Options**
Pump	Isometric Pump
	Binary Pump System
	Quaternary Pump System
Autosampler	Manual Injection
	Autosampler
	Autosampler(Cooling)
Column Oven	Heated Column Oven
	Heated Column Oven (Air Circulation)
	Heated and Cooled Column Oven(Air Circulation)
Detector	UV Detector
	DAD Detector
	FLD Detector
	ELSD Detector
Smartlab Workstation	Chromatography Workstation
Optionals	Accessory kit
	Solvent switching device
	Four-channel in-line degassing unit
	Dual-channel in-line degassing unit
	Chromatography column
	Amine column
	Photochemical derivatizer
	Columns for polycyclic aromatic hydrocarbons
	Double pump post-column derivatizer
	Computer
	Printer

Heavy Metal research

Atomic absorption Spectrometry(AAS) is a fairly universal analytical method for determination of metallic elements when present as a trace or in higher concentrations. AAS is a spectro-analytical procedure for the qualitative and quantitative determination of chemical elements employing the absorption of optical radiation (light) by free atoms in the gaseous state. In analytical chemistry the technique is used for determining the concentration of a particular element (the analyte) in a sample to be analyzed. AAS can be used to determine over 70 different elements. In Atomic Absorption Spectrometry, the sample solution is first vaporized and atomized in a flame.

Then it transforms it to unexcited ground state atoms, which absorb light at specific wavelengths. A light beam from a lamp whose cathode is made of the element in question is passed through the flame. Radiation is absorbed, transforming the ground state atoms to an excited state. The amount of radiation absorbed depends on the amount of the sample element present. Absorption at a selected wave length is measured by the change in light intensity striking the detector and is directly related to the amount of the element in the sample. Flame atomic absorption methods are referred to as direct aspiration determinations. They are normally completed as single element analyses and are relatively free of inter element spectral interferences.
For some elements, the temperature or type of flame used is critical. Graphite furnace atomic absorption spectrometry replaces the flame with an electrically heated graphite furnace. The major advantage of this technique is that the detection limit can be extremely low. Cold vapor technique has been especially useful for the determination of mercury level in fish. The hydride generation method is especially suitable for arsenic, antimony and selenium determinations. In this method water (H2O) is used as an acid. Stannous chloride (SnCl2) is used as a reductant and it helps to release the Hg into the sample cell. The main purpose of the preparation of an SOP for method validation is to have a document that the laboratory staff of the quality control laboratory-chemistry can apply for validation of the analytical procedure used for trace metal analysis a step towards acquiring ISO/IEC-17025 accreditation. The SOP presents a summarization of the characteristics that should be considered during the validation of the analytical procedures and it is based on the following documents. f the validation of analytical procedures is directed to the one of the most common types of analytical procedures: quantitative tests for contaminants content. At chemical laboratory, three types of methods are used

for trace metal analysis: one of them is a standardized method (i.e. AOAC method); another one is based on modification of an established method; and the third one is an analytical procedure that is used by several laboratories in EU.
The methods used for trace heavy metals analysis and are categorized under the third type of analytical procedure. The extent of the method validation and character depends on which category the analytical procedure in question falls under.
The factor affecting the test results and their uncertainty can be grouped into three main categories:

- Instrument and technical factors (sampling, homogeneity, test method, equipment);
- Human factors;
- Environmental factors

Instrument and technical factors are related to various causes. In order to minimize their effects the following measures should be taken; maintain equipment under SOP, Maintain daily and annual calibration procedures.
Human factors are related to the competence and training of laboratory staff. This issue can be dealt with in a numbers of ways; Provide internal and external training opportunities. Assess staff competence internally every year (e.g. using internal control samples). Participate in external proficiency testing schemes.
Environmental factors include humidity, temperature, water quality, maintenance of the cold chain, etc. Close control of environmental factors is essential in guaranteeing a valid test result.

Estimated Costs for Training

The proposed training sessions will be carried out for a period of six weeks with the help of a tutor who will constantly follow the three candidates.

The tutor is a young graduate in food technology sciences with excellent knowledge of the English language. The training period will be divided into five days per week of attendance in the IZS laboratories. The use of the IZS space will be provided free of charge by the laboratory, as a form of technical assistance to a developing country.

Below the table for the provisional costs. In this cost estimate it is considered a Hotel working under an agreement with IZS. In addition the trainees can use the IZS canteen for the lunch.

As shown in the below table the total cost is estimated at USD 28 500.

	unit cost	number	total
Flight	3500	3	10500
Pocket money	70	120	8400
accommodation	50	120	6000
Tutor	120	30	3600
Total			**28500**

Fiji

For exporting purposes to the European Union (EU), the IAS Laboratory Services offers accredited tests for fish & fish products such as Histamine in Fish, Lead, Cadmium & Mercury in Fish, coagulase positive Staphylococci in fish and other microbiological tests.

The IAS also offers courses for laboratory staff from neighbouring countries. The course includes safety skills and introduction to the 3 areas of training, chemical, biological and physical parameters where applicable and in line with the Laboratory Manual designed for Kiribati.

The tentatively course content includes

- Lab Safety
- Equipment handling, use, storage
- Cell Structure
- Data Analysis
- DNA
- RNA
- Documentation and Reporting
- Proper collection, storage, transportation, receiving and discarding of samples
- Result Analysis
- Quality Management Systems
- Lab Certification and standards

The total duration of the course is 6 months, intended for 3 staff from the laboratories.

Table 5: Budget of Fiji Capacity Building Course (in USD)

	unit cost	number	total
Flight	2100	3	6,300
DSA	120	180 days x 3 staff	64,800
accommodation	80	180 days x 3 staff	43,200
Tutor	350	144	50,400
TOTAL COST			**164,700**