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Review paper

Official control of food safety and quality, requirements for national reference laboratory

Toni Mickov[1*], Biljana Bauer[2]

[1]P.H.I Institute of Public Health of the Republic of North Macedonia, 50th Division 6, 1000 Skopje, Republic of North Macedonia
[2]Faculty of Pharmacy, Ss. Cyril and Methodius University in Skopje, Majka Tereza 47, 1000 Skopje, Republic of North Macedonia

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Abstract

Delivering safe food is a shared responsibility of many stakeholders. Each participant in the food chain has their share in providing safe food. Developing a management system can better ensure that food is safe and of good quality. The Food Safety Law establishes an integrated system of official controls for food safety, monitoring, and other activities which covers all stages of production, processing, and distribution. Wherever food is produced, processed or put into circulation the competent authorities carry out regular controls and upon a plan or suspicion take samples for examination in official laboratories. An important part of the food control system is laboratory analysis. Food analysis is performed by manufacturers, suppliers, research laboratories, and official laboratories. With laboratory testing of food, all stakeholders receive information about various parameters that affect food safety and quality, such as composition, structure, physicochemical properties, and sensory characteristics. One of the most important reasons for food analysis is to make sure that it is safe and nutritious and meets the desired quality standards. Microbiological and chemical contamination is hard to detect without testing. Laboratories involved in the analysis of official samples should operate and should be accredited following the ISO/IEC 17025 standard. The purpose of this paper is to review the basic principles of food control systems, with special reference to the requirements for reference laboratories. This descriptive study describes the features of formal food control with a focus on the performance of a quality management system in a national reference food control laboratory.

Keywords: food safety, food quality, quality management system, reference laboratory, accreditation

Introduction

Access to safe and healthy (nutrient-rich) food is a basic human right. Food safety, nutritional value, and food reliability are closely linked. The globalization of food trade, the growing world population, climate change, and rapidly changing food treatment systems impact food security. Food borne illness is an important cause of morbidity and mortality and a significant factor in socio-economic development worldwide. Despite the remarkable development in the field of food safety in recent decades, the global burden of food borne illness is still unacceptably high. The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) estimate that each year about 600 million, almost 1 in 10, people worldwide become ill after eating contaminated food and 420 000 of them die (WFS, 2021) Safe food is crucial not only for better health, but also for the livelihood, economic development, trade, and international reputation of each country. Because contamination can occur at any stage in food

* tonimickov@gmail.com

management, the "Farm to Table“ approach, ensuring food safety is the shared responsibility of everyone who produces, processes, transports, stores, sells, and consumes food.

National governments and food safety authorities play a key role in ensuring that we can all eat safe and nutritious food. Even today, without safe food, human development cannot happen. Safe food is key to promoting health and ending hunger, two of the primary goals of the 2030 UN Agenda (UN, 2015). Safe food saves lives. According to the WHO, a healthy diet protects against malnutrition in all its forms, as well as non-communicable diseases such as diabetes, heart disease, stroke, and cancer. Unsafe food creates a cycle of disease and malnutrition, especially affecting infants, young children, and the elderly. The dangers of consuming unhealthy foods that cause over 200 acute and chronic diseases are well known. A poor quality diet is also a leading risk factor for obesity-related deaths. A healthy diet provides not only adequate calories but also adequate levels of all the necessary nutrients for a healthy and active life. Also, a healthy diet ensures that a person's need for macronutrients (proteins, fats, and carbohydrates, including dietary fibre) and essential micronutrients (vitamins and minerals) specific to their gender, age, physical activity level, and physiological condition, are met. The UN General Assembly decides to declare 2021 the International Year of Fruits and Vegetables as a unique opportunity to raise awareness of the important role of fruits and vegetables in human nutrition, food security and health.

Today, protection of consumer health ranges from controlling the content of additives, heavy metals, and pesticide residues in food, preventing chemical and microbiological contamination, or assessing the safety of new, sometimes controversial, practices such as genetically modified food or promoting growth and better yields using antimicrobial drugs. Although historically, times are changing, the goal of protecting the health of end consumers remains the same. Whether we produce, process, sell or prepare food, we all have a part to play in keeping it safe.

Basic principles and elements of a national food control system

Every year, unsafe food conduces national economies in lost productivity and medical costs. Preventive measures, including greater investment, better regulatory frameworks, and measures that promote behaviour change, can help countries avoid food safety problems. An inclusive approach to food safety management will be the most effective if food safety is understood as a shared responsibility between the government, primary producers, food businesses, and consumers. An effective national food control system is essential to ensure food safety and adequacy for consumers. A national food control system should be based on the following principles (Codex Alimentarius, 2013. CAC/GL 82-201, Section 3):

Consumer protection. National food control systems should be designed, implemented, and maintained with the primary objective of protecting consumers.

Access to the entire food chain. The national food control system should cover the entire food chain from primary production to consumers.

Transparency. All aspects of the national food control system should be transparent and open to surveillance while respecting the legal requirements for the protection of confidential information.

Roles and responsibilities. All participants in the national food control system should have clearly defined specific roles and responsibilities. Food business operators have a primary role and responsibility to manage food safety and to comply with requirements regarding those aspects of food under their control. National governments have a role and responsibility to establish and maintain up-to-date legal requirements. The competent state body (agency) has the responsibility to ensure the efficient operation of the national food control system. Consumers also have a role to play in managing food safety risks under their control. Academic and scientific institutions have to play a role in contributing to the national food control system, as they are a source of expertise in risk assessment and the scientific basis of such a system.

Consistency and impartiality. All components of the national food control system should be applied consistently and impartially. Competent authorities and all participants acting in official institutions should be free from undue or inappropriate influence or conflict of interest.

Making decisions based on risk assessment, scientifically justified, and evidence-based. Competent authorities should make decisions within the national food control system based on scientific information, evidence, and/or risk analysis principles.

Cooperation and coordination between several competent institutions. Competent authorities within the national food control system should work in a cooperative and coordinated manner for the most effective use of resources and facilitate the exchange of information.

Preventive and corrective measures. To prevent and, where necessary, respond to food safety incidents, the national food control system should address the essential elements of prevention and correction.

Self-assessment and checks. The national food control system should have the capacity and the ability to participate in continuous improvement.

Legal foundation. National governments should enable the establishment of food laws and competent authorities that can develop, implement, and maintain a national food control system.

Harmonization. When designing and implementing a

food control system, competent authorities should take into account the standards, recommendations, and guidelines of international organizations and the Codex, as appropriate, as elements of their national food control system.

Acknowledgement of other systems. Competent authorities need to recognize that there may be other, nationally and internationally equivalent food control systems.

Resources. The national food control system should have sufficient resources (material, financial, human) to enable the system objective to be met.

While the components and priorities of a food control system will vary from country to country, most systems will typically comprise the following components (FAO and WHO, 2003).

Food Law and Regulations. The development of relevant and enforceable food laws and regulations is an essential component of a modern food control system

Food Control Management. Core responsibilities include the establishment of regulatory measures, monitoring system performance, facilitating continuous improvement, and providing overall policy guidance.

Inspection Services. The administration and implementation of food laws require a qualified, trained, efficient and honest food inspection service.

Laboratory Services. Laboratories are an essential component of a food control system. The laboratories should have adequate facilities for physical, microbiological and chemical analyses. In addition, the laboratories can be equipped with more sophisticated instruments, apparatus and library facilities as required. The accuracy and reliability of analytical results also determine the qualification and skill of the analyst and the reliability of the method used.

Information, Education, Communication and Training. Food control agencies should address the specific training needs of their food inspectors and laboratory analysts as a high priority.

Advanced food legislation is a fundamental pillar of an effective food control system. In all countries, food is regulated by a series of laws and regulations that set out the requirements that must be met to ensure that food is safe and of adequate quality. The Codex Alimentarius Commission (CAC), a joint venture between the FAO and the WHO is an international inter-governmental food standards body. Its standards are published as Codex Alimentarius, also known as the 'Food Code'. This 'code of food' covers the entire production chain, enabling national governments to establish internationally accepted science-based standards to establish food safety criteria and harmonize food trade, taking into account appearing challenges and opportunities. The Codex system was founded in 1963 and has been working on food safety and the food trade for over 50 years. Codex Alimentarius international food standards, guidelines, and codes of practice contribute to the safety, quality, and fairness of the international food trade. Although recommendations for voluntary application by members, Codex standards, in many cases, serve as the basis for national legislation. Codex standards are not a substitute or alternative to national legislation. Hence, Codex is an invisible link between working on the food chain and the end-users (https://www.fao.org/fao-who-codexalimentarius/about-codex/en/).

Food safety in the European Union

The European Union has one of the highest food safety standards thanks to the existing set of EU legislation, which ensures that food is safe for consumers. The European Commission's General Directorate for Health and Food Safety (DG SANTE) is working to ensure the effective and proper implementation and enforcement of EU Legislation in food safety, food quality, and each health area. This is achieved through audits and other control activities in the Member States and third countries exporting to the EU (plus those included in an EU trade agreement).

Regulation (EC) No 178/2002 provides a high level of protection of human health and the interests of consumers about the food. It establishes the basic principles and tasks, effective organizational mechanisms, and procedures that support decision-making regarding the health of food. The purpose of the General Food Law is to achieve the free movement of food in the EU. To achieve this goal of high protection of human life and health, national food laws should be based on risk analysis. The General Food Law establishes a food safety system that divides responsibilities related to risk assessment (which is a scientific area) and risk management (which is policymaking) (Regulation (EC) No 178/2002b).

The law, with the amendments and regulations which more closely define the requirements for food quality and safety, is a basic legal act that regulates the conditions for ensuring food safety and establishes rights and obligations for individuals and legal institutions engaged in food production and trade, to protect human health. The law specifies the fundamental principles of food safety, regulates the organisational structures of the food safety system and the official controls for the enforcement of this system.

The food safety system is composed of legislation, competent state bodies (agencies, inspection services, control bodies), and national reference and official laboratories for food analysis. The competent authority plays a key role in the country's food control system. The European Food Safety Authority (EFSA) is an organization established in 2002 by the European Union, to provide scientific advice and activities related to the communication of risks related to the food chain. The EFSA is responsible for drafting scientific opinions and

providing scientific advice that forms the basis for the establishment of European Union policies and legislation. It has authority under the following areas:

- food safety and feed safety;
- diet;
- animal health and welfare;
- plant protection,
- plant health.

The EFSA has a legal basis for action in all EU Member States. The Agency also cooperates with EU Candidate Countries, which has concluded agreements with the EU and has adopted and implemented the legislation in the areas covered by this regulation (Regulation (EC) No 178/2002c)

Dealing of food safety information

A key tool in ensuring the exchange of information for a rapid response when are detected public health risks in the food chain is the Food and Feed Rapid Alert System (RASFF). Established in 1979, RASFF enables efficient sharing of information among its members and provides a sustained service to ensure that notifications are sent, received, and responded collectively and efficiently. Thanks to RASFF, many food safety risks are effectively avoided before they cause harm to European consumers. Essential information exchanged through RASFF can lead to the withdrawal of products from the market. The authorized Rapid Alert System for Food and Feed provides food control institutions with an effective tool for exchanging information on measures taken to respond to identified serious food risks. This exchange of information helps EU countries to act more quickly and in a coordinated manner in response to the health threat posed by food or feed. The RASFF, for direct or indirect food-based risk of human health, has been established as a network of EU Member States, the European Commission, and The European Food Safety Authority. Participation in this network is also possible for countries that have applied for EU membership. Each EU Member State shall designate a contact point. In case some member has information about the existence of risk, it informs the European Commission, and that information is immediately forwarded to all network members (Regulation (EC) No 178/2002d).

Requirements to national reference laboratories

Food control has evolved from a focus on the testing of the final product with an emphasis on prevention through appropriate process controls. However, laboratory services continue to play an essential role within the overall food control system, finally proving that the practices of food producers, suppliers, and processors result in safe products for consumers. Food control laboratories can provide the necessary scientific evidence for a better understanding of food safety/quality issues affecting public health. Testing remains an important component of any control system that aims to produce safe food. Carefully planned sampling and testing programs assure that the hygiene measures and practices applied by operators in the food chain result in safe food products that comply with national regulations and meet international food safety requirements. The operation of a control system is based on risk assessment, where the frequency of controls is set according to the level of risk. Higher estimated risk requires a greater number of mandatory controls.

- European Union reference laboratories shall (Regulation (EU) 2017/625a). operate in accordance with standard EN ISO/IEC 17025 and be accredited under that standard by a national accreditation body;
- be impartial, free from any conflict of interest;
- have access to, suitably qualified staff with adequate training in analytical, testing and diagnostic techniques applied in their area of competence;
- possess the infrastructure, equipment and products necessary to carry out the tasks assigned to them;
- ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices;
- be equipped with the necessary equipment to perform their tasks in emergency situations.

In the absence of the Union rules, and in the context of official controls and other official activities, official laboratories shall use one of the following methods according to the suitability for their specific analytical, testing and diagnostic needs (Regulation (EU) 2017/625b):

- available methods complying with relevant internationally recognised rules or protocols including those that the European Committee for Standardisation (CEN) has accepted; or
- methods which comply with relevant rules established at the national level, or, if no such rules exist, relevant methods developed or recommended by national or by the European Union reference laboratories and validated by internationally accepted scientific protocols or developed and validated with inter or intra-laboratory methods validation studies following internationally accepted scientific protocols.

National reference laboratories operate, are evaluated, and accredited following the European standards:

1) EN ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories" and

2) EN ISO/IEC 17011 "Requirements for accreditation bodies accrediting conformity assessment bodies".

Accreditation is usually applied on a voluntary or mandatory basis, which refers to conformity assessment. Accreditation is the independent assessment of these conformity assessment bodies against recognized standards for a specific activity to ensure their integrity, impartiality, and competence. In many economic areas, now accreditation is widely accepted by national governments and has become "mandatory" in many regulated areas. Increasingly, governments and regulators recognize the benefits of accreditation to help them fulfil their responsibilities and protect public interests such as health and safety and environmental protection. Accreditation is further strengthened by the implementation of Regulation (EC) No 765/2008, by providing a legal framework for the provision of accreditation services throughout Europe and for the acceptance of certificates and reports issued by national accredited conformity assessment bodies upon signing of the EA Multilateral Agreement (EA MLA) (https://european-accreditation.org/mutual-recognition/the-ea-mla/). By signing the ILAC MRA / IAF MLA agreements, national accreditation bodies provide a framework for mutual recognition and acceptance of accredited conformity assessment results, to promote and enhance accreditation in Europe and globally. ISO/IEC 17025 standard is an international reference for testing and calibration laboratories, to demonstrate their capacity to deliver reliable and credible results.

ISO/IEC 17025 should not be confused with the quality management standard ISO 9001. The latter is the generic standard for quality management systems. It applies to all organizations, regardless of the type, size, product, or service provided. ISO 9001 should not be considered as an "acceptable" alternative to ISO/IEC 17025. ISO 9001 certification focuses on establishing organizations' compliance with quality management system requirements and does not contain technical requirements for staff and operations. Organizations providing testing and calibration services can be certified to ISO 9001 for their quality systems management, but this should not be understood that the organization demonstrates technical competence to produce valid and accurate results. Identifying an accredited laboratory by ISO/IEC 17025 is simple, any accredited laboratory test is allowed to display the logo of the national accreditation body (Tsimillis, 2010).

Requirements for reference laboratories and quality standards

Demonstrable confidence in analytical data is demanded by the rapid increase in national legislation on food control and consumer protection and by international trading agreements which are based on mutual recognition of laboratory results. That mutual recognition must be supported by clear evidence. The accreditation laboratories use the internationally recognized standard ISO/IEC 17025, to assess the determinants relevant to the ability of laboratories to produce accurate and precise data. This includes:

- Documenting the quality management system.
- Technical competence of the staff.
- Validity and appropriateness of testing methods.
- Suitability and maintenance of testing equipment.
- Maintaining the necessary environmental conditions.
- Quality control of test results.

The primary objective of the laboratory testing services is to produce reliable results, which is the activity to be fully focused on. Quality assurance for these results is not an additional burden or activity that can be taken or left behind. The overall objective is defined as the production of analytic data of adequate accuracy and reliability within an acceptable timeframe and cost. The quality system is the total of all the things which contribute to meeting regulatory requirements and client expectations.

Documenting the quality system

An effective and functional quality system offers many operational advantages. It provides a track record to ensure sample integrity, with documentation to verify that laboratory instruments are functioning properly and that laboratory data were generated according to approved written protocols. Such documentation is especially important in regulatory laboratories where analytical findings must withstand the scrutiny of legal proceedings. The advantage of the quality system is an increase in analyst confidence derived from knowing that the results are reliable. This increased trust, in turn, can lead to an improvement in performance. The quality system must not only deliver quality data but also must ensure that a record is kept that allows the reliability and validity of any result to be proven. The formalization of the quality management system and its documentation ensures complete, adequate and consistent quality management. Another benefit of a quality system is to ensure that errors are detected and minimized or eliminated. If there is a problem, we can track it and make any necessary changes to the system. This will reduce the possibility of recurrence through the implementation of corrective actions that address the root cause of the problem. The quality system involves management procedures designed to minimize the risk that something is going wrong. It is impossible to eliminate all errors. It is possible to ensure that very few serious mistakes are made that have not been discovered before the results are sent outside the laboratory. This confidence comes from the body of evidence that gradually accumulates around the laboratory in the range of analyses it conducts. In case of investigation or disagreement, records are available to resolve the issue. Provide a review of deficiencies, errors

and complaints to ensure corrective actions can be systematic and lead to inherent improvements. In the quality system, the focus is more on error prevention regarding error detection and correction. Preventive action, based on risk assessment, requires an orderly program of planning and positive actions before or during testing to ensure that all analytical systems are operating appropriately (e.g. calibration and maintenance of instruments, analysis of data including trend and risk analyses and proficiency-testing results, training of personnel). Corrective actions are taken to determine the cause(s) of the non-conforming work and to restore the proper functioning of the analytical operations (e.g. correct malfunctioning equipment, re-evaluation of test methodology, retraining of personnel) (ISO/IEC 17025:2017a).

Documentation, therefore, is one of the major features of the Quality Management System (QMS). The initial production of the documentation for all laboratory activities can be demanding. It is essential to any management system that its documentation is used fully and properly; involving all personnel in its preparation and listening to what they say about how to set it out to minimize the additional work. It is a crucial ingredient to ensure that it is introduced smoothly and is then used convincingly and effectively (ISO/IEC 17025:2017b).

The management of documents and records is one of the essential elements of the quality system. The management system addresses both the use and maintenance of documents and records. A major goal of keeping documents and records is to find information whenever it is needed. (WHO, 2011a).

The *Quality Policy* is a documented statement of goals and responsibilities regarding the quality assurance of services. It includes a commitment to good professional practice and the quality of testing and a commitment to the continuous improvement of the effectiveness of the management system.

The key part of quality documentation is the *Quality Manual*. This is a document that outlines, in detail, the structure of the QMS. The Quality Manual describes some of the established management and technical procedures and policies and defines the main responsibilities of technical management. Authorized for its issuance is the top management. This ensures that the Quality Manual has the strongest authority in the document hierarchy, and also demonstrates top-level management commitment towards the management system meeting the customers' requirements and ensuring compliance with the standard (WHO, 2011b).

Procedures are documents of the management system, which prescribe activities that have an impact on quality. They describe (WHO, 2011c):

- what activities are performed and in what order;
- who is responsible for performing certain activities;
- the necessary additional documents (work instructions, forms, and records) related to the specific activity.

SOP/Work instructions are documents that describe the manner of performing specific activities, which directly or indirectly have an impact on the quality. Work instructions give a full, step-by-step guide on how to perform some activity. They describe each task in detail, including timeframes and resources required to complete assignments and achieve expected outcomes. A fundamental part of laboratory work instructions is documenting test methods and instructions on the use of equipment. The detail in these documents is such that it allows competent personnel to perform tests and operate the equipment appropriately and consistently. Work instructions should follow a single style. Work instructions should ensure consistency in terms of terminology, considering the knowledge and skills of potential users and the level of detail to present the process description. Every user should be able to understand work instructions (WHO, 2011d).

Records are a type of document that shows the actual evidence of the activity performed, obtained at the time of occurrence. Management system records improve the traceability and transparency of data and processes, therefore, improving the reliability of results. Technical records are the original observations, data, and calculations. They are written down at the moment they are made and are identifiable to the product, person or event to which they pertain. The records of each test contain sufficient information to detect the factors contributing to the measurement uncertainty, quality control, statistical analysis, interpretation, and validation of the results and enable the repetition of the laboratory test under conditions as close as possible to the original (WHO, 2011e). Technical records refer to (ISO/IEC 17025:2017c):

- test data and observations;
- information to ensure traceability of measurements;
- equipment checks;
- information about competence and personal training;
- information that ensures the confidentiality of test results;
- data from monitoring and control of environmental conditions;
- test reports, calibration certificates;
- data obtained from instruments;
- graphs, drawings, and tables;
- other documents relating to the evaluation and interpretation of data.

All data, calculations, and observations are recorded on worksheets, laboratory notebooks/diaries, or personal computers. Analysts rely increasingly on instruments that produce a hard-copy record of the instrumental readings.

When instrument-generated reports are included, chromatographic charts, spectrograms, as an example, the report should provide all information needed to interpret results, including absorbencies, peak areas, retention times, baseline noise, replicate injection number, wavelength maxima, and other characteristics used in the generation of results. Each sheet of a report is clearly labelled (sample number, analyst, date, and any other necessary identifiers) and stored in a logical sequence. The sequence of records should form a continuity of documentation to produce a clear, accurate, and indisputable history of the test material. Chromatograms of standards, recoveries, and sample extracts must be cross-referenced to each other and in the responsible analyst's laboratory notebook for easy checking of results. The intention is to have as much information as possible to support quality assurance procedures and to monitor for possible errors. The original recording of the information constitutes the raw data that must be retained. Any subsequent transcription of this information will not substitute the originally recorded information. The traceability is ensured by preserving the original and amended data. The analyst worksheet provides a written account of the laboratory's analytical results. The laboratory analyst records on worksheets all descriptive information of the sample, sample handling in the laboratory, and analytical findings and observations. Although a variety of worksheets and related forms have been developed to support laboratory sample data recording and handling, certain requirements apply to all (WHO, 2011e).

The document control system is needed to ensure that (ISO/IEC 17025:2017b):

- the management approves all the documents used by the employees and that only the valid documents are available at the place of use;
- all documents have been reviewed and checked by personnel with appropriate knowledge and experience to ensure that they are accurate, technically justified, and unambiguous;
- there is a record of issuing all copies (versions) of documents so that if the documents need to be revised or amended, all copies (versions) can be subjected to the same approval procedure;
- all personnel have access to the management system documentation and related information that apply to their responsibilities.

Technical competence of the personnel

The testing laboratory must have a sufficient number of competent employees with the authority to discharge their duties as reflected in the prepared job descriptions. This authority includes the implementation, maintenance, and improvement of the management system and performing activities that affect the quality of testing. There are two general types of laboratory personnel: analysts, who perform the actual analyses, and supporting personnel - technicians, who, with adequate training and supervision by the analysts, prepare solutions/reagents, handle equipment and prepare maintenance activities, clean glassware, prepare specimen and weigh test portions for analysis. The laboratories independently, competently, autonomous, and impartially carry out testing by the applicable legislation and other acts. The duties and responsibilities are allotted to competent persons with many years of experience. The job description, duties and responsibilities of each position are documented in the QMS. The job description contains three elements. First, an introductory paragraph giving a summary description of the position, indicating exactly how the position fits in the overall organizational structure. Second, detailing all the duties and responsibilities of the analyst. Third, describe the overall degree of supervision by the supervisor and the extent of the analyst's work-related independence (FAO, 1993).

The competence of the qualified person engaged in the testing is consisting of formal education, acquired experience; training received and demonstrated skills. Employees are aware of the importance of properly performing their testing activities, as a contribution to ensuring and maintaining technical competence. They have the responsibility and authority to implement the procedures, standards, laws, and regulations for the achievement of the objectives of the management system. Authorization of staff to perform specific laboratory activities is given based on the assessed level of competence. The authorizations of the staff refer to the following laboratory activities (Launey, 2018):

- development, modification, verification, and validation of methods;
- analysis of results, including giving statements of conformity and/or opinions and interpretations. Competent staff authorized to express an opinion and interpretation and to declare conformity is a specialist in the relevant field with proven experience and documented training. The qualifications, experience and training of the staff involved in forming opinions and interpretations vary, depending on the type of testing;
- review and approval of test results. Full knowledge of the test method, assessment of measurement uncertainty, appropriate standards and specifications are an accepted ground for the competence for approving the results.

Professional and technical staff do not perform any procedure and testing until they have completed all appropriate training and demonstrated competence. Personnel training is an ongoing activity for all and takes account of both long-term and short-term needs. The analytical staff has an adequate fundamental understanding of the science underlying the processes that they use. This knowledge is obtained during formal education but if there are gaps, these need to be identified and filled by attendance at working courses and seminars,

by reading, or by in-house training. The level of training is determined by the employee's educational qualifications, experience, the complexity of the test method, and knowledge of the test method performed. The highest level of training relates to the interpretation of data. The training should be following the current situation and the future planned activity. The training is mandatory for new employees, for introducing the new procedures and methods/techniques, and for retraining. Before starting any activity in the laboratory, the employee should be familiar with all the documents related to his work. These documents include procedures, work instructions, applicable manuals, regulations, and laws. The training program involves (Holmgren, 2018):

- activity/method for which the person is trained;
- type of training (experimental, theoretical, self-study);
- training time frame;
- the time frame for supervised work.

Review of work performance, the training status, and requirements for each member of personal take place on a planned basis. The purpose of the review is not just individual accountability: it should provide identification and action on both immediate and long-range training needs; possibility for the analyst to discuss particular work-related problems; an opportunity for the supervisor to recognize, commend, and document efficient analyst performance, and the opportunity for both parties to suggest improvements.

Validity and suitability of test methods

Food analysis can be required for a range of purposes: control of banned substances; control of permitted substances; food composition; dietary intake. The tests are performed according to validated methods, national and international standards, and the current legislation, which meets the customer and regulatory requirements. In routine work, test methods fall into one of three categories:

- The first category is reference methods that are published as standard specifications, including ISO, AOAC, EN, NMKL, Codex Alimentarius - Methods of analysis and sampling, U.S. EPA, Regulation published in the Official Journal, and specialized professional publications. These methods must be followed exactly as they are written, with no modifications to the published specification. The laboratory does not need to perform full validation but must have data to show that they can achieve the level of performance required by the standard method specification or the level of performance appropriate to the purpose for which the tests are intended. These methods may be specified by regulatory authorities for enforcement purposes or be stipulated by responsible organizations as the official methods.
- The second category is non-standard and internal laboratory-developed methods. Although some may be novel methods, more frequently they are based on methods already published in scientific literature. These methods must be subject to a high level of validation to demonstrate that they are technically justified, acceptable to the customer, and suitable for the intended purposes. As part of the quality system, all "in-house" methods must be documented as working instructions/SOPs. The Quality Manual sets out the procedure for approving a new SOP; usually, this will involve the procedure of the review of the documentation and its in-house validation.
- The third category is modified standard methods or documented internal methods based on standard specifications. The scope of validation/verification of these methods will depend on the degree to which it deviates from the standard specification. It is also necessary to ensure that customers consider the modifications and that the methods are appropriate for their purposes. These are analytical methods, more often based on a standard method that has been simplified in some way to make it easier, quicker, cheaper, more convenient to use.

The laboratories in the scope of their accredited activities use standard test methods, whenever possible, or unless otherwise specified by national legislation and agreed with the customer. Non-standard methods are used in cases where there is no standard method and are subject to consensus with the customer. When more of one version of a published method exists, the list must make it clear which version is currently in use. Only methods and procedures which have been authorized as fit for use are applied. (ISO/IEC 17025:2017d).

The test method must be shown to be fit for purpose so that customers can have confidence in the results produced by its application. Method validation and verification provide objective evidence that a method is fit for its purpose, meaning that the particular requirements for specific intended use are fulfilled. Validation for standard methods is not compulsory. However, the laboratory needs to verify the performance of the method. Verification of standard methods is necessary to demonstrate that the laboratory is capable of satisfactory replication of the method within an acceptable level of performance. Analysts must have readily available written copies of the methods in use and must follow the method exactly as written. Analysts must not make significant amendments to methods on their authority; minor variations are recorded. The approval process should include a consideration of the extent to which re-validation of the method is necessary and an examination of the outcome of any revalidation they call for. When the laboratory adopts a method that has been published as a standard, basic verification work has already been carried

out but it shall confirm its ability to apply the method. It means that some experimental work must be done to demonstrate that the method works in the laboratory. Before use in the analysis of test material, all methods must first undergo in-house validation or verification and the quality system must specify what this is to involve. Methods developed elsewhere must be checked and shown to produce reliable results in the circumstances prevailing in the laboratory even though they have already been subjected to extensive interlaboratory validation by expert organizations. The aim will be to verify that the performance characteristics achieved in-house are consistent with those established in the inter-laboratory validation. Some form of an ongoing check that the method is continuing to work properly is necessary. The nature and frequency of these checks need to reflect the complexity of the method, the degree of skill required, its reliability "track record", the number of samples analyzed, and the quality of data required. Analytical methods need to be verified or revalidated (Patil et al., 2017):

- when introducing a standard method;
- after each change or major service instrument;
- in certain periods;
- if the quality control data show that results obtained by the method change over time.

The performance characteristics of the method, namely the parameters that are determined by the validation, are based on the intended use of the method. There are no official guidelines on the correct sequence of validation experiments, and the optimal sequence may depend on the method itself. The validation work is performed, and the results are reported, according to a documented procedure (for instance Eurachem guides, ISO guides, reputable scientific papers, laboratory working instructions). The analyst outline a validation protocol with a brief explanation of the performance characteristic, any specific requirements, and the experiments which are done, and how the results are evaluated. Results and conclusions from the experiments also are stated. The laboratory needs to keep comprehensive records of method validation/verification, including the procedures used for validation, the results obtained and a statement as to whether the method is fit for the purpose. They must also continually check that a method of analysis meets the values for the performance characteristics documented in connection with validation/verification. This can be achieved by tracking the behaviour of internal quality control samples over time. The most important performance characteristics usually included in a validation study are (*NATA*, 2018):

- Sensitivity refers to the smallest quantity that can be accurately measured. It also indicates the capacity of the method to measure small variations in concentration.
- Specificity/selectivity of a method refers to the ability of the method to measure accurately and specifically the substance of interest in the sample as impurities, degradation products. For this, the test results of analysis of samples containing other ingredients are compared with the samples without containing ingredients.
- Working range (measuring interval) and linearity (linearity of calibration). The linearity of an analytical method is its ability to obtain test results that are directly proportional to the concentration of analyte in the sample. The range of an analytical method is the interval between the upper and lower concentration of analyte in the sample.
- Limit of detection (LOD) and limit of quantification (LOQ); Detection limit of an individual analytical procedure is the lowest amount of analyte in a sample that can be detected but not necessarily quantitated. The quantification limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy.
- Precision (measurement repeatability, measurement reproducibility); Precision refers to the agreement among the individual test results when a method is applied repeatedly to the same sample. It is a measure of the degree of repeatability or reproducibility of a method. The precision of an analytical procedure is usually expressed as relative standard deviation (RSD. Repeatability expresses the precision under the same operating conditions over a short interval of time. Reproducibly expresses the precision in the laboratories.
- Trueness/measurement accuracy (bias, recovery); Accuracy is the agreement between the test results obtained by the proposed method and the true value. It expresses the correctness of the method. It is expressed as a percentage by the assay of a known amount of substance. The absolute error is a measure of the accuracy of the measurement.
- Ruggedness (robustness); Robustness is the measure of the capacity of the analytical method to remain unaffected by small but deliberate variations in procedure. The degree of reproducibility of test results obtained by analyzing the same sample under a variety of normal test conditions is known as ruggedness.
- Measurement uncertainty.

Not all parameters need to be assessed for all methods. The degree/scope of validation/verification will depend on the limitations imposed such as time available, the competence of personal, technical possibilities, the amount of sample or materials, intended use of the method or type of information. The most important is a type of analytical application: identification test, screening test, quantitative test for the main component, limit test for impurity, trace analyses. (Magnusson et al., 2014).

For an analytical result to be fit for its intended use it must be sufficiently reliable that any decision based on it can be taken with confidence. Thus the method must be validated/verified and the uncertainty on the result, at a given level of confidence, estimated. Each measurement, like testing, involves a certain measurement error. If the measurement is repeated, it often gives a different result, although very similar to the original result. Therefore, measurement gives only an approximation of the true value of the quantity to be measured. The measurement is complete only if incorporates measurement uncertainty. Measurement uncertainty is defined as a parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand. The "measurand" is defined in analytical chemistry as a particular quantity or concentration of a species subject to measurement. In general, the result of a measurement is only an approximation or estimate of the value of the measurand and thus is complete only when accompanied by a statement of the uncertainty of that estimate. Uncertainty of measurement comprises, in general, many components. Some of them may be evaluated from the statistical distribution of the results of a series of measurements and can be characterised by experimental standard deviations (Type A). The other components, which can also be characterised by standard deviations, are evaluated from assumed probability distributions based on experience or other information available (Type B). Therefore, the difference is how the data is collected, not how it is evaluated. Type A uncertainty is collected from a series of observations. Type B data is collected from other sources. Although Type B uncertainty found in publications may have been collected from a series of observations, it wasn't collected by us or our laboratory personnel (JCGM 100, 2008).

Type A evaluation of standard uncertainty is based on any valid statistical method in the analysis of a series of observations. It is sometimes commercially impractical to investigate the Type A standard uncertainty for every measurement. Where a type of measurement is performed frequently, provided there are no changes in the measurement system or procedure, it may be sufficient to estimate uncertainty in terms of an investigation carried out earlier and verified at discrete intervals of time to ensure that the measurement has not been degraded.

Type B evaluation of standard uncertainty is obtained by means other than the statistical analysis of a series of observations. It is usually based on scientific judgment using all relevant information available, which may include:

- previous measurement data,
- experience with, or general knowledge of the behaviour and property of relevant materials and instruments,
- manufacturer's specification,
- data provided in calibration certificates and other reports.

In laboratory practice, there are many possible sources of measurement uncertainty that are not necessarily independent of each other. The nature of microbiological, chemical, and radiological testing does not always require rigorous, metrologically, and statistically valid calculations of uncertainty. Considering this, the assessment of uncertainty is based on data from the validation/verification of the method and the inclusion of factors that have the greatest impact on the budget of uncertainty. The calculation and expression of measurement uncertainty are performed according to a laboratory procedure, ISO/IEC GUIDE 98-3:2008 (GUM), and guidelines from some other international organizations: EA, Eurachem, Eurolab, UKAS and Nordtest. The following steps summarise the tasks that analysts are performing to estimate the uncertainty associated with a measurement (Ellison et al., 2012):

- Step 1 – Specifications of the measurand.
- Step 2 - Identification of uncertainty sources (Cause-and-Effect Diagram) It is a good practice to write down all possible sources of uncertainty and then simplify by re-grouping them under more general headings.
- Step 3 - Quantify uncertainty components. It is to be aware that not all the components of uncertainty are going to make a significant impact on the combined uncertainty to be evaluated. The first step in the quantification of uncertainties is to make a preliminary estimate of the contribution of each component to the combined uncertainty and to eliminate those which are not significant. The extent of the components of uncertainty related to the identified potential sources of the uncertainty shall be estimated by carrying out the appropriate experiments or from other available information.
- Step 4 – Calculating the Combined Uncertainty and Expanded Uncertainty. The result of the measurement is obtained by appropriately combining the standard uncertainties of the input estimates. The final stage is to multiply the combined standard uncertainty by the chosen coverage factor to obtain an expanded uncertainty. The coverage factor is chosen after considering some issues like the level of confidence required and any knowledge of underlying distributions.
- Step 5 - Reporting Uncertainty. Unless it is required otherwise, the result should be reported together with the expanded uncertainty, *U*, calculated using a coverage factor. The standard uncertainty of 'y', where 'y' is the estimate of the measurand 'Y'. The combined standard uncertainty of the estimate of 'y' is denoted by

uc(y). For most purposes, a coverage factor k=2 is normally chosen that gives a confidence level of approximately 95%. The following standardized format is usually applied to express the entire measurement uncertainty interval, accompanied by a statement: (Analyte): Result (units) ± U (units). In chemical analysis, only significant figures of a test result are reported generally. The measurement uncertainty is presented in the same units as the measurement quantity is expressed or in units that are in proportion to the measurement quantity (e.g. percentage).

Uncertainty of measurement, in general, contains many components. It is necessary to develop and make a list of sources of uncertainty relevant to the method. It is often helpful to structure this process and provide comprehensive coverage to avoid unnecessary duplication. In practice, the use of the Cause/Effect ("Fishbone") Diagram could provide a useful approach to evaluating measurement uncertainty and presenting the sources and components of measurement uncertainty. The analyst indicates a list of experiments to be executed to estimate uncertainty. The initial list from the analyst is reviewed to simplify the presentation and to ensure that the effects are not repeated unnecessarily. The analyst collects and reports information on possible sources of uncertainty. There are many possible sources of uncertainty of measurement in testing. Some of them refer to (Birch, 2003):

- Non-representative sampling, the sample analyzed may not be representative of the defined population, particularly when it is not homogeneous. Non-homogeneity nature of the sample, leading to uncertainty in testing a sub-sample from the sample;
- Incomplete definition of the measurand (e.g. failing to specify the exact form of the analyte being determined). Matrix effects and interference;
- Measurement conditions. Imperfect realization of the definition of the test method. Even when the test conditions are defined clearly, it may not be possible to produce these conditions in a laboratory;
- Approximations and assumptions incorporated in the measurement method and procedure;
- Sample preparation for analysis. Incomplete extraction and pre-concentration of the test solution before analysis. Contamination during sample and sample preparation;
- Environmental conditions. Inadequate knowledge of the effects of environmental conditions on the measurement or imperfect measurement of environmental conditions;
- Instrument resolution and personal bias in reading measurements (e.g. colour readings);
- Uncertainty of weights and volumetric equipment;
- Uncertainty in the values assigned to measurement standards and reference materials;
- Values of constants and other parameters obtained from external sources.

It is to be noted these sources are not necessarily independent. It is important to know that not all components will make a significant contribution to the combined uncertainty. In practice, it is more likely that only a small number will make a substantial contribution. Based on the author's experience, the components, unless there are a great number of them, contributing less than one-third of the largest should not be considered in the assessment. A preliminary assessment should be made of the contribution of each component or a combination of components of uncertainty, and those found that are not significant to eliminate. The major sources of variability can often be associated with trueness and precision of measurement methods and results, which provide estimates of repeatability (repeatability standard deviation), reproducibility (reproducibility standard deviation) and trueness of the method (measured as a bias concerning a known reference value). In the case of microbiological analysis, it is difficult to build a comprehensive model of the measurement process. It appears difficult to quantify accurately the measurement uncertainty contribution of each step of the microbiological measurement process where: the analyte is a living organism present in a natural sample and the target organism includes different strains, different species, or different genera.

For the laboratories performing testing, the need to estimate the uncertainty of the measurement depends on factors such as (ISO/IEC 17025:2017e):

- requirements of the testing method;
- requests from the customer, or
- if there is a narrow limit on which decision on compliance/non-compliance of the result with the specification and application of the decision rule, are applied.

The measurement uncertainty in the Test reports is related to the application of the decision rule when stating conformity with a specification or standard. Conformity assessment requires objective criteria in what is called a "decision rule", which aim to define boundaries. The decision rule is a documented rule that describes how the measurement uncertainty will be taken into account concerning the acceptance or rejection of the sample, given the specified requirement and the measurement result. These specified requirements can be stated in normative documents such as laws, regulations, standards, and technical specifications. The specified requirements for the property (parameter) of interest consist of limiting values, named tolerance limits, which separate the intervals of the allowed values of the measured property from the intervals of the impermissible values (ILAC, 2019).

Suitability and maintenance of test equipment

Equipment management is one of the essential elements of a quality management system. Proper management of the equipment in the laboratory is necessary to ensure accurate, reliable and timely testing. The laboratories, to ensure easier management and administration of records, classified their equipment according to the purpose of the following groups (van Reeuwijk, 1998):

- General-purpose equipment and auxiliary equipment, not used for measuring or having minimal impact on measurements. This is processing equipment such as blenders and grinders, driers, ovens and furnaces, centrifuges, refrigerators and freezers, hot plates and water-baths, water stills, and purifiers.
- Volumetric equipment.
- Measuring devices and apparatus. Measuring equipment such as balances, pH meters, spectrophotometers (UV/visible and AA), high-performance liquid chromatographs, gas chromatographs, colourimeters is included in this category.
- Standards, certified reference materials, reagents, quality control materials
- Software and microprocessors for data processing

Records shall be retained for equipment that can influence laboratory activities. These records contain the following information (ISO/IEC 17025:2017f):

- Name of the equipment;
- Identification of type/model of equipment;
- Equipment manufacturer;
- Inventory number (or other identification, e.g. serial number);
- Dates and results of all calibrations;
- Checks and maintenance carried out;
- Location of the equipment.

Measuring equipment requires some degree of regular maintenance, performance check and verification and calibration. All equipment is checked for proper operation before being put into routine use. This includes checks according to the manufacturer's specifications and checks to confirm that the equipment gives satisfactory results when used for its intended purpose. The acceptance criteria are values of parameters established relative to the target value or specification, and any other information that contributes to the evaluation of the instruments. Equipment manufacturers should be providing Installation Qualification (IQ) and Operational Qualification (OQ) services when new equipment is put in place. Services may be available externally on a contract basis. Some expertise may exist in-house (WHO, 2011f).

To ensure traceability, measuring equipment is calibrated or verified following laboratory procedures, guidelines, and recommendations of the national accreditation body and international accreditation organizations. With calibration, we establish, under specified conditions, the relationship between values of quantities indicated by our measuring instrument or measuring system and the corresponding values realized by standards. Measurement traceability is important because it gives us confidence and assurance that our measurement results agree with national or international standards within the statement of uncertainty in measurement. All equipment used for testing, including auxiliary measurement equipment, which significantly affects the accuracy and validity of the test results, is calibrated and traceable to the International System of Units (SI). When laboratories cannot provide traceability to SI units, traceability is ensured using appropriate measurement standards, such as certified reference materials (CRM) or reference materials (RM) (ILAC, 2020). Acceptable CRM and RM are provided by competent suppliers and manufacturers that provide a reliable and steady physical or chemical characterization of the material. Calibration using RMs is a particularly common practice in chemical testing where traceability to SI units is rarely achievable. Consequently, the use of accepted CRM serves as an appropriate alternative, and the realization of calibration is achieved through instrument performance verification (IPV). Certified reference materials obtained from relevant manufacturers operating under ISO 17034 standard provide acceptable metrological traceability. Reference material is any material or substance in which one or more of the characteristics of a property are homogeneous, stable, and well accepted that can be used for verification of test methods or apparatus (UKAS, 2020). Two general types of RM s are:

- single compounds or articles with established purity or properties, and
- matrix references that represent specific types of a sample.

The certificate for traceability or information on the properties of the reference material shall be kept. All this information on the equipment is documented in the equipment log.

For each measuring device is determined its calibration and performance status. In the first place, an initial calibration interval is introduced based on the manufacturer's recommendations, the intensity of use of the instrument, the required accuracy, one's personal experience, and the impact of the behaviour of comparable instruments. Qualified and competent laboratories for performing calibrations are those laboratories that are accredited by the accreditation bodies that are on the list of signatories of the EA MLA/MRA for the field of calibration, and laboratories accredited by the international organizations that are signatories to the CIPM MRA (ILAC, 2007). For many analytical determinations, a set of standards may be run every day as part of the calibration of the whole method; the results of

these will provide an incidental check on the instrument. The results of the reference samples are recorded either in the equipment records or together with the analytical data. Each piece of equipment that is subject to regular inspection, calibration, or verification has a visible label indicating the date of the last, as well as the scheduled date for the next one. Equipment to be calibrated daily or with each use is also marked, in such a way the text replaces the calibration dates, for example, 'calibrated daily or calibrated with each use.'

Accommodation and environmental conditions

The laboratory work space and facilities must be such that the workload can be performed without compromising the quality of work and the safety of the laboratory staff. The workspace must provide an adequate movement of staff, materials, equipment, samples, and other resources following the technical requirements for testing. Minimum safety requirements for potentially dangerous situations also should be met. Generally, testing laboratories are consisting of (WHO, 2011g):

- administrative premises for staff (offices);
- working rooms (laboratories): which could be for: preparation, testing, calibration, rooms with apparatus;
- storage rooms: for samples and calibration items, glassware and chemical warehouses, and
- special-purpose rooms. Such rooms could be with sterile conditions and rooms with biosafety levels. Specialized rooms are, also, required for "clean air" work (e.g. some environmental contaminants) or for work with substances that need to be handled with special care either for safety or for cross-contamination reasons (e.g. radioactive materials and some particularly toxic substances) or storage and dispensing of standards of pure compounds which are being analyzed at trace levels. There is a specialized room for dusty sample preparation activities, e.g. grinding, blending, mixing, stirring, particularly if work is foreseen on heterogeneous analytes (e.g. aflatoxins in nuts).

Preserving a safe and secure working environment affects risk management in a way that minimizes any risk or negative effect on employee health, physical safety, working condition, material goods, and the immediate surroundings. Some of the test samples and materials (chemical, microbiological, radiological) used in the laboratory are articles that may contain harmful contaminants. Many common laboratory procedures can create aerosols. These include pipetting, vortex mixing, blending, stomaching, centrifugation, flaming loops, and sonication. Each of these procedures can be done safely and appropriate safeguards are in place. Danger to public safety can also be harmful reagents, radionuclides, or microorganisms that can cause disease or actions that have the potential to cause immediate physical injury or other adverse effects on employees as well as endanger working conditions. Laboratory coats, gloves, and safety glasses are the minimal personal protective gear for all food analysts. Employees who have access are well informed about the purpose of individual premises, the restrictions on working in such premises, and the extent of restrictions on individual premises. Locked doors should prevent access by unauthorized persons during tests. Visitors can enter some individual laboratory, only accompanied by an employee (WHO, 2011h).

The occurrence of cross-contamination between the samples, and the possible contamination of the samples from the surrounding environment can be prevented by the existing organization of the space. The design provides complete segregation of trace analyses from highly concentrated formulations and from pure substances used in preparing analytical standards. Another factor to consider is that ultra-pure samples or concentrated solutions for trace element, analysis are often used in chemical testing. The rooms in which chemical tests are performed are equipped with ventilated cabinets, to remove volatile substances generated during the analysis and to protect employees from dangerous concentrations of toxic substances in the air. Ventilation intakes and fume cupboard (fume hood) exhaust is sited carefully to avoid re-circulation of laboratory air and the associated risk of contamination of test materials and hazard to laboratory staff. Air monitoring is performed whenever there is a strong-smelling or other suspicious indication of the presence of a chemical. The chemicals are stored according to their compatibility in conditions reported by the manufacturers and in agreement with the safety and protection recommendations (Material Safety Data Sheets). All reagents and solutions in the laboratory areas are labelled to indicate identity, titer or concentration, storage requirements, and expiration date. All organic solvents, acids and bases are stored and disposed of in their original packaging. They must not be mixed. The bottles must be marked with a self-adhesive label on which is written the chemical name. Drainage from chemical testing devices is collected in suitable plastic bottles. Solid non-toxic chemical waste is disposed of in plastic bins lined with plastic bags. Every chemical laboratory contains substances that are actually or potentially dangerous. The working practices of the laboratory ensure that the risk to which personnel (and the public at large) are exposed to this hazard is acceptably low. This will usually be achieved through laboratory design, selection, and training of employed and by introducing appropriate documented measures for controlling the hazard (EPA, 2000).

In the rooms where microbiological tests are performed the work is organized in such a way as to prevent contamination, meaning the movement of samples and test materials in one direction. Biological Safety Cabinets and Laminar Flow Chambers are available for procedures that generate aerosols. ATCC

reference collections, microbiological materials (substrates, Microbiology Test Kits) are handled and stored in conditions recommended by the manufacturers and protected from contamination and spoilage. Test samples before and after the test, ready-made substrates, and reference strains of microorganisms are stored in particular refrigerators and freezers. In the microbiological laboratories, biological sterility is monitored, make periodically swabs are taken from the work surfaces (on the desks and in the cabinets). Additionally, in these laboratories, the microbiological contamination of the air is monitored by incubation of placed open plates. In some cases, the tests are performed in a more controlled environment, such as a biosafety cabinet or incubator. All laboratory benches are made of impervious material that is easily disinfected. Desks, floors, and walls are designed to minimize areas of damage and cracks that can cause debris to accumulate and serve as a breeding ground for microorganisms. Facilities to decontaminate material before disposal, such as autoclaves, are also in place. All infectious materials require autoclaving before disposal. (WHO, 2011i).

Laboratories monitor, control, and record environmental conditions provided by relevant specifications, methods, and procedures, where they may adversely affect the required quality of the measurements. Environmental conditions requiring monitoring include room temperature and humidity, background radiation dose, microbiological contamination on bench surfaces and air sampling. Dust is important to instrumental performance and for safety working (e.g. with flammable solvents). To operate properly optical instruments often require stable temperature conditions. Electronic equipment may have prescribed operating ranges for environmental temperature and humidity. Some substances are affected by sunlight or fluorescent lights and must be protected from them. Delicate balances and optical instruments are protected from vibration (e.g. from blenders, shakers, and centrifuges). It can be noted that volumetric measurements, in particular, are affected by temperature variations, but, in practice, this is significant only concerning other sources of measurement uncertainty. In the rooms where radiological testing is performed the natural background radiation is monitored. All these needs are identified and documented so that proper procedures for monitoring them and taking necessary action are included in the QMS. Testing activities are stopped when environmental conditions contribute to invalid test results (ISO/IEC 17025:2017g).

Assuring the quality of test results

Quality assurance is an integrated system of management activities that include planning, implementation, evaluation, reporting, and improvement to ensure that the process, item, or service is of the type and quality required and expected by the customer. According to ISO, quality assurance (QA) addresses the activities the laboratory undertakes to provide confidence that quality requirements will be fulfilled, whereas quality control (QC) describes the individual measures which are used to fulfil the requirements. Quality control is a term used to describe a set of procedures performed by laboratory personnel to continuously evaluate test results and their degree of confidence, reliability, and consistency. Laboratory quality control is very important to confirm that the published results are appropriate for the intended purpose. The use of official methods does not relieve the analyst of the responsibility of proving method performance through quality controls, positive and negative controls, and recovery and reproducibility studies. Verification of the result is consists of confirming that quality control is acceptable, the management system is functioning properly, and the results make sense. In cases where performance is beyond acceptable limits, the results can be questioned, the situation revised, and a decision made on their validity. Quality control combined with professional experience and analytical judgment is a powerful tool for providing and publishing confidential results (Barwick et al., 2016a).

The laboratories are ready to evaluate the quality of their results daily. The quality control program is established on (ISO/IEC 17025:2017h):

- internal quality control measures - refer to procedures undertaken by personnel in the laboratory for the continuous monitoring of operations and measurement to decide whether results are reliable enough to be released. This includes the use of reference materials or quality control materials, use of check or working standards with control charts, replicated analysis of stable test samples, blanks, standard solutions or materials similar to those used for the calibration, spiked samples, blind samples, and quality control samples, and
- external quality control measures - based on laboratory performance in the programs of proficiency testing (PT schemes) and interlaboratory comparisons (ILC).

Internal quality control involves the practical steps undertaken to ensure that errors in analytical data are of a magnitude appropriate for the use to which the data will be put. The basic approach to internal quality control involves the analysis of control materials alongside the test materials under examination. The outcome of the control analyses forms the basis of a decision regarding the acceptability of the test data. The interpretation of control data must be based on documented, objective criteria, and statistical principles wherever possible. The results of control analyses should be viewed primarily as indicators of the performance of the analytical system, and only secondarily as a guide to the errors associated with individual test results. Control charting is a powerful and simple tool for the daily quality control of routine analytical work. The basis is that the laboratory runs

control samples together with the test samples in an analytical run. Material of control samples can be standard solutions, test samples, blank samples, in-house control materials and certified reference materials. Immediately after the analytical run is completed the control values are plotted on a control chart. The central line in the control chart represents the mean value of the control values or a reference value. In addition to the central line, the control chart normally has four lines. Two of these, the so-called warning limits, are located at a distance of ± two times the standard deviation from the central line (± 2s). Provided that the results are normally distributed, about 95 % of the results should be within these limits. In the control chart, two other lines are also drawn at a distance of ± three times the standard deviation from the central line (± 3s). These lines are called the action limits and 99.7 % of the data normally distributed should be within these limits. The following types of control charts are the most important ones used for the internal quality control of chemical analyses (Hovind et al., 2018a):

- X-charts;
- Range-charts, R or r %

Ideally, the control samples should go through the whole measurement procedure. They should also be very similar to test samples and stable over time. There should also be a sufficient amount for years and a suitable analyte concentration. This is however seldom the case and therefore we use several types of control samples (Hovind et al., 2018b):

- Certified Reference Material – matrix CRM. The results from repeated determinations of a matrix CRM will give a good indication of any systematic effect (bias). Repeated determinations in each analytical run give a possibility of using the standard deviation (or range) as an estimate of the repeatability of the measurement.
- Standard solution or in-house material. This type of control sample gives an indication of some of the systematic effects as well as the random effects. A control sample is usually prepared by the laboratory. It can be either stable, homogeneous test samples or synthetic samples. Standard solutions can be bought from external suppliers but are often prepared in-house. For in-house matrix materials, the laboratory collects the stable natural sample itself (or selects from samples received for analysis). Synthetic in-house materials are prepared from pure chemicals and purified solvent (e.g. water) simulating the matrix of test samples. A blank sample may be used for the surveillance of the limit of quantitation (LOQ). The blank may be a reagent blank, a method blank or a sample blank. Furthermore, this type of control sample serves to reveal contamination. Errors in the blank cause systematic effects at low concentrations.
- Test sample. The control sample will generally be selected at random among the test samples submitted for measurement in the laboratory. Duplicate measurements give a realistic picture of the within-run random variations for natural samples.

It is difficult to suggest an appropriate quantity of control samples to be included in the test and applied to each test method/technique. It is the responsibility of the Quality Manager to set and justify an appropriate level of quality control, based on risk assessment, taking into account the reliability of the method, the criticality of the work, and the feasibility of repeating the analysis if it doesn't work correctly the first time. The testing frequency of control samples depends on several factors, the most important of which is the stability of the testing process. Until the analytical process is well understood, control samples will need to be tested more frequently. Once the method is adopted and proven to be under control, fewer control samples will be required to display continuous control. It is widely accepted that for routine analysis, a level of internal quality control of 5 % is reasonable, i.e. 1 in every 20 samples analyzed should be a quality control sample. If the analytical results are particularly important, a higher percentage of representation is more appropriate. (Barwick et al., 2016b).

Once the control samples have been tested, the next question is how to analyze the data generated in a way that shows whether the method is under control or not. It is common practice to set warning limits. The recommended method for displaying and analyzing the results of quality control samples is the quality control scheme known as the Shewhart scheme. This type of presentation has the advantage of being easy to interpret and fast in the feedback of the analytical process. Conventionally 'warning limits' are set at ±2 SD, and 'action limits' are set at ±3 SD about the mean value. As long as the quality control sample value is acceptable, it is likely that results from samples in the same batch as the quality control sample can be taken as reliable. Furthermore, control charts will reveal trends and cycles of possible causes of correctable errors. It should be emphasized that in all these analyzes and assessments, the experience and sound judgment of analysts is very important for evaluating the analytical system, applied technique, and analytical interpretation of the data generated by the method. If the result of the quality control happens to be above or below the control limits on the control diagram, the samples are re-examined. The review is a planned action to correct the problem and to prevent the issuance of a test report with inaccurate results. If the review determines a specific reason for the deviation, such as reagent obsolescence, improperly prepared reagents or standards, etc., testing is repeated. Control diagrams provide information on trends or changes. The trend will show a tendency or movement in

a certain direction. If a series of consecutive results, graphically displayed, are constantly moving in one direction, either up or down, a trend is shown. If a series of consecutive results, graphically displayed, fall above or below the centre line, a change is indicated. When a trend or change is detected, it is marked as such on the chart and reviewed to identify potential problems. If any inconsistency is found after the evaluations, corrective action is taken to discover the cause. Quality control data is analyzed and, where they are found to be outside of established control limits, there is a high probability that there is an error in testing. The Laboratory must undertake the following steps:

- control of reagent and standards;
- check the correctness of the equipment;
- equipment calibration check, and/or
- check for other factors that influence testing (e.g ambient conditions).

If the review shows that the reliability of the test results is in question, all tests after the last acceptable values will be repeated. (Hovind et al., 2018c).

Regular participation in proficiency testing (PT) and interlaboratory comparisons (ILC), also known as external quality control, is a method used by the laboratories to monitor its performance. Participation in PTs regularly can result in an improvement of the laboratory's performance. Quality and reliability of analytical results are, in general, key issues for all laboratories but have become a top priority for laboratories accredited according to ISO/IEC 17025:2017. In this international standard, proficiency testing (PT) is regarded as a means to assure the validity of results. Nowadays, the proven competence of laboratories is an essential requirement especially for those organizations that are involved in the official controls aimed at ensuring the safety of food products and public health. Positive participation in appropriate PT and ILC programs is a prerequisite for obtaining and maintaining the accreditation of a laboratory. Following the recommendations of European and international accreditation organizations, the laboratory must have satisfactory participation in appropriate PT/ILC schemes. The laboratories must choose the appropriate scheme depending on their needs, compatible with the type of samples that they are dealing with the most. Competent organizers of such programs are those who have implemented the international standard ISO 17043 in their work (EA, 2010).

Participating in a PT scheme provides the laboratory with the opportunity to compare their results with other laboratories through an independent external assessment. The results and information received from the participation in PT schemes will provide laboratories with either a confirmation that their performance is satisfactory or an indication that there are potential problems and those corrections should be made. The interpretation of the PT performance concerns all management levels of the laboratory, from the operator to the top management. The personnel responsible for the measurement will be familiar with the operation of the PT scheme and should normally proceed with the initial evaluation. If a laboratory's result in a PT scheme indicates unsatisfactory performance, this should start a process of investigation of potential sources of error. In other cases, the participation may provide an opportunity to compare the results achieved by the laboratory using different measurement procedures (or when determining different concentration levels, etc.) to those normally used by the laboratory. If sufficient PT items are available to allow more than one operator within a laboratory to carry out the analysis, the laboratory has the added benefit of being able to compare the results of its operators. In addition, this might also provide some inputs to the laboratory's evaluation of its measurement uncertainty for the relevant measurements. When a laboratory is not satisfied with its results in a PT scheme, this provides an opportunity for the laboratory's management to investigate areas where its future testing could be improved. This might, for example, include additional operator training, adoption of new or modified measurement procedures, enhancing internal quality control, or equipment modifications or calibration. In some PT schemes, where there is sufficient, stable material provided to participants, the unused material could be used as a QC material for monitoring measurement performance as part of the laboratory's internal quality control procedures. If after a thorough investigation, the laboratory concludes that the result is indeed unsatisfactory, then corrective actions should be initiated. In addition to the careful evaluation of results from individual PT rounds, the performance over time should be monitored, to identify potential problems related to imprecision, systematic error or human error. There are a variety of ways that an individual laboratory can monitor its performance over time. In proficiency test, each participating laboratory measures a specified quantity (or several specified quantities) on a sample or specimen received and submits its result to the organiser. In return, the laboratory receives a score, based upon the deviation of its result from the assigned value, e.g. a Z-score. When the value of $|Z| \leq 2$, the results are considered satisfactory. The laboratories may in some situations achieve unsatisfactorily (e.g. ($|Z| \geq 3$) or 'questionable' test results (e.g $2 < |Z| < 3$) (Brookman et al., 2021).

The reasons for obtaining a poor performance are unfortunately numerous, potentially resulting in a time consuming and complex investigation. However, as the investigations should result in an improvement of the laboratory's performance, it is worthwhile to put in the necessary effort. To facilitate the investigations, it is useful to have in mind the main causes for poor performance so that the investigations can be better focused. Typical causes of poor performance include (Ellison and Hardcastle, 2012):

- sample preparation (e.g. weighing, drying, extraction, digestion, clean-up, dilution, storage/pre-treatment of the PT item, etc.);

- measurement procedures;
- human error (e.g. inappropriate training, transcription errors);
- equipment/reagents/calibration;
- selection of measurement procedure;
- calculation error; reporting problem (e.g. format, unit, interpretation);
- the problem arising from the PT item (matrix difference between PT item and routine samples, concentration levels outside the scope of application of the measurement procedure, lack of stability or homogeneity of the PT items);
- primary sampling and sample transport and storage;
- environmental conditions;
- sample tracking (e.g. labelling, chain of custody);
- the problem arising within the PT provider.

Proficiency testing schemes have a clear and positive contribution to make as part of a laboratory's quality assurance program. Successful performance in a PT scheme can provide individual staff and their direct managers with additional confidence. External users of laboratory services, including their customers and the parties affected by the outcome of the measurement, can also be given added confidence.

Conclusion

Government inspections ensure that all the criteria for food safety are met. Regulatory agencies may set policy requirements or detailed technical requirements and rely on accredited laboratories, inspection bodies, or certification bodies to verify product compliance. Conformity assessment is one way of preventing the entry into the market of dangerous products which are harmful to health or the environment. Regulatory agencies consistently conducting official controls enables to improve overall performance when it comes to food safety and the ability to provide food-related products and services that are safe and meet regulatory requirements.

Accreditation is a basic tool for decision making and risk management. It is a mark of quality that can be used to easily identify technically competent, safe, efficient, customer-focused services that meet all regulatory requirements. Accreditation of testing laboratories according to international standard ISO 17025 provides support to the work regulatory agencies for reliable monitoring of food safety. While the benefits of obtaining ISO/IEC 17025 accreditation is widely understood and accepted by analytical laboratories worldwide, accreditation can be especially critical in a regulatory reference laboratory. It is important to emphasize that the inspector, who collect the sample, and the laboratory personnel, who conduct the testing, are using an appropriate chain of custody procedures. An accredited laboratory is recognized to be capable of producing accurate and defensible data. Consistent and concise documentation has helped us to ensure our data is trustworthy. It is very easy for the laboratory to follow-up investigations, produce records, standard operating procedures, analyst training records and other documentation. This provides results safe enough to be used in databases for food surveillance, public health, nutrition and other local, national or international food-related policies. These databases form an extremely valuable resource for monitoring food products over a while. This leads to identifying changes in products over time and the ability to compare analytical results quite easily.

Confidence is important because many important decisions can be based on laboratory results, and wrong decisions can have serious consequences. Whether it is health services, water and food quality, medicine, personal consumption items, the public sector provides a structure that should ensure that products and services are safe and that the environment in which we live is clean and healthy. Accreditation limits the need for increased state control over industry and other activities. It provides alternative ways and means of ensuring the confidentiality of activities that have the potential to affect public confidence and safety. The signing of the EA MLA (https://ilac.org/ilac-mra-and-signatories/) supports the provision of local or national services, such as providing safe food and clean drinking water, providing energy, delivering health and social care or maintaining an unpolluted environment.

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Резиме

Официјална контрола на безбедност и квалитет на храната, барања за национална референтна лабораторија

Тони Мицков[1*], Билјана Бауер[2]

[1]Ј.З.У.Институт за јавно здравје на Република Северна Македонија, Ул. „50 ma Дивизија“ бр.6, 1000 Скопје Република Северна Македонија
[2]Фармацевтски факултет, Универзитет „Св. Кирил и Методиј“, Мајка Тереза 47, 1000 Скопје, Република Северна Македонија

Клучни зборови: безбедност на храна, квалитет на храна, систем за управување со квалитет, референтна лабораторија, акредитација

Обезбедувањето на безбедна храна е заедничка одговорност на многу засегнати страни. Секој учесник во синџирот на исхрана: од производителите во примарното производство, индустриските производители и преработувачи, дистрибутерите и продавачите на храна, органите за контрола на безбедноста и квалитетот, научната заедница се до крајните потрошувачи, соодветно, имаат свој удел во обезбедувањето на безбедна храна. Развивањето на систем за управување може подобро да гарантира дека храната е безбедна и со добар квалитет. Законот за безбедност на храна воспоставува интегриран систем на официјални контроли за безбедност на храната, мониторинг и други активности за управување со синџирот на исхрана, кој ги опфаќа сите фази на производство, преработка и дистрибуција. Каде што се произведува, преработува или пушта во оптек храна, надлежните органи вршат редовни контроли и според план или сомневање земаат мостри за испитување во официјални лаборатории. Важен дел од системот за контрола на храната е лабораториската анализа. Анализата на храната ја вршат производителите, добавувачите, истражувачки лаборатории, референтни и овластени лаборатории. Со лабораториско тестирање на храната, сите засегнати страни добиваат информации за различни параметри кои влијаат на безбедноста и квалитетот на храната, како што се составот, структурата, физичко-

хемиските својства и сензорните карактеристики. Една од најважните причини за анализа на храната е да се увериме дека е безбедна и хранлива и дали ги исполнува посакуваните стандарди за квалитет. Микробиолошката и хемиската контаминација е тешко да се открие без тестирање. Лабораториите вклучени во анализата на официјалните примероци треба да работат и да бидат акредитирани според меѓународниот стандард EN ISO/IEC 17025 „Општи барања за компетентност на лабораториите за тестирање и калибрација“. Целта на овој труд е да ги разгледа основните принципи на контрола на храната, со посебен осврт на барањата за работа на националните референтни лаборатории. Оваа дескриптивна студија ги опишува законските барања на официјалната контрола на храната во Европската Унија. Фокусот на овој труд е на имплеметацијата на систем за управување со квалитет во национална референтна лабораторија за контрола на храната.