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Abstract:

The outcomes of the project support the establishment of a more structured commercial offer for plant health diagnostic through the establishment of the European Plant Diagnostic Industry Association (EPDIA) and the creation of a Quality Charter for commercial products production and validation in plant health diagnostic. This document defines the quality procedures for the validation and the production of EU commercial tests for plant pests diagnosis.

The EPDIA Quality Charter is based on six pillars: legal framework, quality system, quality procedures for products development and validation, quality procedures for products manufacturing, communication and marketing ethics and sustainability and social impact. The application of the EPDIA Quality Charter will contribute to guarantee end-users of the quality of manufacturers' working processes and the reliability, the quality and the performances of the commercial tests they use. The adhesion to this Charter and its application will permit EU SMEs to increase their competitiveness by ensuring the quality and the reliability of EU manufacturers' product worldwide.

Partners involved: IPADLAB, BIOREBA, LOEWE, EPPO, NIB, ULG, CD, WR (Prime Diagnostics), SEDIAG, GIORIN

TABLE DES MATIERES

INTRODUCTION **4**

1. SCOPE AND APPLICATION FIELD **5**

1.1 Scope 5

1.2 Application field 5

2 REFERENCES **5**

3 LEGAL FRAMEWORK **6**

3.1 National and international laws and regulations 6

3.2 GDPR (General Data Protection Regulation) 6

4 QUALITY MANAGEMENT SYSTEM **6**

4.1 Management responsibility: 6

4.2 Quality assurance 6

4.3 Quality audit 7

4.4 Personnel and infrastructure resources 7

5 QUALITY PROCEDURES FOR PRODUCT DEVELOPMENT AND VALIDATION **7**

5.1 New product/test development process 7

5.2 New product/test validation process 8

5.3 EPDIA validation datasheet 10

6 QUALITY PROCEDURES FOR PRODUCT MANUFACTURING **11**

6.1 Production procedures 11

6.2 Quality production certificate 12

6.3 Production staff 12

6.4 Equipment, maintenance, and calibration 13

6.5 Workspaces, environmental conditions and contamination control 13

6.6 Identification and traceability 14

6.7 Reagents and equipment purchase and supply procedures 14

6.8 Storage and handling procedures 15

6.9 Final product labeling 15

6.10 Packaging and distribution 16

6.11 Documentation 16

6.12 Customer satisfaction 16

7 COMMUNICATION AND MARKETING ETHICS **17**

8 SUSTAINABILITY AND SOCIAL IMPACT **17**

9 USE OF EPDIA QUALITY LOGO **17**

9.1 Use restricted to EPDIA members 17

9.2 EPDIA trademarks and reputation 17

9.3 End of EPDIA logo use 18

10 CONCLUSION **18**

APPENDIX **19**

INTRODUCTION

This Quality Charter has been established in the framework of the VALITEST project. One of the VALITEST project's main aims is to swiftly bring onto the market tests validated according to international standards and produced by SMEs that manufacture diagnostic kits. To achieve this goal, the Quality Charter describing the quality procedures for the development, the production and the validation of commercial products/tests produced by EU manufacturers has been developed. This Charter will contribute to guarantee the quality and the reliability of the products/tests to end-users worldwide.

The development and supply of plant diagnostic products/tests with 'state-of-art' quality to the agro-industry, to national reference laboratories and service laboratories in the agricultural sector is the key objective of the association EPDIA. The Quality Charter will be validated and approved by the EPDIA board and all the members of the association will have to adhere to the Quality Charter (hereafter "EPDIA Quality Charter"). The EPDIA Quality Charter describes the Quality Management System (QMS) including documentation processes, procedures, and responsibilities needed to ascertain a unify high standard in quality assurance and quality control (QA/QC) of the manufacturers' plant pest diagnostic products.

Key elements addressed in the EPDIA Quality Charter are legal framework, QMS, quality procedures for product development and validation as well as for manufacturing of the plant pest diagnostic products, product safety, open and transparent communications with end-users, authorities and society and how plant diagnostic manufacturers aim to conduct business in an ethical manner with respect to public health, safety and the environment.

1. SCOPE AND APPLICATION FIELD

1.1 Scope

The provisions of the EPDIA Quality Charter are addressed to all the companies developing and manufacturing plant pests' detection products/tests. The scope of the EPDIA Quality Charter covers the general required competences for the development, production and sale of high-quality diagnostics and detection kits.

Each manufacturer must establish and maintain a Quality Management System that is appropriate for the design, validation and/or production of plant pests' detection kits', and that meets the requirements of the EPDIA Quality Charter.

The commitment to the EPDIA Quality Charter must give confidence to the final user that the kits are designed, validated, produced and supplied according to high quality standards. Only manufacturers that follow the EPDIA Quality Charter requirements are entitled to use the EPDIA Quality Charter logo.

The EPDIA Quality Charter consists of the following components:

- DEVELOPMENT
- VALIDATION
- PRODUCTION
- PACKAGING
- DOCUMENTATION AND RECORDS FOR FULL TRACEABILITY
- USE OF THE EPDIA QUALITY CHARTER LOGO

1.2 Application field

The EPDIA Quality Charter may be applied by all organizations and/or companies which design and/or develop and/or produce diagnostics and kits for the detection of plant pests.

The compliance with national laws and regulations of the operations of the manufacturers is beyond the scope of this Quality Charter.

2 REFERENCES

The EPDIA Quality Charter was drafted following these international standards:

UNI CEI EN ISO/IEC 17025:2005	"General requirements for the competence of testing and calibration laboratories", 2005
EPPO PM 7/98 (4)	"Specific requirements for laboratories preparing accreditation for a plant pest diagnostic activity", 2019
EPPO PM 7/76 (5)	"Use of EPPO diagnostic protocols", 2018
UNI EN ISO 9001:2015	"Quality management system – Requirements", 2015
Good Manufacturing Practices (GMP)	World Health Organisation

3 LEGAL FRAMEWORK

3.1 National and international laws and regulations

Each manufacturer must know and apply the existing national rules and regulations on worker protection and safety, taxes, protection of the environment, social protection and all the rules and regulations needed for their business operations. The Charter is based on a voluntary adhesion. The compliance with National and/or EU laws and regulations on the correct operations of manufacturers is beyond the scope of this Charter.

3.2 GDPR (General Data Protection Regulation)

Each manufacturer must comply with the requirements of GDPR by securing personal data, such as those of their employees and customers in accordance with the specific regulations, including their sensitivity.

Each manufacturer guarantees that its employees treat sensitive data confidentially.

4 QUALITY MANAGEMENT SYSTEM

The Quality Management System (QMS) defines the documents, processes, procedures, and responsibilities needed to achieve the quality objectives of an organization. The QMS helps to coordinate and organize the company's activities to meet regulatory and customer requirements and to improve its effectiveness and efficiency on a continuous basis.

In order to adhere to the EPDIA Quality Charter, a company does not need a pre-defined QMS. Each manufacturer can establish its own QMS procedures (e.g. internal, ISO,…) as long as the adopted QMS procedures meet the requirements of the EPDIA Quality Charter. In case of non-appropriate or missing procedures, the manufacturer must implement these in their QMS.

4.1 Management responsibility:

The Quality Management System (QMS) defines the documents, processes, procedures, and responsibilities needed to achieve the quality objectives of an organization. The QMS helps to coordinate and organize the company's activities to meet regulatory and customer requirements and to improve its effectiveness and efficiency on a continuous basis.

In order to adhere to the EPDIA Quality Charter, a company does not need a pre-defined QMS. Each manufacturer can establish its own QMS procedures (e.g. internal, ISO,…) as long as the adopted QMS procedures meet the requirements of the EPDIA Quality Charter. In case of non-appropriate or missing procedures, the manufacturer must implement these in their QMS.

4.2 Quality assurance

Quality assurance (QA) processes are implemented to guarantee that all products are produced and controlled according to quality standards. QA processes are aimed at diminishing the risks inherent to production. QA ensures that all the manufacturing processes are clearly defined, the validation is performed and that all necessary resources are provided including qualified and trained personnel, adequate workspaces, suitable equipment and services, appropriate materials, labels, approved procedures and instructions, suitable facilities for storage, etc. The EPDIA Quality Charter contains all the criteria of QA to be applied in plant health diagnostic products/tests production.

4.3 Quality audit

Each manufacturer must, periodically and in accordance with the determined procedure, conduct audits of its activities to verify that the company's operations continue to comply with the requirements of the established QMS. Quality audits can be conducted internally or externally in accordance with the requirements of the QMS.

Each manufacturer establishes and maintains procedures to control that the requirements of the established QMS are met. In case of non-conformity to the established QMS, the manufacturer takes corrective actions. The corrective actions procedures must address the identification, documentation, evaluation, and correction of non-conforming product. The non-conformity evaluation and any investigation must be documented.

In case non-conformity in production is observed, the manufacturer must apply specific internal procedures to manage its resolution.

4.4 Personnel and infrastructure resources

All manufacturer's operations are performed by qualified personnel with the required skills, background and experience to ensure that its activities meet the QMS requirements.

Each manufacturer ensures that their staff is well trained and plans training sessions according to their staff needs. According to the QMS requirements, each member of the staff has appropriate responsibility and is accountable for the specific activities that they must perform.

The company must have managerial and technical personnel who have the appropriate authority and resources needed to carry out their tasks, including the implementation, maintenance and improvement of the Quality Management System.

5 QUALITY PROCEDURES FOR PRODUCT DEVELOPMENT AND VALIDATION

This section indicates all the steps to be followed by manufacturers in the development and validation process of new products/tests.

In order to bring coherence to the development and validation process for all types of products/tests, this chapter focuses on the criteria that must be fulfilled during products/tests development and validation of all assay types (serological methods, molecular methods, etc.).

Each manufacturer must ensure that all the development and validation processes are kept under control through a suitable and accurate management of all the process steps. Each manufacturer conducts, controls, and monitors their development and validation processes to ensure that new products/tests are conform to their own specifications.

5.1 New product/test development process

To develop new products/tests according to EPDIA Quality Charter, each manufacturer must define the scope of the new product/test, design it and optimize the test on which the new product/test is based.

a. Scope of the new product/test:

The manufacturer must define the scope of the new product/test and follow the suitable steps in the development process. By defining the scope, the manufacturer must identify and establish the factors/variables that can influence the new product/test performances. The main variables are the type of sample (e.g. individual or pooled, matrix, host/organism interactions affecting the target quantitatively or qualitatively), the type of test and the interpretation of its results.

b. Design of the assay

The manufacturer must design the test's protocol used in the product/test based on the variables that can affect and/or influence the test's performance. To design the new test accurately, the manufacturer must use suitable and accurate procedures and tools. In particular, the development of new product/test depends on the availability of reference material samples that reflect the target organism and the matrix in which the organism is found. For the design of the assay the manufacturer must identify and use proper reference material that will also be used in the validation process.

c. Optimization of the product/test

Optimization is the process by which parameters of the product/test are evaluated and adjusted to ensure that the performance characteristics are reached. For this purpose, the manufacturer must use identified and reliable reference material samples. The manufacturer can obtain the reference material by external sources (e.g. national reference collections). When such reference material is difficult to obtain, the manufacturer can prepare the reference material internally (e.g. by spiking a sample with a known amount of the target or by diluting a high positive sample in a negative sample). Each manufacturer must ensure that all the optimization processes are kept under control through a suitable and accurate management of all the process steps. Each manufacturer conducts, controls, and monitors optimization processes to ensure that new products/tests comply with their own specifications.

5.2 New product/test validation process

The validation process determines the fitness of a new product/test that has been correctly designed, developed and optimized for its intended use. Besides, product/test validation provides an assurance of reliability for normal intended use.

The validation process allows to obtain the analytic and diagnostic performance data of a product/test. In the context of EPDIA Quality Charter, the performance criteria for plant health diagnostic are indicated hereafter.

1. Reference material

For a proper validation process, certified or appropriate reference material must be used by the manufacturer (e.g. living cultures, infected plant material, DNA/RNA preparations). The reference materials used should be documented and appropriate to the product/test scope being performed. The reference material can be provided by a competent producer (e.g. national or private reference collections). If possible, certified biological reference material should be used, from which biological reference material, and subsequent working material, can be produced. Unfortunately, such material is not always available. In this case, the manufacturer may also produce its own reference material (e.g. by spiking a sample with a known amount of the target in the matrix or by diluting a high positive sample in a negative sample).

The manufacturer must ensure that the choice and sources of reference materials for its evaluation should reflect the product/test scope and test's type.

Manufacturers can provide the reference material data by fulfilling the requirements set in EPPO standard. When reference material data are indicated in the EPDIA validation datasheet, the manufacturer must always indicate the reference material sources (see article 5.3).

2. Analytical specificity:

Analytical specificity is defined as the ability of a product/test to distinguish the target (e.g. antigen, organism or genomic sequence) from other non-targets, whether related or not, and the degree of the product/test to distinguish known variants of the target.

Analytical specificity includes inclusivity (the performance of a test with a range of target organisms covering genetic diversity, different geographical origin and hosts) and exclusivity (the performance of a test with regards to cross-reaction with a range of non-targets: e.g. closely related organisms, contaminants).

The assessment of the analytical specificity is qualitative, and the manufacturer must ensure that the choice and sources of samples for its evaluation should reflect the product/test scope.

The manufacturer can provide the analytical specificity data by fulfilling the EPPO PM 7/98 requirements and/or by following specific internal procedures and/or by providing external sources results (e.g. projects, TPS). When the analytical specificity information is indicated in the EPDIA validation datasheet, the manufacturer must always indicate the data sources (see article 5.3).

3. Diagnostic specificity

Diagnostic specificity is defined as the ability of a product/test to detect uninfected samples (true negatives) testing negative compared to results from another test.

To assess the diagnostic specificity, the manufacturer must ensure the choice and sources of infected samples and uninfected reference samples to obtain the proportion of samples from known uninfected reference samples that test negative in the evaluated product/test.

Manufacturers can produce the diagnostic specificity data by following the EPPO PM 7/98 requirements and/or by following specific internal procedures and/or by providing external sources results (e.g. projects, TPS). When the diagnostic specificity information is indicated in the EPDIA validation datasheet, the manufacturer must always indicate the methodology applied to obtain the data (see article 5.3).

4. Analytical sensitivity

The analytical sensitivity is the smallest amount of target that can be detected reliably by a product/test. It is referred to as the limit of detection (LOD) that is the estimated amount of target in a specified matrix that would produce a positive result.

To assess the analytical sensitivity, the manufacturer must ensure the choice and sources of infected samples to obtain the proportion of smallest amount of target that can be detected reliably in the evaluated product/test.

Manufacturer can produce the analytical sensitivity data by following the EPPO PM 7/98 requirements and/or by following specific internal procedures and/or by providing external sources results (e.g. projects, TPS). When the analytical sensitivity information is indicated in the EPDIA validation datasheet, the manufacturer must always indicate the methodology applied to obtain the data (see article 5.3).

5. Diagnostic sensitivity

The diagnostic sensitivity is the proportion of infected/infested samples tested positive by a product/test compared to results from alternative test (or combination of tests).

Diagnostic sensitivity = true negatives/(true negatives + false positives)

To assess the diagnostic sensitivity, the manufacturer must ensure the choice and sources of samples and the choice of the alternative test.

Manufacturer can produce the diagnostic sensitivity data by following the EPPO PM 7/98 requirements and/or by following specific internal procedures and/or by providing external sources results (e.g. projects, TPS). When the diagnostic sensitivity information is indicated in the EPDIA validation datasheet, the manufacturer must always indicate the methodology applied to obtain the data (see article 5.3).

6. Reproducibility

The reproducibility is defined as the ability of a product/test to provide consistent results when applied to aliquots of the same sample tested under different conditions (e.g. time, persons, equipment, location). Repeatability along with reproducibility provide information on the level of uncertainty of the product/test result. Reproducibility can be assessed through internal control and/or by external quality control programs such as proficiency testing (see article 5.3).

When the reproducibility information is indicated in the EPDIA validation datasheet, the manufacturer must always indicate the control method chosen to obtain the data (see article 5.3).

7. Repeatability

The repeatability indicates the level of agreement between replicates of a sample tested under the same conditions. Repeatability is estimated by evaluating variation in results between replicates. Repeatability along with reproducibility provide information on the level of uncertainty of the product/test result.

When the repeatability information is indicated in the EPDIA validation datasheet, the manufacturer must always indicate the control method chosen to obtain the data (see article 5.3).

5.3 EPDIA validation datasheet

Manufacturers that adhere to EPDIA Quality Charter are authorised to produce EPDIA validation datasheets on their own products/tests. The veracity of the data and information indicated in the technical sheet is the responsibility of the manufacturer and EPDIA cannot be held responsible for that information.

Once performance characteristics for a product/test become available, the manufacturer can produce a EPDIA validation datasheet (see appendix) including as much as possible data that are available for each product/test among the following criteria: analytical specificity, analytical sensitivity, reproducibility, repeatability, reference material and other performance criteria (e.g. diagnostic sensitivity, diagnostic specificity).

To fulfil the EPDIA Quality Charter requirements, each manufacturer must supply to the final end-user a EPDIA validation datasheet including at least the following information: analytical specificity, analytical sensitivity, list of tested isolates (detected and not detected), and cross reactions. The manufacturer must clearly indicate if data are not available for a specific criterion. The EPDIA validation datasheet includes 5 parts.

1. Information on the kits and manufacturer

Each manufacturer must clearly indicate the following information on the kit:

Product/test code	*indication of the product/test code*
Product/test description	*brief description of the product and the technology used*
Manufacturer	*manufacturer contact and address*

2. General information on the assay

Each manufacturer must indicate the following general information on the kit.

Target Organism(s)	*pests' name (e.g. Meloidogyne chitwoodi)*
Method	*information of the method (e.g. "Real-Time PCR, based on detection of a fluorescent dye" or "ELISA")*
References	*link or details (e.g. internal validation, validation following EPPO PM7/98 requirements, publications, ring test, TPS, EPPO datasheet…)*

3. Scope

Each manufacturer must indicate the scope of the product/test and the matrix on which it has been validated. If relevant, the tested species must be indicated.

Scope	*information on the scope of the product/test (e.g. identification of plum pox virus by DAS ELISA.)*
Matrix	*information on the tested matrix (e.g. leaves, wood, roots, seeds. flowers…)*
Tested species	*list of the tested plant species (if relevant)*

4. Validation performance characteristics

Each manufacturer must indicate the analytical specificity, the cross reaction and the diagnostic specificity if the data are available.

Analytical specificity	*data indicated in %, list of tested target and non-target organisms tested indicate the source or methodology*
Cross reaction with	*list of species*
Analytical sensitivity	*LOD data indicated or "no data available"*
Reproducibility	*data indicated in % or "no data available"*
Repeatability	*data indicated in % or "no data available"*
Other performance characteristics	*e.g. data on diagnostic specificity, diagnostic sensitivity,…*

5. Reference material

Each manufacturer must indicate the type of reference material and the type of control used.

Type of reference material	*indicate the most information available on the type of positive samples used for validation (e.g. leaves of plant, nematode suspension, greenhouse material, strain collections)*
Reference material control	*indicate how the reference material was controlled and by whom (e.g. control with alternative test, strain collection number)*

6 QUALITY PROCEDURES FOR PRODUCT MANUFACTURING

6.1 Production procedures

a. Quality process

Each manufacturer must ensure that all the production processes are kept under control through a suitable and accurate management of all the production process steps.

Each manufacturer conducts, controls, and monitors production processes to ensure that final products comply with their specifications. Each manufacturer establishes and maintains procedures for controlling process criteria for validated products to ensure that the specified requirements continuously will be met. The manufacturer establishes control procedures that describe how the conformity to the specifications is ensured. The Quality Management System documentation of the manufacturer includes SOPs, instructions, and methods that describe the production control procedures.

b. Production procedures changes

Each manufacturer establishes and keeps procedures for changes to a specification, method, process or procedure. When the manufacturer operates any change in the production procedure or any process deviation occur, the manufacturer must review or re-evaluate the process. These activities must be documented.

Each manufacturer must have its own procedures that must be implemented when any aspect of its production or the performance of the final product does not meet the quality requirements.

6.2 Quality production certificate

Each manufacturer performs a test of the product quality in order to control that the final product supplied to the customer meets the requirements in terms of quality and performance. If the final product does not meet these requirements, the manufacturer must not supply the final product. Each time that the test of the product quality fulfils the requirements, the manufacturer must produce a certificate of quality that includes specific information for the customer. To fulfil the EPDIA Quality Charter requirements, each manufacturer must supply to the final end-user a quality certificate sheet including at least the following information:

- number and date of the certificate;
- name of the product;
- catalogue reference;
- method;
- format;
- batch number;
- expiration date;
- storage conditions;
- quality control results: the quality control must include at least the testing of a positive control, a negative control and a water/buffer control. As positive control, the manufacturer must use reference material (see the definition of “reference material” in article 5.2).

The quality production certificate can contain additional information according to the wishes of each manufacturer. The use of the EPDIA Quality Charter logo on the quality control sheet is only authorised if all the listed information above is indicated on it.

6.3 Production staff

Each manufacturer must identify, define and regularly control staff competences, staff procedures, staff training and staff education.

a. Production staff competence

In order to maintain and control the production process to guarantee the quality of the production, each manufacturer must implement control procedures on staff involved in the production. The manufacturer management must ensure the competences of all the staff operating with specific equipment, performing the production, calibrating the equipment, and evaluating results.

b. Staff training and education

The manufacturer management must also identify and formulate the objectives for the education, the training and the skills evaluation of the personnel involved in the production. Manufacturer ensures that the production staff is professionally trained and supervised to guarantee that all activities and/or procedures are correctly performed according to the manufacturer's quality system.

c. Production staff procedures

Each manufacturer must establish procedures for proper handling of materials and equipment by production staff if contact between such staff and the products or the environment can reasonably be expected to have an adverse effect on the quality of the product.

d. External production staff

The manufacturer must ensure that external personnel that is temporarily required to work in the production process is appropriately trained and follows the procedures indicated in the Quality system.

6.4 Equipment, maintenance, and calibration

a. Use of equipment:

The laboratory must be provided with all equipment required for the correct execution of the production activities. Each manufacturer ensures that all the equipment used in the manufacturing process meets specified requirements and are appropriately used by qualified and trained staff. All the equipment position must be documented.

b. Equipment maintenance

Each manufacturer ensures that all the equipment is appropriately cleaned and maintained by qualified and trained staff to ensure that manufacturing specifications are met. Maintenance activities, including the date, must be documented in the Quality system.

c. Equipment calibration

Each manufacturer ensures that all the equipment is appropriately calibrated by qualified and trained staff to ensure that manufacturing specifications are met. The calibration procedures include specific limits for accuracy and precision. If they are not met, the manufacturer must have procedures to remediate in order to re-establish the correct limits. Each manufacturer plans the calibration activities considering conditions of the equipment use, frequency of use, accuracy required, and other conditions where they are requested.

All equipment used for production and/or calibrations having a possible effect on the performance of the final product must be calibrated before being put in service.

Calibration activities, including the date, must be documented.

d. External equipment

The manufacturer must ensure that external equipment required to produce temporarily is controlled, properly maintained, and used by trained and qualified staff.

6.5 Workspaces, environmental conditions and contamination control

a. Workspaces

Each manufacturer must well define the workspaces to perform and maintain operations isolated from each other that could have undesirable effects of one on the other. In the case that different operations are performed in the same workspace, the manufacture must establish control procedures to prevent undesirable effects between such operations. All the operating area definitions must be documented.

b. Environmental control

When environmental conditions can have an undesirable effect on product quality, the manufacturer must establish and maintain procedures to adequately control these environmental conditions. Environmental control procedures must be periodically checked to verify that all production processes work properly. All these activities must be documented and reviewed.

c. Contamination control

Each manufacturer establishes and maintains procedures to prevent contamination of equipment or product by materials that could reasonably be expected to have an undesirable effect on product quality.

6.6 Identification and traceability

Product traceability allows the knowledge of the complete history of all batches of products from the starting materials to the final product. Each manufacturer establishes and maintains procedures and documentation for identifying each kit's components and/or each reagent during all the production stages from the receipt, the storage, the production, and the distribution to prevent mixing, contamination and control shelf life.

Each component/material is identified and controlled at receipt.

All final products are identified with a unique code including the unique batch number for the product identification. The product identification is noted on the Certificate of Quality of the final product.

The traceability from all the reagents used in the production process must be documented.

6.7 Reagents and equipment purchase and supply procedures

a. Supplier identification

Each manufacturer establishes quality criteria for the choice and the management of reagent and equipment suppliers based on requirements that meet with the Quality system. Each manufacturer will choose their suppliers based on their ability to meet the manufacturer's needs. Each manufacturer has a procedure for the selection of suppliers of reagents and equipment.

b. Suppliers' evaluation

Each manufacturer evaluates suppliers for critical consumables and services which can affect the quality of the production. Each manufacturer re-evaluates suppliers periodically and these evaluations have to be listed and recorded.

c. Purchasing procedures

Each manufacturer must have procedures to guarantee that all incoming and purchased products are conform to their specific requirements.

The company must maintain purchasing data in order to ensure traceability of their production processes.

d. Checks on purchased products and equipment

Products and equipment supplies must be verified to comply with the conditions described by the supplier. Incoming products and equipment must be checked upon their arrival at the manufacturer. All reagents and equipment must be supplied with a data sheet with the conditions indicated by the supplier and they must comply with what has been announced by the supplier in terms of useful expiration date, storage, working conditions and performance.

e. Non-conformity in supply

In case of non-conformity in supply identified after the control procedures of the reagents or equipment received and their performance, the manufacturer must put in place all the corrective actions that are necessary to correct the non-conformity.

6.8 Storage and handling procedures

Each manufacturer ensures that reagents and other material/equipment are stored in appropriate areas, in order to maintain their effectiveness.

a. Storage of equipment

Each manufacturer must store equipment in accordance with the conditions indicated by the suppliers and compatible with the production activity of the producer in order to operate optimally and avoid any possible damage, deterioration and interference or risk of contamination with other equipment.

b. Storage of reagents

Each manufacturer must store reagents and materials in accordance with the conditions indicated in the data sheet by the suppliers and compatible with the production activities of the producer in order to operate optimally and avoid any possible damage, deterioration or risk of contamination with other reagents/materials. In particular, reagents and material management include control of the optimal reagent temperature, optimal place for storage, optimal time for storage, separate used spaces and storages in order to avoid cross contamination. Each manufacturer must document the place of storage of single reagents.

c. Storage of preparations

Each manufacturer must label reagent preparations with essential indication and characteristics (e.g. concentration, expiring date…). For the preparation of reagent preparations, manufacturers must have a written unique data sheet indicating the protocol of preparation. All reagent preparations must be stored following their specific conditions and their technical characteristics.

d. Storage of reference materials

Each manufacturer stores the reference materials in appropriate areas in order to avoid any possible damage or contamination that could affect the efficiency. Each manufacturer must have documentation listing and indicating the place and conditions of storage of each of the individual reference materials.

e. Storage of final products

Each manufacturer must store their final products in accordance with the optimal conditions avoiding any possible damage, deterioration, or risk of contamination with other reagents/materials. Final product storage management include control of the optimal reagent temperature, optimal place for storage, optimal time for storage, separate used spaces and storages in order to avoid cross contamination. Each manufacturer must have documentation indicating the place of storage of single final products.

f. Handling procedures

Each manufacturer must ensure that the staff dedicated to the production follow procedures to guarantee that mistakes, deterioration, contamination or other undesirable effects to equipment, reagents and final products do not occur during handling of equipment, reagents and/or final products.

6.9 Final product labeling

Each manufacturer must establish procedures to control labelling operations.

a. Label integrity

Each manufacturer must ensure that labels are printed and applied on final products. The label integrity must be ensured during all the handling and use phases such as shipment, handling and storage.

b. Label contains

The final products label must include all the needed information for customers use and handling such as name, code, lot or batch number, storage conditions, expiring date or shelf life, typology and number of tests.

In the case of final products developed and produced according to EPDIA Quality Charter, manufacturer is allowed to use and affix the logo of EPDIA Quality Charter as indicated in article 10 of the present charter.

6.10 Packaging and distribution

Each manufacturer must maintain shipping and packaging procedures and conditions to ensure that products maintain their performance and shelf life upon arrival at the customer.

a. Product packaging integrity

Each manufacturer selects packaging boxes in order to ensure the integrity of the packaging during the shipment and to maintain the performance of the final product throughout all the processes of storage, handling and distribution during the shelf life indicated on the label.

b. Product packaging content

Each manufacturer must include in the final product packaging all the needed information for the customer to store, handle and use of the final product. The data sheet for use and the Certificate of Quality of the final product must be included in the packaging. Upon request of the customer, the manufacturer must be able to send the electronic format of the data sheet and/or the Certificate of Quality.

The data sheet must include at least the following information: name of the kit, typology and number of tests, protocol of use and references, if available.

The Certificate of Quality must include at least the following information: name of the kit, typology and number of tests, test performance results, batch number.

c. Distribution

Each manufacturer selects adequate packaging material and shipping conditions in order to ensure the integrity of the final product packaging and the preservation of the final product performance during the shipment. Each manufacturer should keep distribution records that include the name and address of the first recipient, the quantity of kit shipped, and the date of shipment.

6.11 Documentation

Responsibility and operating modes for the control of production processes are at the discretion of the company. All the production process criteria indicated in the EPDIA Quality Charter must be documented.

The company must establish and maintain procedures to control all documents that are part of its management system (internal documents or from external sources), such as regulation, standards, other normative documents.

The disclosure and use of the documents are carried out in accordance with the internal rules of the company to satisfy customer's requirements. Some documents can be made available in read-only mode upon request from customers.

6.12 Customer satisfaction

In order to guarantee the customer’s satisfaction, manufacturers must identify process problems and solve them.

a. Complaints

Each manufacturer must have a policy and procedure for the resolution of complaints received from customers or other parties. Records must be maintained of all complaints and of investigations and corrective actions taken.

Following the receipt of a complaint from a customer, the manufacturer ensures that the complaints, either oral or written, are registered and processed in a timely manner.

b. Corrective actions

Each manufacturer establishes procedures to correct potential causes that require corrective actions such as customer complaints or requirements.

All corrective actions and their results must be documented.

7 COMMUNICATION AND MARKETING ETHICS

Each manufacturer ensures that the importance of meeting customer requirements as well as compliance with statutory and regulatory requirements is clearly communicated to its staff.

Each manufacturer must promote a transparent approach with the customers by committing to provide to the customers clear, complete and verified information.

In carrying out their business, each manufacturer undertakes to behave with suppliers, competitors, customers, regulatory agencies and the general public in an ethical and respectful manner, in accordance with the laws and regulations of each country in which they carry out their activities, avoiding situations of conflict of interest and preserving confidentiality.

8 SUSTAINABILITY AND SOCIAL IMPACT

Each manufacturer must act as a responsible citizen company throughout responsible purchasing, respecting the environment and respect individual's safety, health rights and dignity.

By adhering to the EPDIA Quality Charter, each manufacturer must:

- provide safe and effective products,
- produce, pack and label products and materials in a safe and effective way,
- operate with respect for the environment,
- operate with respect for the animals,
- operate with respect for public health and safety.

9 USE OF EPDIA QUALITY LOGO

9.1 Use restricted to EPDIA members

The use of the EPDIA logo is granted to EPDIA members which comply with all the requirements set out in the EPDIA Quality Charter. The EPDIA logo may be used exclusively by the legal entity member of EPDIA in accordance with the requirements set out in the EPDIA Quality Charter.

All others are not allowed to use the EPDIA logo.

The EPDIA logo can be used only in advertisements, packaging, promotional and marketing of final products validated and produced that comply with all requirements set out in the EPDIA Quality Charter.

9.2 EPDIA trademarks and reputation

For end-users, laboratories and growers, EPDIA means quality, confidence, trust, safety and other positive brand values. That is why EPDIA members must care about how EPDIA trademarks are used and whether unauthorized use of the EPDIA trademarks could mislead, create false impressions, or cause confusion.

EPDIA and its members must take appropriate action if they consider the misuse of EPDIA trademarks puts our reputation at risk.

9.3 End of EPDIA logo use

The EPDIA logo may only be used if the manufacturer is member of EPDIA. If the manufacturer does not maintain its membership, or if its membership has expired or is terminated, the licence granted by this Charter will automatically terminate with respect to the use of the EPDIA logo and the manufacturer must immediately discontinue the use of the EPDIA logo and destroy all materials bearing the EPDIA logo.

10 CONCLUSION

The EPDIA Quality Charter will be approved by EPDIA board and it will be available on the website of the association by month 41 (www.epdia.eu).

All companies that will adhere to the EPDIA Quality Charter will have to follow the Charter in their daily operations and apply the Charter's rules in accordance with their national legislation. The EPDIA Quality Charter will be applicable for all organizations producing plant pest diagnostic products/tests, regardless of the number of personnel. Adherence to the EPDIA Quality Charter will be on a voluntary basis and it will imply compliance with the guidelines of the EPDIA Quality Charter, allowing the use of the EPDIA logo on products/tests. All products/tests labelled with the EPDIA logo will be developed and produced in accordance with the requirements of the EPDIA Quality Charter.

The EPDIA Quality Charter is an open and 'living' document, that can be adjusted to new requirements of end-users, members or institutions or to new European legislation. EPDIA will have the role of managing and implementing the current Quality Charter.

APPENDIX

VALIDATION DATASHEET

MANUFATURER'S LOGO

Member of the European Plant Diagnostic Industry Association

This validation data sheet has been produced following the recommendation of EPDIA quality Charter.
For more information, please, visit EPDIA website (www.epdia.eu)

PRODUCT/TEST CODE	*indication of the product/test code*
Product/test description	*brief description of the product/test and the technology used*
MANUFACTURER	*manufacturer contact and address*

GENERAL INFORMATION

Target Organism(s)	*pests' name (e.g. Meloidogyne chitwoodi)*
Method	*information of the method (e.g. "Real-Time PCR, based on detection of a fluorescent dye" or "ELISA")*
References	*link or details (e.g. internal validation, validation following EPPO PM7/98 requirements, publications, ring test, TPS, EPPO datasheet…)*

SCOPE

Scope	*information the scope of the product/test (e.g. identification of Plum Pox virs by DAS ELISA.)*
Matrix	*information on the tested matrix (e.g. leaves, woods, roots, seeds, flowers…)*
Tested species	*list of the tested plant species (if relevant)*

PERFORMANCE CHARACTERISTICS

Analytical specificity *(ability of the product/test to distinguish the target organism from other organisms and the degree in which the product/test can distinguish known variants of the organism)*	*data indicated in %, list of tested target and non-target organism tested indicate the source or methodology*
Cross reaction with	*list of species*
Analytical sensitivity *(limit of detection)*	*data indicated in % or "no data available"*
Reproducibility *(ability of the kit to provide consistent results when applied to aliquots of the same sample tested under different conditions)*	*data indicated in % or "no data available"*
Repeatability *(the level of agreement between replicates of a sample tested under the same conditions)*	*data indicated in % or "no data available"*
Other performance characteristics	*e.g. diagnostic sensitivity, diagnostic sensitivity*

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