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On the basis of Articles 61, 66 and 68 of the Act on plant health (Official Gazette of the Republic of Slovenia, No 45/01) the Minister of Agriculture, Forestry and Food hereby issues these

RULES
On conditions with regard to professional, spatial and technical qualification of laboratories for carrying out laboratory tests with a view to diagnosing harmful organisms

Article 1
(content)

These Rules shall regulate the conditions with regard to professional, spatial and technical qualification of laboratories for carrying out laboratory tests (hereinafter referred to as: “tests”) of samples with a view to diagnosing harmful organisms, the notification system and the form of test reports to be issued by laboratories.

Article 2
(definitions)

The terms used in these Rules shall have the following meaning:

– “laboratory” shall mean a body carrying out tests of samples with a view to diagnosing harmful organisms;

– “sample” shall mean a certain quantity of plants, plant products, soil, harmful organisms, or any other organism, object or substance, which may contain or spread harmful organisms;
– “official sample” shall mean a sample taken by a competent inspector or a legal or natural person carrying out public authorisation or public service under the Act on plant health;
– “test” shall mean technical operation including determination of one or more characteristics of a given sample under the specified procedure;
– “diagnostic method” shall mean technical procedure with a view to carrying out the test;
– “harmful organism” shall mean an organism belonging to the animal or plant kingdom, a viruses, mycoplasma (phytoplasma) or other pathogen harmful to plants or plant products;
– “quality assurance system” shall mean an internal system for managing the organisation of the laboratory with a view to carrying out specific tests in such a way so as to ensuring permanent effectiveness of the set system;
– “test report” shall mean a document issued by a laboratory, stating accurately, clearly and unambiguously the analytical result with test results, and other prescribed data related to the test.

Article 3
(laboratory)

(1) Laboratory shall carry out tests of samples taken by a legal or natural person (furtheron as: “the orderer”) or by itself on the basis of a programme approved by the Administration of the Republic of Slovenia for plant protection and seeds (furtheron as: “the Administration”).

(2) The laboratory shall register each received sample under a corresponding identification number in order to enable its traceability during the test procedure.

(3) After having executed the test, the laboratory shall provide the orderer with a test report (furtheron as: “the report”), on the basis of which the suspicion of the presence of a harmful organism is confirmed or ruled out, or shall state reasons for no results having been obtained by the test.

(4) All orderers shall be provided tests of equal quality and reliability of results. For this purpose the laboratory shall dispose of a list of tests and a price-list.

Article 4
(organisation)

(1) A laboratory can be an independent organisation or a part of a bigger organisation.

(2) The laboratory shall be organised for carrying out tests. It shall posses a document indicating:

– laboratory’s organisation and assignment of responsibilities;
– the name of the head of the laboratory;
– the name of the head of quality assurance;
– standard operational procedures for carrying out the test;
– Quality Rules in compliance with the third paragraph of Article 9 of these Rules.

(3) The document from the previous paragraph shall be kept up to date and shall represent actual situation of the organization and responsibilities.

Article 5
(personnel)

A laboratory shall have documentation indicating:

– to be provided with a sufficient number of personnel with appropriate professional education and training, and with technical knowledge and experiences as required for individual assigned working functions;
– description of working places and specifications of professional education, technical knowledge, training and experience for all personnel;
– that the laboratory and its personnel are not subject to any commercial, financial or other pressures, which may possibly effect their technical evaluation, and are not involved in any activity whatsoever, which could possibly cause the trust in independence of its evaluation and integrity of its activity to be jeopardised;
– that it provides for continuous improvement of the knowledge of its personnel.

Article 6
(premises)

(1) Validity of results shall not be jeopardised, or no negative impact shall be put on the requested test accuracy, by the environment in which the activity is performed. The premises for carrying out the activity shall be protected against excessive impacts of heat, moisture, steam, vibrations, etc. and shall be regularly maintained. Premises of enough space shall reduce the risk of damages or danger and the personnel shall be able to move free and efficient.

(2) All premises intended for carrying out the activity shall be accessible and serviceable so as to meet the purpose.

(3) Conditions for the access of persons who are not the employees of the laboratory shall be specified.

(4) Appropriate measures shall be established with a view to ensure tidiness and cleanness in the entire laboratory and so that all the equipment necessary for carrying out of the activity is accessible in the easiest way. Any special procedures in the connection therewith shall be documented.

Article 7
(equipment)

(1) Laboratory's equipment shall correspond to requirements for the proper carrying out of the tests.

(2) All equipment shall be maintained properly. All maintenance procedures shall be described in detail.

(3) Any part of the equipment or a device, which has been subject to overloading or mishandling, or which gives suspect results, or has been shown defective when calibrated or in any other way, shall be taken out of service and marked clearly as being out of service. It shall be kept at a place assigned in advance for such purpose until it will have been repaired and shown by means of a test or calibration to perform its functions satisfactorily. It is also necessary to examine the impact of such disorders on the previously performed tests.

(4) The laboratory shall, for each important part of the equipment, keep records including the following information:

- name of the device;
- name of producer, identification of the type and serial number;
- date of the receipt and date of the entry into service;
- current location if appropriate;
- technical condition at the time of receipt;
- detailed description of maintenance work carried out;
- description of breakdowns, malfunctions, modifications or repairs.

(5) Laboratory equipment, which is used in the laboratory and is intended for calibration, shall be calibrated prior to being delivered to usage. Further calibrations shall be carried out in accordance to the programme set for such equipment. Between regular calibrations, the laboratory equipment shall be, if necessary, subjected to additional checks.

(6) Laboratory equipment shall provide the required accuracy and shall correspond to all standard specifications, which are relevant for the tests concerned. Prior to using, the new equipment shall be subjected to calibration and checked whether corresponding to the relevant standard specifications.

(7) Personnel shall dispose of appropriate, up-to-date and written instructions for use of the equipment, together with manuals of producers of the equipment.

(8) All requirements laid down in this Article shall also apply for the equipment used indirectly (auxiliary equipment).

Article 8
(diagnostic methods)

(1) A laboratory shall use diagnostic methods, internationally recognized and correspondingly validated. Diagnostic methods for carrying out tests are defined in Standards of the European and Mediterranean Plant Protection Organisation – EPPO or in other normative documents, which may be provided by or are available at the Administration.

(2) In case when not-standardized diagnostic methods or other procedures are applied, these shall be properly documented.

(3) The laboratory shall participate in inter-laboratory comparative tests or its staff shall be a part of international diagnostic network in their specified field of work, wherever possible.

Article 9
(quality assurance system)

(1) A laboratory shall have an established quality assurance system, which corresponds to the kind, field and extent of the laboratory in compliance with Articles 3 and 4 of these Rules.

(2) Elements of the quality assurance system shall be documented in the Quality Rules, which shall be at the disposal for use by all personnel of the laboratory. An appointed responsible member of the laboratory's personnel shall take care of the Quality Rules to be amended and kept up-to-date.

(3) The Quality Rules shall include at least the following items:

- statement on quality policy;
- structure of the laboratory;
- operational and functional activities in relation to quality, so that each person participating in such activities is acquainted with the extent and limitations of his responsibilities;
- instructions in relation to quality assurance procedures, specific for each test, if appropriate;
- procedures to be followed in case if any member of the personnel acts, for whichever reason, contrary to the documented policy and procedures. When such deviation could possibly have impact on the tests' results, such procedures shall request the work to be stopped immediately, the samples concerned to be identified and properly separated or

eliminated. All necessary investigations and measures for eliminating defects in the procedure shall be carried out prior to proceeding with the work;

- procedures preventing harmful organism to be released into the environment;
- procedures for taking measures in case of the test orderer's disagreement with the results thereof.

(4) In order to ensure permanent efficiency of the set organization and initiate possible necessary measures for elimination of procedural errors, the management or its authorized persons shall systematically and periodically carry out examinations of the quality assurance system. Examinations including details on the measures for elimination of procedural errors shall be documented.

(5) Deviations from the documented policy and from the procedures or standard specifications may be allowed in cases when solid technical reasons therefor may be proved and when this shall not jeopardise the quality of the tests. Justification of the deviation shall be explained, together with the approval by the management, in all records concerned.

Article 10
(test report)

(1) After having concluded the test procedure, the laboratory shall issue a report, which shall include at least the analytical result in accordance with Article 11 of these Rules.

(2) The report may state also other data, separate from the analytical result and indicated as "Addition to analytical result" in accordance with Article 13 of these Rules.

(3) With regard to the kind of the test, the form of the report shall be as standard as possible.

(4) After the report has already been issued, amendments or supplements thereto shall be executed in such a way that a special document shall be drawn up, marked traceably, for example »Appendix to the test report no….".

Article 11
(analytical result)

(1) Analytical result shall contain at least the following information:

1. name and address of the laboratory and place of performance of the test, if different from that of the laboratory;
2. identification of analytical result (e.g. serial number);
3. name and address of the orderer of the test;
4. description and identification of the sample;

5. acceptance date of the sample and date(s) of carrying out of the diagnostic examination;
6. identification of the test's specification or description of diagnostic method or procedure;
7. each deviation from the test's specification, appendix to the specification or discharge of an item of the specification, as well as any other information important for a certain test;
8. identification of the applied not-standardised diagnostic methods or procedures;
9. test result in accordance with Article 12 of these Rules;
10. signature and name or a corresponding mark of a person(s), technically responsible for the analytical result, and the date of the analytical result;
11. statement that the results of the test refer only to samples, which have been examined;
12. statement that reproduction of the analytical report shall not be allowed without a written consent of the laboratory.

(2) The analytical result shall not contain any advices or recommendations arising from the results of the test.

Article 12
(test result)

(1) Test results referred to in point 9 of the previous Article may be measured values, findings of a visual examination, determinations, practical use of the sample, derived results or any other observation during the course of the test.

(2) Test results shall be presented in an accurate, clear, complete and unambiguous manner and in accordance with instructions, which may represent an integral part of diagnostic methods. On the basis of the test result, the suspicion of infection with a harmful organism shall be confirmed or rejected.

(3) Characteristics of a lot, series or quantity may be concluded from test results obtained from samples statistically selected from a bigger lot, series or quantity. Each extrapolation of the test's results on the characteristics of a lot, series or production quantity shall be stated in a separate document.

(4) If no results are acquired by the test, this shall be indicated in the analytical result and the reasons thereof shall be stated in the appendix to the analytical result in compliance with these Rules.

(5) If the laboratory receives an inadequate sample, it may reconsider the reasonableness of testing. If the test is not carried out this shall be indicated in the analytical result and the reasons thereof shall be stated in the appendix to the analytical result in compliance with these Rules.

Article 13
(appendix to analytical result)

The following data may be included in the "Appendix to the analytical result":

- measurements, researches and results, supported by tables, diagrams, sketches and photographs, as appropriate for a case concerned, as well as all irregularities observed;
- description of sampling procedure, where appropriate;
- advices and recommendations;
- other data.

Article 14
(notification)

(1) Orderer shall be delivered one copy of the report.

(2) Payer shall be delivered one copy of the report, if being other than the orderer.

(3) In the case of confirmed presence of a harmful organism from lists I.A and II.A of the Rules on protective measures with regard to the introduction, spread and suppression of organisms harmful to plants, plant products and other regulated articles (furtheron referred to as: "quarantine pests"), the laboratory shall immediately notify the competent inspector or authorised performer of public service thereof, as well as the Administration.

(4) In the case of the laboratory's first confirmation of a quarantine pest, it shall immediately notify the Administration and the Inspectorate of the Republic of Slovenia for agriculture, forestry, hunting and fisheries. Such sample shall be sent by the laboratory to another domestic or foreign laboratory with corresponding references for additional confirmation.

(5) First notification referred to in the third and fourth paragraph of this Article may be done by e-mail or telephone. Final notification shall be executed in the written form.

(6) In the case referred to in the third and fourth paragraph of this Article, when the sample has not been taken officially, the diagnostic laboratory shall inform the orderer to have notified the competent authorities of the finding.

Article 15
(public authorisation)

(1) A laboratory shall acquire public authorisation of the Administration of the Republic of Slovenia for plant protection and seeds so as to be permitted to carry out tests of official samples for quarantine pests.

(2) The laboratory shall be assigned public authorisation with a decision, issued by the Administration in accordance with the act governing plant health, for carrying out tests of official samples, provided it is organised as a public institution operating in the field of agriculture and forestry and having lodged a written application with the Administration

together with the Quality Rules and evidences on meeting the conditions laid down in these Rules.

(3) Other legal and natural persons shall be assigned public authorisation by the Administration on the basis of public tender.

Article 16
(public services)

(1) Laboratories shall carry out tests for diagnosis of non-quarantine pests as a public service if meeting general conditions laid down in particular in Articles 3, 5, 6, in the first and second paragraph of Article 7, in Articles 8, 10, 11, 12, 13 and 14 of these Rules.

(2) Public institutions operating in the field of agriculture and forestry shall be granted concession by the Administration in accordance with the act governing plant health, with a decision in an administrative procedure.

(3) Other legal and natural persons shall be granted concession by the Administration on the basis of public tender.

Article 17
(transitional provision)

Provisions of Articles 4, 9 and 15 of these Rules shall begin to apply on 1 January 2005, until this date tests shall be carried out by authorised providers of certain tasks of the public plant health service.

Article 18
(final provision)

These Rules shall take effect fifteen days after publication in the Official Gazette of the Republic of Slovenia.

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M.Sc. Franc But
Minister of Agriculture,
Forestry and Food