

**REGULATION No. 8 OF 31 OCTOBER 2013 SETTING OUT THE CONDITIONS
AND PROCEDURE FOR APPROVAL AND LICENSING OF NATURAL PERSONS
TAKING SEED SAMPLES (SAMPLERS) AND THE CONDITIONS AND PROCEDURE
FOR APPROVAL OF LABORATORIES TESTING THE USEFULNESS OF SEED
AND LABORATORIES TESTING THE HEALTH OF SEED
AND PROPAGATING MATERIAL**

Effective date 12 November 2013

Issued by the Minister of Agriculture and Food

*Promulgated, SG No. 98 of 12 November 2013, amended, SG No. 88 of 23 October 2018,
amended and supplemented, SG No. 45 of 7 June 2019*

**Chapter One
GENERAL PROVISIONS**

Article 1. This Regulation shall apply to:

1. the conditions and procedure for approval of persons taking samples;
2. the granting, refusal and revocation of licenses granted to natural persons taking samples (samplers);
3. the activities of natural persons (samplers);
4. the supervision of samplers by the official authority;
5. the conditions and procedure for approval of laboratories pursuant to Articles 7 and 8 of the Seed and Propagating Material Act (SPMA) for laboratory testing of the usefulness and, if appropriate, the health of agricultural plant species;
6. the granting, refusal and revocation of authorisations to carry out laboratory testing of the usefulness and, if appropriate, the health of agricultural plant species;
7. laboratory activities;
8. the supervision of laboratory activities;
9. this Regulation shall not apply to seed potatoes.

**Chapter Two
CONDITIONS AND PROCEDURE FOR APPROVAL OF NATURAL PERSONS
TAKING SAMPLES (SAMPLERS)**

Article 2. Any legally competent Bulgarian national, citizen of an EU Member State or third country national who holds a work permit granted by the Republic of Bulgaria may be licensed to take seed samples (as a sampler) provided that the person satisfies the following conditions:

1. (Repealed, SG No. 45/2019, effective date 07.06.2019)
2. a natural person (including a sole proprietor within the meaning of the Commerce Act) who is not employed under an employment contract; or
3. a person who is employed by a natural or legal person whose activity is not related to seed production and/or marketing; or
4. (Amended, SG No. 88/2018, effective date 23.10.2018) a person who is employed by a natural or legal person whose activity is related to seed production and/or marketing;
5. a person who has completed a specialised training course to acquire the qualifications required for samplers and has successfully passed the exam provided for in this Regulation.

Article 3. (1) The training for the acquisition of the qualifications required for samplers shall be organised and carried out by the Executive Agency for Variety Testing, Field Inspection and Seed Control (IASAS).

(2) (Supplemented, SG No. 45/2019, effective date 07.06.2019) The persons willing to complete the course and to acquire the qualifications of a sampler shall submit an application in writing to

the IASAS in the format approved by the Executive Director of the IASAS, which is set out in Annex No. 1. The application shall be submitted in person or by proxy or electronically pursuant to Articles 5 and 22 of the E-Government Act or via a licensed postal operator.

(3) The following shall be attached to the application referred to in paragraph 1:

1. (Repealed, SG No. 88/2018, effective date 23.10.2018)
2. (Repealed, SG No. 45/2019, effective date 07.06.2019)
3. a medical certificate;
4. a CV.

Article 4. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) (1) The application shall be reviewed by a committee appointed at an order of the Executive Director of the IASAS.

(2) (Amended, SG No. 45/2019, effective date 07.06.2019) In the cases in which the application does not comply with the established format or any document referred to in Article 3(3) is missing, the IASAS shall notify the irregularities to the applicant within seven days as from the receipt of the documents and give the applicant seven working days as from the date of receipt of the notification to eliminate such irregularities.

(3) (Amended, SG No. 45/2019, effective date 07.06.2019) Where the applicant fails to eliminate the irregularities within the established time limit, the licensing procedure shall be terminated with an order by the Executive Director of the IASAS. The order shall be served and it may be appealed in accordance with the Administrative Procedure Code.

Article 5. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) Within a month as from the date of acceptance of the application referred to in Article 4, the Executive Director of the IASAS shall fix the date of the training course.

(2) The date on which the training course begins shall be communicated to the applicants in writing and/or via [the website](#) of the IASAS.

(3) (Amended, SG No. 45/2019, effective date 07.06.2019) Persons willing to take part in a training course and sit for an exam shall pay a fee in accordance with the rates approved by the Executive Director of the IASAS. The document on the payment of the fee shall be made available at the time when the training course starts.

(4) Training courses shall be conducted in accordance with the curriculum approved by the Executive Director of the IASAS.

(5) The curriculum of the training course and the list of questions for the exam shall be made available to the trainees one week before the beginning of the course or published on the [website](#) of the IASAS, together with instructions on the venue and the dates of the course. The course shall continue for three days. Per diem costs and travelling and accommodation costs shall be borne by the trainees.

Article 6. (1) Within three days after the completion of the training course, the Executive Director of the IASAS shall issue an order appointing a panel of IASAS experts to conduct the exam for samplers and specifying the venue of the exam.

(2) The exam referred to in paragraph 1 shall be held not later than 10 days after the training course is completed.

Article 7. (1) Applicants who pass the exam for samplers successfully shall be granted a license in the format set out in Annex No. 2 by the Executive Director of the IASAS within five days and licensed samplers shall be entered into the IASAS register of samplers which is in the public domain and published on the [website](#) of the IASAS.

(2) The license shall indicate the unique identification number of the sampler.

(3) (Amended, SG No. 88/2018, effective date 23.10.2018) The sampler license shall be valid for four years and it shall be revoked only in the cases provided for in this Regulation.

(4) (Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019) Upon receiving their license, samplers shall sign an affidavit in the format set out in Annex No. 3 on the discharge of their duties in accordance with the sampling rules and

methods approved by the Minister of Agriculture, Food and Forestry and the provisions of this Regulation.

(5) (Amended, SG No. 88/2018, effective date 23.10.2018) Once in every four years prior to the expiration of their license, samplers shall attend a two-day refreshment course organised by the IASAS and sit for an exam at the end of the course. Samplers who pass the exam successfully shall be granted a new license valid for another four-years period.

(6) The Executive Director of the IASAS shall specify the date and venue of the course referred to in paragraph 5 at least twice a year.

(7) (New, SG No. 88/2018, effective date 23.10.2018). The persons referred to in paragraph 5 shall apply for participation in the refreshment course organised by the IASAS during the last year of validity of their license.

(8) (Ex Paragraph 7, SG No. 88/2018, effective date 23.10.2018) The updated list of samplers who are licensed and who have completed the course referred to in paragraph 5 shall be published on the [web site](#) of the IASAS.

Chapter Three **ACTIVITIES CARRIED OUT BY SAMPLERS**

Article 8. (Amended, SG No. 88/2018, effective date 23.10.2018) Samples shall be drawn from the homogeneous seed lots already handled for the purpose of laboratory testing of the seed usefulness.

Article 9. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) In the course of their sampling activities, samplers shall use appropriate devices (triers) and dividers which satisfy the conditions laid down in the Methodology of Sampling and Testing of Analytical Purity and Germination and Weight per One Thousand Seeds which is approved by the Minister of Agriculture, Food and Forestry and published on the [website](#) of the IASAS.

(2) Samples shall be sealed in accordance with the Methodology referred to in paragraph 1.

(3) (Amended, SG No. 88/2018, effective date 23.10.2018) When taking samples, the persons referred to in Article 7(1) shall fill in a sampling protocol in the format approved by the Executive Director of the IASAS. The protocol shall be issued on the date on which the sample was drawn. Samples shall be sent to an IASAS laboratory or a laboratory referred to in Article 7 SPMA and, where health is to be tested for the species concerned, also to a BFSa laboratory or a laboratory referred to in Article 8 within three days.

(4) The samples referred to in paragraph 3 shall be sent to the relevant laboratory at the sole expense of the applicant.

(5) (Amended, SG No. 88/2018, effective date 23.10.2018) The sampling protocol referred to in paragraph 3 shall be issued in the relevant number of counterparts: one for the sampler, one for the seed trader, one for the IASAS territorial unit at the place where the samples were taken, and one for the laboratory concerned.

Article 10. Natural persons licensed to take samples (samplers) shall:

1. keep sampling records in the format approved by the IASAS;
2. abide by the Methodology of Sampling and Testing of Analytical Purity and Germination and Weight per One Thousand Seeds;
3. draw and divide samples with the sampling devices provided for in the Methodology of Sampling and Testing of Analytical Purity and Germination and Weight per One Thousand Seeds;
4. store a sample for verification purposes for at least 12 months after the date on which it was taken;
5. abide by the affidavit referred to in Article 7(4);
6. announce the price list for their services.

Article 11. (1) The samplers referred to in Article 2(4) may draw samples only from seed lots

produced and/or marketed by their employers.

(2) Samplers may draw samples from seed lots which are not owned by their employer provided that the applicant for certification and the employer have signed a contract to that effect.

Chapter Four **SUPERVISION OF SAMPLERS**

Article 12. (1) Licensed samplers shall operate under the supervision of the IASAS.

(2) For the purposes of the supervision under paragraph 1, the IASAS shall perform annual verification sampling of at least 5% of the lots from which samples were drawn.

(3) (Amended, SG No. 88/2018, effective date 23.10.2018) The lots included in the verification checks referred to in paragraph 2 shall be distributed proportionately to the number of lots and the number of species belonging to the applicants for certification. Lots for which doubts or alerts of violations in the sampling process exist shall also be covered by the verification checks.

(4) The number of the lots of any applicant, which have been included in the 5 percent for the verification check, shall be proportionate to the number of lots which the applicant has included in the application for certification and to the number of species.

(5) Where it is established by the verification check referred to in paragraph 2 that the samples do not characterise the seed lot (they are not representative of the lot) and this may lead or has led to laboratory test results which are not reliable for the lot and the actual indicators deviate from the allowable levels laid down in Article 29(6) SPMA:

1. the Executive Agency for Variety Testing, Field Inspection and Seed Control shall terminate the certification procedure or annul the certificate issued for the lot concerned;
2. the seed from that lot shall be withdrawn from the market.

(6) Seed may be marketed where the verification checks referred to in paragraph 2 establish that the actual indicators of the lot are different from those of the tested samples drawn by a licensed sampler but they satisfy the conditions laid down in in Article 29(6) SPMA.

(7) Samples for verification of laboratory testing and for post-control shall be taken only officially by the IASAS.

Article 13. (1) The Executive Director of the IASAS shall issue an order to revoke the license referred to in Article 7(1) in any of the following cases:

1. it is confirmed by the verification checks referred to in Article 12(2) that the results are inaccurate;
2. more than three violations are observed, such as cases in which the details in the protocols do not match with the samples sent for testing (swapped samples) or the details written on the envelope are incomplete or untrue;
3. the records referred to in Article 10(1) are not made available on request by the IASAS;
4. samples are not stored in accordance with Article 10(4);
5. samples are not sent to the relevant laboratory referred to in Article 9(3) within three days.

(2) The persons whose license has been revoked pursuant to paragraph 1 may be reinstated in accordance with this Regulation but not earlier than one year of the date on which the violation was identified.

(3) (Repealed, SG No. 88/2018, effective date 23.10.2018)

(4) (Amended, SG No. 88/2018, effective date 23.10.2018) The order under paragraph 1 shall be subject to appeal in accordance with the Administrative Procedure Code.

Chapter Five **AUTHORISATION OF LABORATORIES** **(HEADING AMENDED, SG No. 45/2019, EFFECTIVE DATE 7.06.2019)**

Section I. **Conditions and Procedure for Authorisation**

(Heading amended, SG, No. 45/2019, effective date 07.06.2019)

Article 14. (1) Laboratory testing to establish the usefulness of seed shall be carried out at:

1. (Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019) laboratories authorised by the Minister of Agriculture, Food and Forestry pursuant to Article 7(1) SPMA;

2. (Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019) a laboratory which is owned by or organisationally and financially related to a person engaging in seed production and/or marketing pursuant to Article 7(3) SPMA, which has been authorised by the Executive Director of the IASAS.

(2) (Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019) Laboratory testing to check the health of the seed and propagating material shall also be carried out at laboratories authorised by the Minister of Agriculture, Food and Forestry in accordance with Article 8 SPMA.

(3) (Amended, SG No. 45/2019, effective date 07.06.2019) Laboratories referred to paragraphs 1 and 2 shall satisfy the conditions laid down in Article 9 SPMA so as to be granted an authorisation to carry out laboratory testing.

Article 15. (1) (Amended, SG No. 45/2019, effective date 07.06.2019) Laboratories which carry out laboratory testing of the usefulness of seed and/or the health of seed and propagating material shall be authorised within the scope indicated in the application provided that they satisfy the conditions laid down in this Regulation.

(2) (Amended, SG No. 45/2019, effective date 07.06.2019) The laboratories referred to in Article 14, paragraph 1, subparagraphs 1 and 2 shall have at least the following equipment for the purposes of applying for authorisation:

1. a divider for the plant species indicated in the application for authorisation;

2. where the condition set out in subparagraph 1 is not satisfied, the laboratory staff may use the manual division method;

3. a stereo microscope or a magnifying glass to identify small seeds and fragments thereof, and others;

4. a seed counter; where this condition is not satisfied, the laboratory staff may use the manual counting method;

5. seed germination equipment;

6. a weighing balance with the precision level required by the methodologies;

7. a moisture meter and a desiccator or only a desiccator.

(3) (Amended, SG No. 45/2019, effective date 07.06.2019) The laboratories referred to in Article 14(2) shall have at least the following equipment for the purposes of applying for authorisation:

1. a stereo microscope;

2. a microscope;

3. an incubator;

4. a desiccator;

5. a seed blower;

6. a weighing balance with the precision level required by the methodologies;

7. a sterilizer;

8. small tools;

9. serology testing equipment.

Article 16. (1) (Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019) Any laboratory applying for authorisation by the Minister of Agriculture, Food and Forestry to carry out laboratory testing of the usefulness of seed pursuant to Article 14(1)(1) or the health of seed and/or propagating material pursuant to Article 14(2) shall submit an application in the format set out in Annex No. 4 or Annex No. 5 respectively, to the Ministry of Agriculture, Food and Forestry.

(2) (Amended, SG No. 45/2019, effective date 07.06.2019) Any laboratory applying for authorisation by the IASAS to carry out laboratory testing of the usefulness of seed pursuant to Article 14(1)(2) shall submit an application in the format set out in Annex No. 6 to the IASAS.

(3) Applicant laboratories referred to in paragraphs 1 and 2 shall attach the following documents to their applications:

1. (Repealed, SG No. 88/2018, effective date 23.10.2018)

2. a copy of the quality assurance manual and accompanying documents of the laboratory prepared in accordance with the quality assurance manual which is approved by the IASAS and published on the [website](#) of the IASAS;

(3) (Amended, SG No. 88/2018, No. 23/10, effective date 23.10.2018) a list of the laboratory staff.

Article 17. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) The application with the attachments pursuant to Article 16(1) shall be registered at the MAFF or the IASAS respectively on the date of its receipt.

(2) (Amended, SG No. 88/2018, effective date 23.10.2018) Within three days after the submission of the documents, the MAFF shall send the set of documents to the IASAS or to the Bulgarian Food Safety Agency (BFSA), depending on the activity which the laboratory applies for.

Article 18. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) A committee appointed with an order by the Executive Director of the IASAS or by the Executive Director of the BFSA respectively shall examine the applications. In the cases in which the application does not follow the prescribed format, the IASAS or the BFSA respectively shall notify the applicant thereof within five days as from the date of receipt of the documents.

(2) (Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019) Within ten days as from the notification date, the applicant shall eliminate the irregularities in the application.

(3) (Amended, SG No. 45/2019, effective date 07.06.2019) Where the applicant fails to eliminate the irregularities within the established time limit, the authorisation procedure shall be terminated with an order by the Executive Director of the IASAS or of the BFSA respectively.

Article 19. (1) The compliance of the applicant laboratory with the requirements laid down in this Regulation shall be checked by the committee referred to in Article 18, which consists of experts from the IASAS or the BFSA respectively, who are appointed with an order by the Executive Director.

(2) The Executive Director of the IASAS or the Executive Director of the BFSA respectively shall designate the chairperson of the committee in his or her order.

(3) The committee members shall satisfy the following conditions:

1. to have knowledge of the approval criteria and the relevant procedures for inspecting and assessing laboratories;

2. to have the requisite technical knowledge of the laboratory testing methods covered by the application for approval;

3. to have knowledge of the legal framework;

4. to be independent of any commercial, financial or other influences or any conflicts of interests;

5. to refrain from disclosing any information brought to their knowledge in the discharge of their duties and to sign the non-disclosure declaration set out in Annex No. 7.

(4) The IASAS or the BFSA respectively shall charge fees for the check referred to in paragraph 1 in accordance with the rates pursuant to Article 6(70) SPMA or the BFSA rates respectively.

Article 20. The committee referred to in Article 19(1) shall prepare a checklist describing the procedures and methods of inspection and assessment of the laboratory concerned.

Article 21. The laboratory which is assessed shall make available all the relevant information on its activities to the committee.

Article 22. (1) Within 15 days of the receipt of the set of documents at the IASAS or the BFSAs respectively, the committee shall fix a date for an on-the-spot check of the applicant laboratory.

(2) The date of the check shall be consulted with the laboratory and shall not be later than 45 calendar days as from the date on which the documents were submitted.

(3) Within the time limits referred to in paragraph 1, the committee shall make arrangements for verification laboratory testing to check the fitness for purpose of the laboratory concerned.

Article 23. The committee may ask for demonstration of any procedure or work with the documents used by the applicant laboratory.

Article 24. (1) The committee shall make out a statement on the results and findings of the check.

(2) The statement concerning the on-the-spot check shall be signed by the committee and by authorised representatives of the laboratory concerned.

(3) Where the results of the check reveal non-compliances with the statutory requirements, the committee shall issue mandatory instructions and fix time limits for the elimination of the non-compliances.

(4) (Amended, SG No. 88/2018, effective date 23.10.2018) After the expiration of the time limits referred to in paragraph 4, the committee shall check within two working days whether the non-compliances have been eliminated. The costs incurred by the committee in the business trip for the on-the-spot check shall be borne by the laboratory.

Article 25. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) After the completion of the check and the expiration of the time limits for the the verification testing referred to in Article 22(3), the committee shall submit, within seven days as from the date of the last check(s) or verification testing completed, a written report to the MAFF or to the Executive Director of the IASAS on the check, including the results of the verification testing and assessment of the applicant laboratory.

(2) The report shall include the following information:

1. the names of the committee members;
2. the name and address of the laboratory;
3. information on the results from the verification testing;
4. assessment by the committee as to the extent to which the laboratory is compliant with the approval criteria and a conclusion on the approval or rejection of the applicant laboratory.

Article 26. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) Within two weeks of the receipt of the report referred to in Article 25, the Minister of Agriculture, Food and Forestry shall grant authorisation to the laboratories concerned at the proposal of the IASAS or the BFSAs respectively in the format set out in Annexes Nos. 8 or 9 respectively on the grounds of the conclusion given pursuant to Article 25(2)(4) and the positive results of the check.

(2) The Executive Director of the IASAS shall grant authorisation to the laboratories referred to in Article 7(3) SPMA in the format set out in Annex No. 10.

(3) The authorisation shall bear a unique identification number.

(4) The authorisation shall not be limited by a fixed term.

Article 27. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) Within the time limits referred to in Article 26(1), the Minister of Agriculture, Food and Forestry or the Executive Director of the IASAS may issue a reasoned refusal to approve and authorise an applicant laboratory on the grounds of the report referred to in Article 25(2)(4) based on the results of the check, where these results reveal non-compliance of the laboratory with the requirements for approval.

(2) Any such refusal shall be subject to appeal in accordance with the Administrative Procedure

Code.

Article 28. (Amended, SG No. 45/2019, effective date 07.06.2019) The Ministry of Agriculture, Food and Forestry shall maintain a public national electronic register of authorised laboratories on its [webt site](#).

Article 29. Having received the authorisation pursuant to Article 26, the laboratory may request, at any point of time, a modification of the scope of its activities in accordance with this Regulation.

Section II. Qualifications of the Staff

Article 30. (1) Head of a laboratory referred to in Article 14, paragraph 1, subparagraphs 1 and 2 may be a person who holds a university degree and who is competent on the entire scope of the authorisation of the laboratory.

(2) Head of a laboratory referred to in Article 14(2) may be a person who holds a university degree in agronomy.

(3) The staff of the laboratories referred to in Article 14, paragraph 1, subparagraphs 1 and 2 shall have completed secondary education.

(4) The staff of the laboratories referred to in Article 14(2) shall have completed secondary education for technical positions and shall hold a university degree in agronomy for expert positions.

(5) The persons referred to in paragraphs 1 and 3 shall have completed a training course and passed an exam at the IASAS Central Laboratory, while the persons referred to in paragraphs 2 and 4 shall have completed a training course and passed an exam at the BFSA Central Plant Quarantine Laboratory.

(6) The management of the laboratory shall ensure annual training of the staff in accordance with a training plan which may include training on the job or external training.

Section III. Conditions for the conduct of training courses in the laboratory testing of the usefulness of seed samples and of the health of seed and propagating material

Article 31. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) The applicant laboratory shall submit an application in writing for training of the laboratory staff to the IASAS or to the BFSA in the format approved by the Executive Director of the IASAS or the Executive Director of the BFSA respectively as set out in Annexes Nos. 11 or 12 respectively.

(2) The list of the staff members with the relevant positions shall be attached to the application referred to in paragraph 1.

Article 32. (1) Within a month of the date of the application referred to in Article 31(1), the Executive Director of the IASAS or the Executive Director of the BFSA respectively shall make arrangements for the training course and the exam.

(2) The date on which the training course begins shall be communicated to the applicant laboratory in writing and via the website of the [IASAS/BFSA](#).

(3) (Amended, SG No. 88/2018, effective date 23.10.2018) A fee shall be charged by the IASAS or the BFSA respectively for each trainee enrolled in the course referred to in paragraph 1 in accordance with the existing rates. The document on the payment of the fee shall be made available at the time when the training course starts.

(4) The training course shall take place at the IASAS/BFSA in accordance with a curriculum approved by the Executive Director of the IASAS or the Executive Director of the BFSA respectively.

(5) (Amended, SG No. 88/2018, effective date 23.10.2018) The curriculum of the training course

and the list of questions for the exam shall be made available to the laboratories one week before the beginning of the course or published on the website of the [IASAS/BFSA](#), together with instructions on the venue and the dates of the course. The course shall continue for five days. Per diem costs and travelling and accommodation costs shall be borne by the laboratories.

(6) Within seven days of the completion of the training course, the IASAS/BFSA shall hold an exam on the basis of the announced list of questions referred to in paragraph 5.

Article 33. (Amended, SG No. 88/2018, effective date 23.10.2018) Within five working days, the Executive Director of the IASAS or the Executive Director of the BFSA respectively shall issue certificates to the trainees who have passed the exam successfully.

Article 34. The provisions of Section III of this Chapter shall also apply to new recruits to the laboratory.

Chapter Six LABORATORY ACTIVITIES

Section I. Laboratory Equipment

Article 35. (1) The laboratory equipment used in the laboratory testing by the laboratories referred to in Article 14, paragraphs 1 and 2 shall satisfy the conditions laid down in the laboratory testing methodologies.

(2) Any technical equipment subject to testing or calibration shall be tested and/or calibrated before it is set into operation in the laboratory.

(3) Any measuring equipment shall be subject to metrological testing/calibration in accordance with the quality assurance documentation of the laboratory.

(4) Schedules shall be worked out for the regular testing/calibration of all measuring equipment and these schedules shall be attached to the quality assurance manual.

(5) All equipment subject to calibration/testing shall be labelled.

(6) All equipment used in laboratory testing shall have a label and a record sheet.

(7) The label and the record sheet shall be affixed on the equipment or, where this is impossible, in close vicinity to the equipment.

(8) The record sheet shall contain the following particulars:

1. name of the equipment, type and serial number, inventory number;

2. (Repealed, SG No. 88/2018, effective date 23.10.2018)

3. date of delivery of the equipment to the laboratory and date of its setting into operation;

4. condition upon delivery (new, second-hand, rehabilitated);

5. dates of calibrations and/or tests and signature of the person responsible for these operations;

6. details of the parameters reported by the equipment;

7. parameters reporting schedule;

8. details of any damage, malfunction, modification or repair to the equipment.

(9) Any equipment, which gives suspect results, or has been shown by calibration and/or tests to be defective, shall be taken out of service and clearly marked until it has been repaired.

(10) After the repair, tests and/or calibration shall be re-performed and, if it functions satisfactorily again, the equipment shall be set into operation again.

(11) (Amended, SG No. 88/2018, effective date 23.10.2018) The laboratory shall keep the specifications and manufacturer's instructions for all equipment throughout its life cycle, where appropriate.

Section II. Laboratory Materials and Consumables

Article 36. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) The laboratory materials

and consumables used in laboratory testing shall satisfy the statutory requirements of the relevant laboratory testing method and the methodologies approved by the Minister of Agriculture, Food and Forestry.

(2) (Repealed, SG No. 88/2018, effective date 23.10.2018).

Article 37. (1) Laboratories referred to in Article 14, paragraph 1, subparagraphs 1 and 2 shall keep a seed collection to identify seeds of other plants, including seeds of crops and weed plants.

(2) The seed collection shall be available to the laboratory staff at all times.

Section III.

Laboratory Premises

Article 38. (1) Laboratories referred to in Article 14, paragraph 1, subparagraphs 1 and 2 shall have premises for delivery of samples, for laboratory testing, and for storage of samples.

(1) Laboratories referred to in Article 14 (2) shall have premises for delivery of samples, for laboratory testing to identify pests, and for storage of samples.

(3) The area of the premises shall be sufficient to ensure normal access to all equipment and apparatuses.

(4) Any laboratory which applies for approval to carry out laboratory testing which must comply with parameters of the environment in accordance with the relevant methodology, shall have the requisite technical equipment to ensure maintenance and control of the required parameters.

Section IV.

Quality Assurance and Management System

Article 39. (1) The laboratory shall design, operate and maintain a quality assurance system appropriate to its scope of activity.

(2) The elements of the quality assurance system shall be documented in a quality assurance manual and standard operational procedures, which shall be available to the laboratory staff.

(3) The quality assurance manual shall reflect the policies, procedures, and structure of the documentation which is used in the quality assurance system.

(4) The quality assurance manual shall contain the following:

1. a statement on the policy and objectives of the quality assurance system;
2. a description of the organisational structure of the laboratory;
3. a description of the general quality assurance requirements;
4. a reference to the laboratory testing methodologies;
5. a description of the activities and functions of the staff;
6. a description of the requirements to the work with the laboratory documents and the movement of documents within the laboratory;
7. a description of the rules for taking appropriate corrective action where deficiencies are detected in laboratory testing or in the work with documents;
8. a procedure to deal with objections and complaints;
9. procedures for regular monitoring and review of the quality assurance system to achieve effective implementation of the work rules and to take corrective actions and improvements.

(5) The laboratory shall design standard operational procedures at least for:

1. the receipt and registration of samples, which includes a sample registration and identification system; the identification shall be kept throughout the testing and retention of the sample in the laboratory or the premises for storage of samples and it shall ensure that samples cannot be mixed physically or in the documentation and that anonymity is guaranteed in the testing process.
2. the retention and preparation of samples for laboratory testing and the subsequent storage of samples;
3. the sequence in the laboratory testing process;

3. the laboratory testing procedures;
5. the issuance, storage and management of the laboratory testing documentation;
6. the rules for the access of visitors to the laboratory.

Article 40. (Amended, SG No. 88/2018, effective date 23.10.2018) Laboratories shall abide by the rules on the testing, time limits and conditions for storage of samples in accordance with the methodologies approved by the Minister of Agriculture, Food and Forestry.

Article 41. (1) The results of each test carried out by the laboratory shall be reported accurately, clearly and unambiguously, and in accordance with the laboratory testing methodologies.

(2) The results of laboratory tests shall be recorded in a laboratory testing document in the formats approved by the IASAS and the BFSAs.

(3) On the basis of the laboratory testing document, the TU of the IASAS at the location of the laboratory shall issue a certificate, within five calendar days, for the seed provided that it satisfies the conditions laid down in the Regulations listed in Article 29(6) SPMA.

(4) The laboratory shall keep the laboratory testing data and a copy of each laboratory testing document for at least six years.

Chapter Seven

SUPERVISION OF LABORATORY ACTIVITIES

Article 42. (1) The Executive Agency for Variety Testing, Field Inspection and Seed Control or the BFSAs respectively shall supervise the activities of laboratories authorised pursuant to Article 26.

(2) For the purposes of supervision, the IASAS/BFSAs shall carry out a planned check once a year, as well as sudden checks of the compliance with Article 9 SPMA.

(3) In the course of the implementation of the supervisory activities by the IASAS or the BFSAs respectively, the laboratory shall provide access to all premises which are used for laboratory testing, the equipment, the records, and the staff.

(4) The Executive Agency for Variety Testing, Field Inspection and Seed Control or the BFSAs respectively shall check the accuracy and precision of the results of the laboratory testing which is carried out by the approved laboratories through verification testing of at least five percent of the total number of lots of certified seed and at least ten percent of the total number of lots of basic seed. The laboratory subject to the check shall pay no fee for the verification testing.

(5) (Amended, SG No. 88/2018, effective date 23.10.2018) The accuracy and precision of laboratory testing which is carried out by the laboratories referred to in Article 14, paragraphs 1 and 2 shall be determined within the ranges set out in the methods approved by the Minister of Agriculture, Food and Forestry pursuant to Article 31, paragraphs 6, 8 and 9 of the SPMA.

(6) Where it is found by these checks that the activities of approved laboratories do not comply with the requirements laid down in Article 9 SPMA, the IASAS or the BFSAs shall give mandatory instructions on the elimination of the non-compliances within a prescribed time limit.

(7) (Amended, SG No. 88/2018, effective date 23.10.2018) The Executive Agency for Variety Testing, Field Inspection and Seed Control shall annul a certificate issued on the grounds of laboratory testing carried out in a laboratory referred to in this Regulation, where it is established by the verification testing pursuant to paragraph 4 that the seed or the propagating material respectively does not satisfy the conditions for certification. In this case, the Minister of Agriculture, Food and Forestry shall stop the marketing of such seed or propagating material respectively.

(8) (Amended, SG No. 88/2018, effective date 23.10.2018) The certification of seed shall be cancelled in the cases in which a non-compliance and/or violation in the laboratory testing or of its implementation rules. A derogation shall be allowed only if the seed continues to satisfy the relevant conditions.

(9) The Executive Agency for Variety Testing, Field Inspection and Seed Control or the BFSAs

respectively shall carry out arbitration laboratory testing of seed or propagating material respectively at the IASAS Central Laboratory or the BFSA Central Plant Quarantine Laboratory in any of the following cases:

1. objections raised by persons whose seed or propagating material is tested in a laboratory referred to in Article 14, paragraphs 1 and 2;
2. alerts filed by users of seed or propagating material marketed within the country.

(10) Paragraph 7 shall also apply to commercial seed.

(11) The time limit for laboratory testing to begin pursuant to paragraph 9 shall be not later than five days of the date of submission of the application.

(12) The IASAS/BFSA shall charge no fees for the verification checks carried out pursuant to paragraph 2.

Article 43. (1) (Amended, SG No. 88/2018, effective date 23.10.2018) The Minister of Agriculture, Food and Forestry or the Executive Director of the IASAS shall issue an order to revoke the authorisation of a laboratory in any of the following cases:

1. it is confirmed by the verification checks referred to in Article 42(4) that the results are inaccurate;
2. the non-compliances referred to in Article 42(6) are not eliminated or they are recurrent;
3. it is established that samples have been mixed physically or in the documentation three times;
4. it is established that the laboratory testing results have not been recorded accurately three times;
5. a laboratory testing document has been issued for agricultural plant species outside the scope of the authorisation of the laboratory.

(2) The laboratories whose authorisation has been revoked pursuant to paragraph 1 may be reinstated in accordance with this Regulation but not earlier than one year of the date on which the violation was identified.

(3) Refusals to grant authorisation under paragraph 1 shall be subject to appeal in accordance with the Administrative Procedure Code.

Article 44. (Amended, SG No. 88/2018, effective date 23.10.2018) Laboratories shall provide information in writing to the MAFF and the IASAS or the BFSA respectively, within two weeks, of any changes as regards the following:

1. the legal or organisational status;
2. the management;
3. the premises;
4. the staff;
5. the analytical methods.

SUPPLEMENTARY PROVISIONS

§ 1. For the purposes of this Regulation:

1. "Sampler" means a person specially trained and licensed to take samples from lots and to be responsible for the implementation of the procedures for preliminary examination of the seed, sampling, filling in statements, packaging and dispatching samples to a laboratory for testing purposes.
2. "Verification testing" means laboratory testing of seeds from the same average sample, which is carried out simultaneously at the IASAS laboratory and the applicant laboratory.
3. "Calibration" means the verification of the accuracy and precision of the laboratory measuring equipment against reference devices and the ensuring of reproduction of the measurements taken with this equipment, which is carried out by laboratories of the State Agency for Metrological and Technical Surveillance and by laboratories accredited by the Executive Agency - Bulgarian Accreditation Service.
4. "Updated list" means the list of persons licensed to carry out activities pursuant to this

Regulation as of the time of its publication.

5. "Laboratory testing to establish the usefulness of seed" means testing of:

- (a) analytical purity;
- (b) germination vigour and germination capacity;
- (c) moisture content;
- (d) varietal purity outside the scope of the certification.

FINAL PROVISIONS

§ 2. This Regulation repeals Regulation No. 3 of 2005 setting out the conditions and procedure for approval of laboratories to carry out laboratory testing of the usefulness of seed and laboratories to establish the health of seed and propagating material (SG, No. 20/2005).

§ 3. This Regulation is issued pursuant to Article 9 and Article 31(1) and (5) of the Seed and Propagating Material Act.

§ 4. This Regulation shall enter into force on the day of its publication in The State Gazette.

§ 5. The implementation of this Regulation is assigned to the IASAS and the BFSA.

AMENDING REGULATION TO REGULATION No. 8 OF 2013 SETTING OUT THE CONDITIONS AND PROCEDURE FOR APPROVAL AND LICENSING OF NATURAL PERSONS TAKING SEED SAMPLES (SAMPLERS) AND THE CONDITIONS AND PROCEDURE FOR APPROVAL OF LABORATORIES TESTING THE USEFULNESS OF SEED AND LABORATORIES TESTING THE HEALTH OF SEED AND PROPAGATING MATERIAL

(PROMULGATED, SG No. 88/2018, EFFECTIVE DATE 23.10.2018)

§ 33. The words "the Ministry of Agriculture and Food" and "(the) Minister of Agriculture and Food" shall be replaced by the words "the Ministry of Agriculture, Food and Forestry" and "(the) Minister of Agriculture and Food" respectively and the acronym "MAF" shall be replaced by the acronym "MAFF" everywhere in the text.

Final Provisions

AMENDING REGULATION TO REGULATION No. 8 OF 2013 OCTOBER 2013 SETTING OUT THE CONDITIONS AND PROCEDURE FOR APPROVAL AND LICENSING OF NATURAL PERSONS TAKING SEED SAMPLES (SAMPLERS) AND THE CONDITIONS AND PROCEDURE FOR APPROVAL OF LABORATORIES TESTING THE USEFULNESS OF SEED AND LABORATORIES TESTING THE HEALTH OF SEED AND PROPAGATING MATERIAL

(PROMULGATED, SG No. 88/2018, EFFECTIVE DATE 23.10.2018)

§ 34. This Regulation shall enter into force on the day of its publication in The State Gazette.

Final Provisions

AMENDING REGULATION TO REGULATION No. 4 OF 2011 MARCH 2011 SETTING OUT THE PROCEDURE AND CONDITIONS TO CONDUCT COMPETITIVE EXAMS FOR FIELD INSPECTORS

(PROMULGATED, SG No. 45/2019, EFFECTIVE DATE 7.06.2019)

§ 11. This Regulation shall enter into force on the day of its publication in The State Gazette.

Annex No. 1 to Article 3(2)
(Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019)

TO
THE EXECUTIVE DIRECTOR
OF THE IASAS

APPLICATION

for participation in a training course for taking samples for laboratory testing (samplers) by

.....

(Full name of the natural person),

Address:

MR./MS. MINISTER,

I hereby declare that I am willing to take part in the training course on taking samples of seed for laboratory testing from:

Encl.:

Medical certificate; CV.

Date:

Signature:

Annex No. 2 to Article 7(1)
(Amended, SG No. 88/2018, effective date 23.10.2018)

REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE, FOOD AND FORESTRY
EXECUTIVE AGENCY FOR VARIETY TESTING, FIELD INSPECTION
AND SEED CONTROL

1113 Sofia, 125 Tsarigradsko Chausse, bl. 1

e-mail: iasas@iasas.government.bg

Tel.: 02 870 03 75; Fax: 02 870 65 17

LICENSE

No. /

FOR SAMPLING SEED

FROM (BOTANICAL SPECIES)

IN ACCORDANCE WITH ARTICLE ... OF REGULATION No.

.....

This license is granted to (person)

.....

VALIDITY: 4 years

EXECUTIVE DIRECTOR:

Annex No. 3 to Article 7(4)
(Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019)

Affidavit by

.....
(full name)

I hereby declare that in the discharge of my duties to take samples for laboratory testing of the usefulness of seed and for establishment of the health of agricultural plant species, where appropriate, I shall abide by the Methodology of Sampling and Testing of Analytical Purity and Germination and Weight per One Thousand Seeds.

City/Date

Signature:

Annex No. 4 to Article 16(1)

(Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019)

TO
THE MINISTER OF
AGRICULTURE, FOOD AND FORESTRY

APPLICATION
by

..... ,
(full name)

.....
(permanent address)

Manager of company/laboratory ,.....
(principal place of business and name of the laboratory/company, address)

BULSTAT.....

Mr. Minister,

....., the laboratory I represent

hereby applies for laboratory testing to establish the usefulness of seed pursuant to Article 7(1) of the Seed and Propagating Material Act (SPMA) with the following scope of activity:

I. Laboratory testing of the usefulness of seed of:

- Cereals
- Oil and fibre plants
- Fodder plants
- Vegetable plants
- Beet
- Ornamental plants

II. Types of laboratory testing:

analytical purity;
germination capacity and germination vigour;
moisture content.

I hereby apply for authorisation of laboratory with the foregoing scope of activity in accordance with Article 10(3) SPMA.

The laboratory submits its application:

for the first time - YES (NO);

for modification of the scope of activity - YES (NO).

Encl.:

1. a copy of the quality assurance manual and the laboratory documents attached thereto;
2. a list of the staff members.

Date:

City

Signature:

Annex No. 5 to Article 16 (1)

(Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019)

TO

THE MINISTER OF
AGRICULTURE, FOOD AND FORESTRY

APPLICATION

by
(full name)

.....
(permanent address)

Manager of company/laboratory ,.....
(principal place of business and name of the laboratory/company, address)

BULSTAT.....

Mr. Minister,

....., the laboratory I represent, hereby applies for laboratory testing to establish the health of seed/propagating material pursuant to Article 8 of the Seed and Propagating Material Act (SPMA) with the following scope of activity:

I. Laboratory testing of the health of:

Species (crop)....., category

Species (crop)....., category

Species (crop)....., category

II. Types of laboratory testing:

mycology;

bacteriology;

virology;

nematology;

.....

I hereby apply for authorisation of laboratory with the foregoing scope of activity in accordance with Article 10(3) SPMA.

The laboratory submits its application:

for the first time - YES (NO);

for renewal of the authorisation - YES (NO).

Encl.:

1. a copy of the quality assurance manual and the laboratory documents attached thereto;
2. a list of the staff members.

Date:

City

Signature:

Annex No. 6 to Article 16(2)
(Amended, SG No. 88/2018, effective date 23.10.2018, amended, SG No. 45/2019, effective date 07.06.2019)

TO
THE EXECUTIVE DIRECTOR
EXECUTIVE AGENCY FOR VARIETY TESTING,
FIELD INSPECTION AND SEED CONTROL

APPLICATION

By
(full name)

.....
(permanent address)

Manager of company/laboratory ,.....
(principal place of business and name of the laboratory/company, address)

BULSTAT.....

Mr/Ms Director,, the laboratory I represent, hereby applies for laboratory testing to establish the health of seed/propagating material pursuant to Article 7(1) of the Seed and Propagating Material Act with the following scope of activity:

I. Laboratory testing of the usefulness of seed of:

- Cereals
- Oil and fibre plants
- Fodder plants
- Vegetable plants
- Beet
- Ornamental plants

II. Types of laboratory testing:

analytical purity;
germination capacity and germination vigour;
moisture content;
weight of one thousand seeds.

I hereby apply for authorisation of laboratory with the foregoing scope of activity in accordance with Article 10(3) SPMA.

The laboratory submits its application:
for the first time - YES (NO);
for modification of the scope of activity - YES (NO).

Encl.:

1. a copy of the quality assurance manual and the laboratory documents attached thereto;
2. a list of the staff members.

Date:

City

Signature:

Annex No. 7 to Article 19(3)(5)
(Amended, SG No. 88/2018, effective date 23.10.2018)

DECLARATION

I, the undersigned, representative of, by signing this declaration, undertake:

1. To use and apply the facts, data and documents made available to me as mandatory information solely for the purpose of the discharge of my duties;
2. To refrain from disclosing or causing the disclosure of the facts, data and documents made available to me as mandatory information for the purpose of the discharge of my duties to any unauthorised persons.

Date: Declarant:

Annex No. 8 to Article 26(1)
(Amended, SG No. 88/2018, effective date 23.10.2018)

<p>REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE, FOOD AND FORESTRY LICENSE № L-00/... (year) FOR THE OPERATION OF A LABORATORY PURSUANT TO ARTICLE 7, PARAGRAPH 1 OF THE SPMA</p>
Name, address:,
Scope of the authorisation;
I. Laboratory testing of the usefulness of seed of:
Species and categories
Species and categories
Species and categories
II. Types of laboratory testing:
analytical purity;
germination;
moisture content.
THIS AUTHORISATION SHALL ENTER INTO FORCE ON
VALIDITY: 4 years
MINISTER:
This authorisation is issued for the first time. X
This Authorisation is issued pursuant to Article 10(3) of the Seed and Propagating Material Act.

Annex No. 9 to Article 26(1)
(Amended, SG No. 88/2018, effective date 23.10.2018)

<p>REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE, FOOD AND FORESTRY LICENSE № LZ-00/.... (year)</p> <p>FOR THE OPERATION OF A LABORATORY PURSUANT TO ARTICLE 8 OF THE SPMA</p> <p>Name, address:</p> <p style="text-align: center;">Scope of the authorisation;</p> <p>I. Laboratory testing of the health of:</p> <p>Species and categories</p> <p>Species and categories</p> <p>Species and categories</p> <p>II. Types of laboratory testing:</p> <p>mycology;</p> <p>bacteriology;</p> <p>virology;</p> <p>nematology;</p> <p>.....</p> <p>THIS AUTHORISATION SHALL ENTER INTO FORCE ON</p> <p>.....</p> <p>VALIDITY: 4 years</p> <p>MINISTER:</p> <p>This authorisation is issued for the first time. X</p> <p>This Authorisation is issued pursuant to Article 10(3) of the Seed and Propagating Material Act.</p>

Annex No. 10 to Article 26(2)
(Amended, SG No. 88/2018, effective date 23.10.2018)

<p>REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE, FOOD AND FORESTRY Executive Agency for Variety Testing, Field Inspection and Seed Control LICENSE № L-00/... (year)</p> <p>FOR THE OPERATION OF A LABORATORY PURSUANT TO ARTICLE 7, PARAGRAPH 3 OF THE SPMA</p> <p>Name, address:</p>
--

Scope of the authorisation;

I. Laboratory testing of the usefulness of seed of:

Species and categories

Species and categories

Species and categories

II. Types of laboratory testing

analytical purity;

germination;

moisture content.

THIS AUTHORISATION SHALL ENTER INTO FORCE ON

VALIDITY: 4 years

EXECUTIVE DIRECTOR OF THE IASAS:

This authorisation is issued for the first time. X

This Authorisation is issued pursuant to Article 10(3) of the Seed and Propagating Material Act.

Annex No. 11 to Article 31(1)
 (Amended, SG No. 88/2018, effective date 23.10.2018)

TO
 THE EXECUTIVE DIRECTOR
 OF THE IASAS

APPLICATION

for participation in a training course for laboratory testing of the usefulness of samples of seed

By
(full name)

Address:

Manager of

Company/laboratory.....
(principal place of business and name of the laboratory/company, address)

DEAR SIR/MADAME,

I hereby express my willingness, in my capacity of head of the laboratory, to have (number) specialists enrolled in the training course for laboratory testing of the usefulness of seed of the following species:

1. ;
2.

Encl.:

List of laboratory specialists and their positions.

Date: Signature:

Annex No. 12 to Article 31(1)
(Amended, SG No. 88/2018, effective date 23.10.2018)

TO
THE EXECUTIVE DIRECTOR
OF THE BFSA

APPLICATION
for participation in a training course for laboratory testing of the health of samples of
seed/propagating material

By
(full name)

Address:

Manager of

Company/laboratory

BULSTAT.....

DEAR SIR/MADAME,
I hereby express my willingness, in my capacity of head of the laboratory, to have (number)
specialists enrolled in the training course for laboratory testing of the health of samples of
seed/propagating material of the following species:

- 1. ;
- 2.

Encl.:

Date:

Signature: