

**REGULATION No. 8 OF 20 MARCH 2007 SETTING OUT THE PROCEDURES  
FOR CERTIFICATION AND/OR APPROVAL OF SEED PRODUCED AND  
MARKETED IN THE FOLLOWING GROUPS OF AGRICULTURAL PLANT  
SPECIES: CEREALS, OIL AND FIBRE PLANTS, FODDER PLANTS,  
VEGETABLES, POTATOES, AND BEET**

*Effective date 6 April 2007*

*Issued by the Minister of Agriculture and Forestry*

*Promulgated, SG No. 29 of 6 April 2007, amended, SG No. 109 of 20 December 2007, amended,  
SG No. 79 of 16 October 2012, amended, SG No. 30 of 9 April 2019*

**Chapter One  
GENERAL PROVISIONS**

**Article 1.** This Regulation shall apply to:

1. the seed certification procedures by category of seed corresponding to the groups of agricultural plant species (cereals, oil and fibre plants, fodder plants, vegetables, and beet) set out in the Regulations listed in Article 29(6) of the Seed and Propagating Material Act (SPMA), which are produced within the territory of the Republic of Bulgaria;
2. (Amended, SG No. 30/2019, effective date 09.04.2019) the procedures for certification and/or approval of seed potatoes in the relevant categories as set out in Regulation No. 16 of 2008 on the marketing of seed potatoes within the European Union (SG No. 54/2008) (Regulation No. 16 of 2008) and Regulation No. 15 of 2015 on the marketing of pre-basic, basic and certified seed potatoes of the relevant grades within the European Union (SG, No. 59/2015) (Regulation No. 15 of 2015), which are produced within the territory of the Republic of Bulgaria;
3. the procedure of packaging in small packages.

**Chapter Two  
SEED CERTIFICATION PROCEDURES**

**Section I  
General Requirements**

**Article 2.** (1) The certification procedures under this Chapter shall apply to the seed in the following groups of crops: cereals, oil and fibre plants, fodder plants, vegetables, and beet, except for seed potatoes.

(2) The Executive Agency for Variety Testing, Field Inspection and Seed Control (IASAS) shall certify cereal seed, oil and fibre plant seed, fodder plant seed, vegetable seed, and beet seed in the categories provided for in Article 30(1) SPMA, depending on the species, which is found by field inspections and laboratory testing for the usefulness and health of the seed to satisfy the conditions laid down in the Regulations listed in Article 29(6) SPMA.

(3) The Executive Agency for Variety Testing, Field Inspection and Seed Control shall certify the seed of the species referred to in paragraph 2 in the cases of marketing or production of certified seed obtained as generations prior to basic seed.

**Article 3.** Seed shall be certified provided that the results of field inspections and laboratory testing are positive.

**Article 4.** (1) For the purposes of certification of the seed of the species referred to in Article 2(2) in the relevant categories, the persons referred to in Article 28 SPMA shall submit an application in the format approved by the Executive Director of the IASAS to the Territorial Unit

(TU) of the IASAS at the location of the seed production areas. The TU shall make available application forms for certification to the applicants.

(2) The following shall be attached to any such application:

1. a sketch map of the property (on which the seed is sown), together with a declaration by the applicant stating the cadastral No. of the property (parcel) and the locality;
2. (Amended, SG No. 109/2007, effective date 20.12.2007, amended, SG No. 79/2012, effective date 16.10.2012) documents on the pre-basic material - a certificate and/or document for the marketing of seed imported from third countries, the official labels for basic seed of wheat, barley, triticale and rice, a plant passport/phytosanitary certificate for the species for which it is required, and a document on the growing trial results, if any, issued by the Executive Agency for Variety Testing, Field Inspection and Seed Control (IASAS);
3. (Amended, SG No. 30/2019, effective date 09.04.2019) a copy of the authorisation granted by the Minister of Agriculture, Food and Forestry for the production of hemp seed containing less than 0.2 percent of tetrahydrocannabinol by dry weight pursuant to Regulation No. 1 of 2018 setting out the conditions and procedure for the authorisation of the growing of plants of the hemp (cannabis) species for fibre, feed and food seed or bred seed containing less than 0.2 percent of tetrahydrocannabinol by dry weight in the leaves, flower buds and fruit buds for marketing and control (SG No. 25/2018), where an application for hemp seed has been submitted.

(3) The application for certification shall be submitted not later than 30 days after the emergence of the plants and it shall be subject to registration at the TU on the date of its receipt.

## **Section II**

### **Field inspection procedure**

**Article 5.** (Amended, SG No. 30/2019, effective date 9.04.2019) Field inspections shall be carried out to establish the compliance of the seed crop with the requirements for the relevant species during the field inspection in accordance with the Regulations listed in Article 29(6) on the basis of methods approved by the Minister of Agriculture, Food and Forestry pursuant to Article 31(6) SPMA.

**Article 6.** The applicant referred to in Article 4(1) shall notify the examination of the plants to the TU of the IASAS at which the application for certification was submitted seven days before the beginning of the relevant plant growth phase.

**Article 7.** (1) The results of the field inspection shall be reported in a field inspection statement in the format approved by the Executive Director of the IASAS.

(2) The statement shall be issued by the inspector who has performed the field inspection within three days of the last examination of the field.

(3) The field inspection statement shall be drawn up in two counterparts. One counterpart shall be made available to the applicant and the other counterpart shall be kept at the TU of the IASAS or by the inspector referred to in Article 6 SPMA where he or she has performed the inspection.

**Article 8.** (Amended, SG No. 30/2019, effective date 9.04.2019) The field inspection statement shall be issued only if the results of the post-control of the genealogical components indicate that each of them is compliant with the requirements for the relevant category as set out in the post-control methods approved by the Minister of Agriculture, Food and Forestry.

**Article 9.** (1) Where the results of the examination indicate any non-compliance of the seed crop with the requirements set out in the relevant Regulation listed in Article 29(6) but the non-compliances can be eliminated, the inspector shall prescribe a deadline for their elimination.

(2) After the expiration of the deadline, the inspector shall re-examine the crop at the same phase of its development.

**Article 10.** Where the results of the field inspection indicate any non-compliance of the seed crop with the requirements set out in the Regulations under Article 29(6) SPMA and the non-compliances cannot be eliminated or the re-examination indicates that they have not been eliminated, the seed crop shall be discarded or, with the consent of the applicant, downgraded to a lower category.

**Article 11.** (1) Where the applicant does not agree with the results of the field inspection (the examination), the applicant may request an arbitration review within five days of the notification of the results.

(2) The arbitration review shall be carried out by a committee appointed with an order by the Executive Director of the IASAS in the presence of the inspector who performed the examination and the applicant or a person duly authorised by the applicant.

(3) The producer shall not perform any additional treatment of the seed crop in the time between the last examination and the arbitration review. The applicant shall make a declaration in writing that he or she will refrain from any additional treatment of the seed crop and submit the declaration together with the request under paragraph 1.

(4) The arbitration award shall be final.

**Article 12.** (1) Where the values established in the course of the examination of seed crops for the production of basic maize seed are close to and not lower than or equal to the minimal values, the inspector may take samples for further control through electrophoresis, which shall be reported in the field inspection statement.

(2) (Amended, SG No. 30/2019, effective date 9.04.2019) The size of the samples and the sampling method shall be established in the methods approved by the Minister of Agriculture, Food and Forestry pursuant to Article 31(6) SPMA.

**Article 13.** (1) After the maize field inspection statement and the electrophoresis document in the cases under Article 12(1) have been issued, a barn inspection of the harvested maize cobs may be carried out by an inspector from the TU of the IASAS at the request of the applicant for certification.

(2) Within three days of the completion of the barn inspection, the inspector from the TU referred to in paragraph 1 duly authorised by the Executive Director of the IASAS shall issue a barn inspection statement in the format approved by the Executive Director of the IASAS.

(3) The barn inspection statement shall be issued in two counterparts. One counterpart shall be made available to the applicant and the other counterpart shall be kept at the TU under Article 4(1).

**Article 14.** Applicants shall pay fees for the inspections under this Chapter in accordance with the rates set out in Decree No. 310 of the Council of Ministers of 2004 on the approval of the Rates of the fees charged by the IASAS under the New Plant Variety and Animal Breed Protection Act and the Seed and Propagating Material Act. (SG No. 104/2004)

### **Section III**

#### **Procedures for the handling, packaging and labelling of seed for certification purposes**

**Article 15.** (1) The seed produced from the seed crops and approved with field inspection statements and, for the maize in the cases under Articles 12(1) and 13(1), approved with an electrophoresis document and a barn inspection statement, if any, shall be cleaned, handled in homogeneous lots, and packaged. Applicants shall establish the net weight of the package or the number of seeds in it.

(2) The maximum size of the lots shall depend on the species as provided for in the Regulations listed in Article 29(6) SPMA.

(3) Where the seed of certain species is handled in size groups, each size group shall form a separate lot.

**Article 16.** (1) Seed shall be packaged in paper, synthetic, metal or other packaging of natural material which has not been used previously and shall not be used for re-packaging.

(2) Depending on the type of package closing, packaging may be any of the following type:

1. machine sewn;
2. bound with a string or another tear resistant material;
3. heat sealed;
4. metal or synthetic containers with closing suitable to the material.

**Article 17.** (1) Prior to the packaging and labelling of the seed, the applicant shall send a written request for labels to the TU of the IASAS at the location of the seed, specifying the size and number of the lots, the net weight and/or the number of seeds in the packages and their location.

(2) The applicant shall return any unused labels to the TU of the IASAS which issued the labels with a cover letter specifying the type and quantity of labels.

**Article 18.** Seed shall be packaged and labelled in accordance with the relevant Regulation listed in Article 29(6).

**Article 19.** (1) Packages shall not be opened, unless there is a written permission by the IASAS to do so in the cases of re-handling for certification purposes, whereby the procedure under Article 17 shall be followed.

(2) (New, SG No. 109/2007, effective date 20.12.2007) The procedure under Article 17 shall also be followed in the cases of subsequent re-packaging of seed in packages with a smaller net weight than the initially packed net weight. An official duly authorised by the Executive Director of the IASAS shall check the sealing of the new packages on the spot at the sole expense of the applicant.

(3) (Ex paragraph 2, supplemented, SG No. 109/2007, effective date 20.12.2007) The labels removed from the packages under paragraphs 1 and 2 shall be returned to the TU of the IASAS in accordance with Article 17(2).

#### **Section IV Sampling procedure**

**Article 20.** (1) For the laboratory testing of seed for certification purposes, samples shall be drawn from the lots after the handling pursuant to Section III.

(2) Samples shall also be drawn in the cases of re-handling and testing of the usefulness of seed.

**Article 21.** (1) Samples shall be drawn officially by samplers who are officials authorised by the Executive Director of the IASAS.

(2) Samples shall be taken in the presence of the applicant or a representative of the applicant.

**Article 22.** (1) Samplers shall draw an initial sample from which a set of samples for calculation of the sample mean shall be formed pursuant to the relevant Regulation listed in Article 29(6). Depending on the type of species, the set of samples shall be used for the following purposes:

1. laboratory tests for analytical purity and germination;
2. moisture content analysis;
3. phytosanitary control;
4. post-control;
5. record keeping at the TU of the IASAS;
6. record keeping by the applicant if the applicant so wishes.

(2) The sample under paragraph 1(5) shall be stored until the expiration date of the certificate and it shall be used, if necessary, for any subsequent testing, including arbitration reviews.

**Article 23.** (1) Samplers shall draw up a sampling statement in the format approved by the Executive Director of the IASAS.

(2) The statement shall be signed by the sampler and by the applicant or a person duly authorised by the applicant.

**Article 24.** (1) Samplers shall send the samples for laboratory testing and/or post-control within three days as from the date on which the samples were drawn.

(2) The samples drawn shall be used only for the purposes of the tests under paragraph 1. Residual quantities shall not be returned to the applicant.

(3) (Amended, SG No. 30/2019, effective date 9.04.2019) For maize, sunflower and other crops subject to post-control on the basis of the methods of laboratory testing and post-control approved by the Minister of Agriculture, Food and Forestry, samples shall be sent to test their usefulness at the relevant laboratory upon receipt of a document with positive results from the post-control.

**Article 25.** Applicants may request laboratory tests to check the usefulness of the seed prior to their final handling at a laboratory pursuant to Section V. The results of such laboratory tests shall not be deemed official.

**Article 26.** The costs incurred in the sending of samples for laboratory tests at the relevant laboratory and for growing trials at the TU shall be borne by the applicant.

## **Section V**

### **Procedure for laboratory testing of the usefulness and health of the seed**

**Article 27.** (1) (Amended, SG No. 30/2019, effective date 9.04.2019) Samples drawn from seed shall be tested for their usefulness - analytical purity, germination and moisture content - at a laboratory of the IASAS or a laboratory approved by the Minister of Agriculture, Food and Forestry testing seed for the purposes of certification and/or approval of commercial seed in accordance with Article 7(1) SPMA and the Regulations under Article 29(6) SPMA.

(2) (Amended, SG No. 30/2019, effective date 9.04.2019) The phytosanitary control of the health of seed from the species listed in Regulation No. 8 of 2015 on phytosanitary control (SG No. 19/2015) shall be performed at a laboratory of the Bulgarian Food Safety Agency (BFSA) and/or a laboratory under Article 8 SPMA.

**Article 28.** (1) (Amended, SG No. 30/2019, effective date 9.04.2019) The laboratory testing of seed for compliance with the requirements set out in the relevant Regulation listed in Article 29(6) SPMA shall be carried out on the basis of methods approved by the Minister of Agriculture, Food and Forestry in accordance with Article 31(8) SPMA.

(2) The laboratory which has made the tests shall issue a document with the laboratory test results in the format approved by the Executive Director of the IASAS.

(3) The document shall be drawn up in three counterparts: one for the laboratory, one for the TU of the IASAS which has taken the samples, and one for the applicant.

(4) (Amended, SG No. 30/2019, effective date 9.04.2019) The BFSA laboratory or the laboratory approved by the Minister of Agriculture, Food and Forestry in accordance with Article 8 SPMA which has performed the phytosanitary control through laboratory testing shall issue a phytosanitary (plant) passport for the species listed in Regulation No. 1 of 1998 on phytosanitary control where the seed is found to be compliant. The phytosanitary (plant) passport shall be made available to the applicant and to the TU of the IASAS which has taken the samples.

**Article 29.** Seed shall be marketed provided that the laboratory test results indicate compliance with the requirements for the usefulness and/or health of the seed and a phytosanitary (plant) passport has been issued, if applicable.

**Article 30.** (1) Where the laboratory test results indicate non-compliance of the seed with the requirements for usefulness and/or health and the phytosanitary requirements, the laboratory

which has performed the tests shall notify in writing the applicant and the TU which has taken the samples.

(2) The seed referred to in paragraph 1 shall not be marketed. The applicant shall return the labels issued to the TU of the IASAS.

**Article 31.** (1) Applicants may eliminate non-compliances with the requirements for seed usefulness and health condition through re-handling, after which the testing shall be re-performed.

(2) Applicants may eliminate non-compliances with the seed germination requirements through mixing seed with other lots of the same species, variety and generation.

**Article 32.** (1) Where the applicant does not agree with the laboratory test results for the usefulness or health of the seed, the applicant may request arbitration laboratory testing from the Executive Director of the IASAS.

(2) The arbitration laboratory testing shall be carried out at the central laboratory of the IASAS.

(3) New samples shall be drawn for the purposes of arbitration.

**Article 33.** Applicants shall pay fees for the laboratory test results in accordance with the rates set out in Decree No. 310 of the Council of Ministers of 2004 on the approval of the Rates of the fees charged by the IASAS under the New Plant Variety and Animal Breed Protection Act and the Seed and Propagating Material Act. The laboratory test document shall be issued within five days of the date of payment of the fee by the applicant.

## **Section VI**

### **Procedure for issuing and using certificates**

**Article 34.** (1) Where the seed is compliant with the requirements under this Chapter, the Executive Director of the IASAS or an official duly authorised by the Executive Director of the IASAS shall issue a certificate in the format approved by the Executive Director of the IASAS.

(2) (Amended, SG No. 30/2019, effective date 9.04.2019) The certificate shall be issued within five days of the date of receipt of the documents for the laboratory tests of the usefulness and/or health and/or the phytosanitary (plant) passport for the crops set out in Regulation No. 1 of 1998 on phytosanitary control and upon payment of the fee in accordance with the rates set out in Decree No. 310 of the Council of Ministers of 2004 on the approval of the Rates of the fees charged by the IASAS under the New Plant Variety and Animal Breed Protection Act and the Seed and Propagating Material Act.

(3) The certificate shall be drawn up in two counterparts: one for the applicant and one for the TU of the IASAS that has taken the samples.

(4) Certificates for seed of all categories shall be valid for one year as from the date of completion of the laboratory tests.

**Article 35.** (1) Basic seed which is not compliant with the germination requirements set out in the Regulations under Article 29(6) SPMA may be certified and marketed in accordance with the terms and conditions laid down in the relevant Regulations.

(2) Certificates shall be issued in accordance with the procedure set out in Article 34.

**Article 36.** Where the certified seed in the relevant category is not compliant with the germination requirements set out in the Regulations under Article 29(6) SPMA, the procedure set out in Article 39 SPMA shall apply for the purposes of overcoming temporary difficulties due to shortage of certified seed in the country and obtaining marketing authorisation of such seed.

## **Chapter Two**

### **PROCEDURES FOR CERTIFICATION AND/OR APPROVAL OF SEED POTATOES**

#### **Section I**

#### **General Requirements**

**Article 37.** (Amended, SG No. 30/2019, effective date 9.04.2019) The Executive Agency for Variety Testing, Approval and Seed Control shall certify seed potatoes in the categories of basic seed potatoes (grade EC1, grade EC2 and grade EC3) and certified seed potatoes of grade A and grade B, which are compliant with the requirements set out in this Regulation, Regulation No. 16 of 2008 and Regulation No. 15 of 2015.

**Article 38.** (1) (Amended, SG No. 30/2019, effective date 9.04.2019) The Executive Agency for Variety Testing, Approval and Seed Control shall control and approve the initial material (initial seed) pursuant to Section II in accordance with the requirements set out in Regulation No. 15 of 2015 and this Regulation.

(2) (Amended, SG No. 30/2019, effective date 9.04.2019) The Executive Agency for Variety Testing, Approval and Seed Control shall certify initial seed as pre-basic seed (seed of generations prior to basic) in accordance with the conditions to be satisfied by basic seed in the cases of placing on the market or at the request of the breeder to produce certified seed of grade A and grade B, where they comply with the requirements set out in Regulation No. 15 of 2015, Regulation No. 16 of 2008 and this Regulation.

(3) (Amended, SG No. 30/2019, effective date 9.04.2019) The BFSA shall perform the phytosanitary control of the health of seed potatoes and issue a phytosanitary (plant) passport to the compliant seed.

**Article 39.** The certification of seed potatoes and/or the approval of the pre-basic seed shall be carried out in accordance with procedures set out in this Regulation.

**Article 40.** (1) For the purposes of certification of seed potatoes in the relevant category, the persons referred to in Article 28 of the SPMA shall submit an application in the format approved by the Executive Director of the IASAS to the Territorial Unit (TU) of the IASAS at the location of the seed production areas. The TU shall make available application forms to the applicants.

(2) The following shall be attached to any such application:

1. a sketch map of the property (on which the seed is sown), together with a declaration by the applicant stating the cadastral No. of the property (parcel) and the locality;
2. (Amended, SG No. 30/2019, effective date 9.04.2019) a document issued by the BFSA to certify that the areas designed for seed production are free of potato cyst nematodes;
3. a declaration by the applicant on the species grown in the areas under subparagraph 2 for the last three years for pre-basic and basic seed or for the last two years for certified seed grades A and B;
4. (Amended, SG No. 109/2007, effective date 20.12.2007) documents on the initial material - a certificate/document on the approval of pre-basic seed and a plant passport/phytosanitary certificate.

(3) The application for certification shall be submitted on an annual basis not later than 20 days after the emergence of the potato plants and it shall be subject to registration at the TU on the date of its receipt.

**Article 41.** (1) For the purposes of the control and approval by the IASAS of pre-basic seed potatoes, the persons referred to in Article 26 SPMA who engage in the maintenance of the variety and who have been approved and registered pursuant to Article 28 SPMA shall submit an application in the format approved by the Executive Director of the IASAS to the Territorial Unit (TU) of the IASAS at the location of the pre-basic seed production facilities (premises, areas). The TU shall make available application forms to the applicants.

(2) The documents under Article 40(2) concerning pre-basic seed shall accompany the application.

(3) The application under paragraph 1 shall be submitted on an annual basis not later than 20 days after the emergence of the potato plants and it shall be subject to registration at the TU on the date of its receipt.

## **Section II**

### **Procedure for the approval of pre-basic (initial) seed potatoes for the production of basic seed**

**Article 42.** (1) The following conditions shall apply to the use of techniques involving micropopagation (*in vitro* propagation):

1. (Amended, SG No. 30/2019, effective date 9.04.2019) the genealogical potato tubers used for micropropagation shall satisfy the conditions laid down in point 1.1 of Annex No. 1 to Regulation No. 15 of 2015;

2. (Amended, SG No. 30/2019, effective date 9.04.2019) mini-tubers obtained through micropropagation of the genealogical potato tubers under subparagraph 1 and pre-propagated mini-tubers shall satisfy the conditions laid down in point 1.2 of Annex No. 1 to Regulation No. 15 of 2015;

3. mandatory official testing or testing under official supervision shall not apply for the purposes of establishing compliance with the requirements under subparagraph 2; the persons referred to in Article 26 SPMA may use the laboratory testing services of the IASAS at their written request.

(2) (Amended, SG No. 30/2019, effective date 9.04.2019) The seed crops (plants) and the tubers of direct progeny as pre-basic seed from the pre-propagated mini-tubers under paragraph 1(2) shall, similarly, comply with the requirements for clonal selection set out in Annex No. 1, point 3 of Regulation No. 15 of 2015 and the requirements for field inspections set out in Regulation No. 16 of 2008 and this Regulation.

(3) The compliance with the requirements to the seed crops under paragraph 2 shall be established through official field inspections. In case of doubt, field inspectors may draw samples from the leaves (of the seed crops) for laboratory ELISA testing for viruses at an IASAS laboratory.

(4) The ELISA test shall be used also for testing pre-basic seed potato tubers at an IASAS laboratory.

(5) Field inspection statements and laboratory test documents shall be issued for field inspections and laboratory testing respectively in the formats approved by the Executive Director of IASAS.

(6) The documents under paragraph 5 shall be issued by officials duly designated by the Executive Director of the IASAS within five days of the completion of the field inspection or testing respectively upon payment of the fee in accordance with the rates set out in Decree No. 310 of the Council of Ministers of 2004 on the approval of the Rates of the fees charged by the IASAS under the New Plant Variety and Animal Breed Protection Act and the Seed and Propagating Material Act.

(7) (Amended, SG No. 30/2019, effective date 9.04.2019) Where the seed crops referred to in paragraph 2 satisfy the conditions laid down in Annex No. 1, point 3 of Regulation No. 15 of 2015 and the conditions for field inspections laid down in Regulation No. 16 of 2008 and this Regulation, the pre-basic seed obtained thereof may be used for the production of basic seed.

(8) The IASAS shall issue an approval document for the pre-basic seed potatoes in the format approved by the Executive Director of the IASAS.

(9) The seed potatoes under paragraph 8 shall be handled under the sole responsibility of the producer and they shall be used for production of basic seed owned by the producer.

**Article 43.** (1) The following conditions shall apply to the use of clonal selection techniques:

1. the genealogical potato tubers used in the clonal selection and intended for re-propagation in progeny (clones) shall satisfy the conditions laid down in Article 42(1)(1);
2. (Amended, SG No. 30/2019, effective date 9.04.2019) the progeny (clones) shall satisfy the conditions laid down in Annex No. 1, point 2.1 of Regulation No. 15 of 2015 and the conditions for field inspections.
  - (2) (Amended, SG No. 30/2019, effective date 9.04.2019) The seed crops (plants) and the direct tubers obtained as pre-basic seed from clones or merged clones shall satisfy the conditions for clonal selection set out in Annex No. 1, point 3 of Regulation No. 15 of 2015 and the conditions for field inspections set out in Regulation No. 16 of 2008 and this Regulation.
  - (3) The compliance with the requirements to the seed crops under paragraph 2 shall be established through official field inspections. In case of doubt, field inspectors may draw samples from the leaves (of the seed crops) for laboratory ELISA testing for viruses at an IASAS laboratory.
  - (4) The ELISA test shall be used also for testing pre-basic seed potato tubers at an IASAS laboratory.
  - (5) The requirements under Article 42, paragraphs 5 to 9 shall apply to pre-basic seed potatoes obtained through clonal selection.

**Article 44.** (Amended, SG No. 30/2019, effective date 9.04.2019) Where pre-basic seed potatoes are marketed (traded) or where they are intended, at the request of the breeder, for the production of certified seed grades A and B, these potatoes shall be certified as pre-basic seed under the conditions applicable to basic seed in accordance with Regulation No. 16 of 2008 provided that they satisfy the conditions laid down in Annex No. 1, point 3 of Regulation No. 15 of 2015.

### **Section III**

#### **Procedure for the conduct of field inspections for certification purposes**

**Article 45.** (1) (Amended, SG No. 30/2019, effective date 9.04.2019) Field inspections shall be carried out to establish the compliance of the seed crop with the requirements set out in Regulation No. 16 of 2008, Regulation No. 15 of 2015 and this Regulation on the basis of methods approved by the Minister of Agriculture, Food and Forestry pursuant to Article 31(6) SPMA.

(2) Field inspections shall be performed officially by IASAS inspectors.

**Article 46.** (1) Field inspections shall be performed through examination of the seed crops at the relevant phases when the plants have well developed varietal features.

(2) The field inspection procedure shall apply in accordance with Chapter Two, Section II.

### **Section IV**

#### **Procedures for the handling, packaging and labelling of seed for certification purposes**

**Article 47.** (1) (Amended, SG No. 30/2019, effective date 9.04.2019) Seed potatoes produced from seed crops approved during a field inspection shall be handled and sorted by size groups in lots in accordance with Regulation No. 16 of 2008.

(2) Seed potatoes shall be transported, sorted, handled and stored separately from the potatoes intended for purposes other than seed production.

**Article 48.** (1) Seed potatoes intended for certification shall be packaged in packages of natural material or in containers.

(2) (Amended, SG No. 30/2019, effective date 9.04.2019) Regulation No. 16 of 2008 shall apply to the packaging and labelling.

(3) Depending on the way they are affixed to the packaging, labels may be:

1. sewn to the packaging;

2. hanging on a string or another tear resistant material and sealed.

**Article 49.** (1) Prior to the packaging and labelling of the seed, the applicant shall send a written request for labels to the TU of the IASAS at the location of the seed, specifying the size and number of the lots, the net weight and/or the number of seeds in the packages and their location.

(2) (Amended, SG No. 30/2019, effective date 9.04.2019) The applicant shall send a copy of the phytosanitary passport issued pursuant to Regulation No. 8 of 2015 on phytosanitary control and verified by the Regional Food Safety Directorate, which shall be attached to the request under paragraph 1.

(3) The applicant shall return any unused labels to the TU of the IASAS which issued the labels with a cover letter specifying the type and quantity of labels.

## **Section V**

### **Seed sampling and quality evaluation procedure**

**Article 50.** (1) (Amended, SG No. 30/2019, effective date 9.04.2019) For the purposes of the quality evaluation of seed potatoes, samples shall be drawn from lots handled pursuant to Section IV and in accordance with Regulation No. 16 of 2008.

(2) (Amended, SG No. 30/2019, effective date 9.04.2019) The size of the samples is specified in Regulation No. 16 of 2008.

**Article 51.** (1) (Amended, SG No. 30/2019, effective date 9.04.2019) Samples shall be drawn by an official sampler duly authorised by the Executive Director of the IASAS on the basis of methods approved by the Minister of Agriculture, Food and Forestry to establish the compliance with the quality requirements set out in Regulation No. 16 of 2008.

(2) Samples shall be drawn in the presence of the applicant or a person duly authorised by the applicant.

(3) Samples shall be tested on the spot for their compliance with the quality requirements set out in the relevant Regulation on the day on which they were taken.

**Article 52.** (1) The quality of seed potatoes shall be evaluated provided that a post-control document is available to prove the compliance of the seed on the basis of the ELISA test.

(2) The document referred to in paragraph 1 shall not be required for the quality evaluation of seed potatoes for the purposes of their certification as certified seed grade B.

**Article 53.** (1) As a result of the grading, an official duly designated by the Executive Director of the IASAS shall issue a document in the format approved by the Executive Director of the IASAS upon payment of the fee in accordance with the rates set out in Decree No. 310 of the Council of Ministers of 2004 on the approval of the Rates of the fees charged by the IASAS under the New Plant Variety and Animal Breed Protection Act and the Seed and Propagating Material Act.

(2) The document shall be drawn up in two counterparts: one for the applicant and one for the TU of the IASAS.

**Article 54.** (1) (Amended, SG No. 30/2019, effective date 9.04.2019) Seed shall not be certified in case it is found to be non-compliant in the quality evaluation procedure.

(2) The seed referred to in paragraph 1 shall not be marketed. The applicant shall return the labels issued to the TU of the IASAS.

**Article 55.** (1) Where the applicant does not agree with the quality evaluation results, the applicant may request arbitration review from the Executive Director of the IASAS.

(2) Arbitration shall be performed by a committee designated by the Executive Director of the IASAS not later than three days after the date of the request.

(3) New samples shall be drawn for the purposes of arbitration.

(4) The applicant or a person duly authorised by the applicant and the official duly authorised by the Executive Director of the IASAS who has performed the initial testing shall attend the conduct of the arbitration review.

(5) Where the arbitration review confirms the results of the initial quality evaluation, applicants shall pay a fee in accordance with the rates set out in Decree No. 310 of the Council of Ministers of 2004 on the approval of the Rates of the fees charged by the IASAS under the New Plant Variety and Animal Breed Protection Act and the Seed and Propagating Material Act.

**Article 56.** After their long-term storage during the autumn and winter, seed potatoes the quality of which has been evaluated shall be subject to re-performance of the quality evaluation procedure.

## **Section VI Procedure for issuing and using certificates**

**Article 57.** (1) Where the seed is compliant with the requirements under this Chapter, the Executive Director of the IASAS or an official duly authorised by the Executive Director of the IASAS shall issue a certificate in the format approved by the Executive Director of the IASAS. Any genetic modification or chemical treatment of the seed shall be indicated in the information contained in the certificate. The chemical treatment products used in such cases shall also be indicated.

(2) The certificate shall be issued within five days of the date of issuance of the quality evaluation document upon payment of the fee in accordance with the rates set out in Decree No. 310 of the Council of Ministers of 2004 on the approval of the Rates of the fees charged by the IASAS under the New Plant Variety and Animal Breed Protection Act and the Seed and Propagating Material Act.

(4) The certificate shall be drawn up in two counterparts: one for the applicant and one for the TU of the IASAS that has received the certification application.

## **Chapter Three PROCEDURE OF PACKAGING IN SMALL PACKAGES**

**Article 58.** (1) Vegetable seed, cereal seed, fodder plant seed and beet seed may also be marketed in the form of small packages.

(2) The relevant Regulations listed in Article 29(6) SPMA shall apply to the small packages referred to in paragraph 1.

**Article 59.** (1) Small packages shall be made of the following material guaranteeing the safe storage of the seed:

1. oil-impregnated paper;
2. metal foil or another synthetic material suitable for heat sealing;
3. metal packages;
4. packaging paper or another synthetic material that cannot be glued.

(2) (Repealed, SG No. 30/2019, effective date 9.04.2019).

## **SUPPLEMENTARY PROVISION**

**§ 1.** For the purposes of this Regulation:

1. "Official label" means a label issued by the IASAS or a certifying/supervisory authority of a seed exporting country.
2. "Growing trials" means a basic method of verification of the varietal identity and purity through field testing of the seed crop on the parcel.
3. "Electrophoresis" means a laboratory method of verification of the varietal purity.

4. (Amended, SG No. 30/2019, effective date 9.04.2019) "Barn inspection" means official control performed by persons duly authorised by the Executive Director of the IASAS on the maize cobs harvested and stored for handling on the basis of methods approved by the Minister of Agriculture, Food and Forestry pursuant to Article 31(6) SPMA.
5. "Size group" of seeds of the species concerned means the quantity of seeds obtained in the handling after their separation by size with sieves of different shape and mesh, depending on the type of species.
6. "Clonal selection" means a method used in the maintenance of potato varieties to obtain separate progeny (clones) through propagation of genealogical potato tubers for the purpose of producing initial (pre-basic) seed.
7. "Merged clones" means the potato tubers from progeny (clones) approved during field inspections and laboratory testing for the purpose of producing initial (pre-basic seed).
8. "Mini-tubers" means the tubers obtained through laboratory micropropagation (*in vitro* propagation) of the genealogical potato tubers.

### **FINAL PROVISIONS**

§ 2. This Regulation is issued pursuant to Article 29(9) of the Seed and Propagating Material Act.

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

#### **Final Provisions**

**AMENDING REGULATION TO REGULATION No. 8 OF 2007 SETTING OUT THE PROCEDURES FOR CERTIFICATION AND/OR APPROVAL OF SEED PRODUCED AND MARKETED IN THE FOLLOWING GROUPS OF AGRICULTURAL PLANT SPECIES: CEREALS, OIL AND FIBRE PLANTS, FODDER PLANTS, VEGETABLES, POTATOES, AND BEET**

(PROMULGATED, SG No. 109/2007, EFFECTIVE DATE 20.12.2007)

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

#### **Final Provisions**

**AMENDING REGULATION TO REGULATION No. 8 OF 2007 SETTING OUT THE PROCEDURES FOR CERTIFICATION AND/OR APPROVAL OF SEED PRODUCED AND MARKETED IN THE FOLLOWING GROUPS OF AGRICULTURAL PLANT SPECIES: CEREALS, OIL AND FIBRE PLANTS, FODDER PLANTS, VEGETABLES, POTATOES, AND BEET**

(PROMULGATED, SG No. 79/2012, EFFECTIVE DATE 16.10.2012)

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

#### **Transitional and Final Provisions**

**REGULATION No. 3 OF 28 MARCH 2019 SETTING OUT THE CONDITIONS AND PROCEDURES FOR GRANTING AUTHORISATIONS TO PERSONS MARKETING SEED FOR SCIENTIFIC PURPOSES OR SELECTION WORK AND SEED FOR DEMONSTRATIONS AND/OR PRODUCTION TESTS AND TRIALS, AND THE ALLOWED QUANTITIES THEREOF DEPENDING ON THE PLANT SPECIES, PACKAGING AND LABELLING OF THE SEED**

(PROMULGATED, SG No. 30/2019, EFFECTIVE DATE 9.04.2019)

§ 6. Regulation No. 8 of 2007 setting out the procedures for certification and/or approval of seeds and propagating material produced and marketed in the following groups of agricultural plant species: fruit plants, vines, ornamental and vegetable species (Promulgated SG No. 29/2007; Amended SG No. 109/2007 and 79/2012) shall be amended as follows:

.....

6. The words:

(a) "Minister of Agriculture and Forestry" shall be replaced by the words "Minister of Agriculture, Food and Forestry" and the acronym "NPPS" shall be replaced by the acronym "BFSA" everywhere in the text;

(b) "Regulation No. 61 on the production and marketing of seed potatoes" shall be replaced by the words "Regulation No. 16 of 2008" everywhere in the text and the words "Regulation No. 78 of 2006 on the production and marketing of basic seed potatoes of the relevant grades on the market of the European Union" shall be replaced by the words "Regulation No. 15 of 2015" everywhere in the text.

.....

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