REGULATION No. 24 OF 28 MAY 2004 ON THE PRODUCTION AND MARKETING OF SEED AND PLANTING MATERIAL OF MEDICINAL AND AROMATIC PLANTS

Issued by the Minister of Agriculture and Forestry

Promulgated, SG, No. 55 of 25 June 2004, amended, SG, No. 77 of 25 September 2007, amended, SG No. 87 of 19 October 2018

Chapter One GENERAL PROVISION

Article 1. (1) This Regulation shall apply to:

- 1. the categories of seed which is produced, certified, approved and marketed in the country;
- 2. the certification of seed;
- 3.the conditions to be satisfied by standard seed;
- 4. the examination of standard seed;
- 5. the approval of commercial seed;
- 6. the repackaging of seed in small packages;
- 7. the marketing of seed;
- 8. the examination of the seed germination capacity;
- 9. the conditions and procedure for post-control of the seed;
- 10. the certification of planting material of medicinal and aromatic plants;
- 11. the conditions to be satisfied by standard planting material;
- 12. the marketing of planting material of medicinal and aromatic plants.
- (2) (Amended, SG No. 77/2007, effective date 25.09.2007) This Regulation shall apply to the seed and planting material of medicinal and aromatic plants grouped into annual plants, biennial plants and perennial plants as indicated in Annex No. 1.

Chapter Two CATEGORIES OF SEED OF MEDICINAL AND AROMATIC PLANTS

- **Article 2.** (1) Seed of medicinal and aromatic plants shall be marketed with a reference to the species and/or variety.
- (2) (Amended, SG No. 77/2007, effective date 25.09.2007) Seed propagating material of medicinal and aromatic plants shall be marketed with a reference to the species. In such cases, the label shall indicate the plant species in a way that does not lead to confusion with the variety denominations.
- (3) (New, SG No. 77/2007, effective date 25.09.2007) Seed propagating material of medicinal and aromatic plants shall be marketed with a reference to the variety provided that the variety is: 1.protected by a plant variety right in accordance with the Protection of New Varieties and Breeds Act; or
- 2. entered into the Official Variety List.
- **Article 3.** Pre-basic seed, certified seed, standard seed and commercial seed of medicinal and aromatic plants shall be placed on the market.
- **Article 4.** (1) Pre-basic seed shall be produced on the basis of methods and schemes to maintain the variety under the supervision of a person referred to in Article 26(1) of the Seed and Propagating Material Act, who maintains the variety.
- (2) The persons referred to in paragraph 1 shall declare in writing to the Executive Agency for Variety Testing, Field Inspection and Seed Control (IASAS) that they comply with the methods and schemes for the production of pre-basic seed.

- (3) Pre-basic seed shall be marketed provided that it is certified in accordance with the requirements to basic seed.
- (4) Pre-basic seed shall be intended for the production of basic seed and certified seed.
- **Article 5.** (1) Basic seed shall be produced from all medicinal and aromatic plant species and from parent components for hybrid seed.
- (2) Basic seed shall be used for the production of certified seed.
- **Article 6.** (1) Certified seed shall be produced from all medicinal and aromatic plant species propagating with seed.
- (2) Certified seed shall be used for the production of medicinal and aromatic plants.
- **Article 7.** (1) Standard seed may be produced from the categories of pre-basic seed, basic seed, or certified seed.
- (2) Standard seed shall be used for the production of medicinal and aromatic plants or for the production of standard seed.
- **Article 8.** (1) Commercial seed shall be produced from all medicinal and aromatic plant species.
- (2) Commercial seed shall be identified with the botanical plant species only.
- (3) Commercial seed shall be used for the production of medicinal and aromatic plants or for the production of commercial seed.

Chapter Three CONDITIONS AND PROCEDURE FOR THE CERTIFICATION OF SEED

Section I General Provisions

- **Article 9.** (Amended, SG No. 87/2018, effective date 19.10.2018) The Executive Agency for Variety Testing, Field Inspection and Seed Control shall certify pre-basic seed, basic seed and certified seed satisfying the minimum requirements for spatial isolation and varietal purity listed in Annex No. 2 and for analytical purity and germination listed in Annex No. 3 and produced on the basis of the methods approved by the Minister of Agriculture, Food and Forestry pursuant to Article 31(6) and (8) SPMA.
- **Article 10.** (1) Certification shall be carried out on the basis of an application submitted in the format approved by the Executive Director of the IASAS.
- (2) The following shall be attached to any such application:
- 1.(Amended, SG No. 87/2018, effective date 19.10.2018) a sketch map of the land property (areas) on which seed is produced, which is attested by the municipal agriculture service at the location of the property;
- 2. documents in relation to the initial material (initial seed) certificates and post-control documents;
- 3. a declaration in writing by the breeder that scientific guidance will be provided in the production of basic seed and pre-basic seed.
- (3) (Amended, SG No. 87/2018, effective date 19.10.2018) The application for certification shall be submitted by the persons referred to in Article 28(1) SPMA to the territorial unit (TU) of the IASAS within the region of which the certified seed production areas are located.
- (4) The application for certification of seed shall be submitted not later than 30 days after sowing and it shall be subject to registration at the TU on the date of its receipt.
- (5) The inspectors at the TU of the IASAS shall compile a file of the seed applied for certification.

Section II Field inspection

- **Article 11.** (1) (Amended, SG No. 87/2018, effective date 19.10.2018) (2) Field inspections shall be carried out to check the compliance with the requirements for minimum spatial isolation and varietal purity listed in Annex No. 2 in accordance with the methods approved by the Minister of Agriculture, Food and Forestry.
- (2) Field inspections shall be carried out by examination of the crops.
- **Article 12.** (1) Field inspections shall be carried out by IASAS inspectors or inspectors licensed in accordance with Article 6(1) SPMA.
- (2) Where the field inspection is carried out by an inspector licensed pursuant to Article 6 SPMA, the contract between the inspector and the applicant shall be attached to the application for certification.
- Article 13. (1) IASAS inspectors shall carry out field inspections of all categories of seed.
- (2) Field inspectors referred to in Article 6 SPMA may carry out field inspections of the category of certified seed.
- **Article 14.** (1) The Executive Agency for Variety Testing, Field Inspection and Seed Control shall control the carrying out of field inspections by the inspectors licensed pursuant to Article 6(1) SPMA through verification checks performed by an IASAS inspector during a crop examination.
- (2) (Amended, SG No. 87/2018, effective date 19.10.2018) Where it is found by a verification check that an inspector does not carry out in the field inspection in accordance with the methods approved by the Minister of Agriculture, Food and Forestry, that inspector shall be penalised pursuant to Article 67 SPMA.
- **Article 15.** (1) (Amended, SG No. 87/2018, effective date 19.10.2018) Field inspections shall be carried out when the crop has the typical characteristics enabling the check of its compliance with the requirements for varietal purity listed in Annex No. 2 in accordance with the methods approved by the Minister of Agriculture, Food and Forestry.
- (2) The applicant shall notify the examination by a field inspector to TU of the IASAS at which the application for certification was submitted seven days before the beginning of the relevant plant growth phase.
- **Article 16.** (1) The results of the field inspection shall be recorded 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 upon payment of the fee in accordance with the rates referred to in Article 6(6) SPMA.
- (3) The field inspection statement shall be drawn up in three counterparts. One counterpart shall be made available to the applicant, the second counterpart shall be attached to the file referred to in Article 10(5), and the third counterpart shall be kept at the TU of the IASAS or by the inspector referred to in Article 6(1) SPMA in case he or she has performed the inspection.
- **Article 17.** (Amended, SG No. 87/2018, effective date 19.10.2018) The field inspection statement for hybrid seed 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 18.** (1) Where the results of the examination indicate any non-compliance of the seed crops with the requirements for varietal identity and varietal purity but the non-compliances can be eliminated, the inspector shall prescribe a deadline for their elimination.

- (2) After the expiry of the deadline, the inspector shall re-examine the seed crops during the same vegetational phase, for which the applicant shall pay a fee in accordance with the rates referred to in Article 6(6) SPMA.
- **Article 19.** (1) Where the results of the field inspection indicate any non-compliance of the seed crop with the requirements for varietal identity and varietal purity and the non-compliances cannot be eliminated or the re-examination indicates that they have not been eliminated, the seed crop shall be discarded by the relevant inspector referred to in Article 12(1) or, with the consent of the applicant, downgraded to and approved in a lower category.
- (2) The discarding or approval of the seed crop in a lower category shall be indicated in the field inspection statement and signed by the applicant.
- **Article 20.** (1) Where the applicant does not agree with the results of the examination, the applicant may request an arbitration review within five days of the date on which the field inspection statement was received.
- (2) The arbitration review shall be carried out by a commission appointed with an order by the Executive Director of the IASAS in the presence of the inspector who performed the field inspection and the applicant or a person authorised by the applicant.
- (3) The producer shall not perform any additional treatments on the seed crops in the time between the last examination and the arbitration review.
- (4) The arbitration award shall be final. Where the arbitration review confirms the conclusions in the field inspection statement, the applicant shall pay a fee in accordance with the rates referred to in Article 6(6) SPMA.

Section III

Handling of the seed; packaging and labelling of the seed

- **Article 21.** (1) The seed produced and approved with a field inspection statement shall be cleaned and prepared by the handler in homogeneous lots.
- (2) Homogeneous lots shall have the size laid down in Annex No. 4 and shall be packages in packages of net weight or number of seeds which shall be determined by the applicant pursuant to Article 10(3).
- **Article 22.** (1) Seed shall be packaged in paper or synthetic packages or packages of natural material or another material suitable for its storage.
- (2) Packages of seed shall be machine sewn, heat sealed, or closed in a matter appropriate for the material.
- **Article 23.** (1) A label containing the particulars listed in Annex No. 5 shall be affixed on the outside of the packaging of the seed intended for certification.
- (2) Labels shall be made out of a tear resistant material with minimum dimensions of 114 mm x 70 mm.
- (3) Depending on the category of seed, labels shall have the following colour:
- 1. white with a diagonal violet line for pre-basic seed;
- 2. white for basic seed;
- 3. blue for certified seed.
- (4) Depending on the way they are affixed to the packaging, labels shall be:
- 1. sewn to the packaging; or
- 2. adhesive; or
- 3. placed inside transparent packages provided that they are legible.
- **Article 24.** (1) The particulars on the labels referred to in Article 23(1) shall be written in the Bulgarian language and printed indelibly.
- (2) In the case of a variety which has been genetically modified, the label shall indicate that the variety has been genetically modified.

- (3) Labels shall indicate any chemical treatment of the seed. Plant protection products authorised for use in this country shall be indicated with their trademark.
- **Article 25.** Packages of seed shall be sealed and labels shall be affixed in such a manner that they cannot be opened without damaging the system of sealing or leaving evidence of tampering on the label or the packaging.
- **Article 26.** (1) Before packaging and labelling the seed, the applicant shall submit an application in writing to the TU of the IASAS at the location of the seed for assigning a reference number to the lot.
- (2) The application shall specify the size and number of lots, the net weight or number of seeds in the packages, their location and the number of labels.
- (3) The TU of the IASAS shall assign reference numbers to the lots on the basis of the application.
- (4) The application referred to in paragraph 1 shall be kept in the file referred to in Article 10(5).
- **Article 27.** The applicant shall not reopen the packages, unless the seed will be subject to rehandling and additional plant protection treatment.

Section IV Sampling

- **Article 28.** (1) Samples for laboratory testing and post-control shall be drawn from lots handled in accordance with Section III.
- (2) Samples for verification testing shall be drawn during the storage of seed and its placement on the market.
- (3) The verification testing referred to in paragraph 2 shall apply only to the quantities of seed from which samples were drawn.
- (4) Samples shall be also drawn in the case of re-handling.
- **Article 29.** (1) (Amended, SG No. 87/2018, effective date 19.10.2018) Samples shall be taken by an official authorised by the Executive Director of the IASAS on the basis of methods approved by the Minister of Agriculture, Food and Forestry pursuant to Article 31(6) SPMA.
- (2) Samples shall be taken in the presence of the applicant or a person authorised by the applicant.
- (3) The person referred to in paragraph 1 shall draw an initial sample from which average samples shall be prepared. Average samples shall have the size laid down in Annex No. 4 and shall be used for:
- 1. analysis of the germination capacity and analytical purity;
- 2. moisture content analysis;
- 3. post-control;
- 4. record keeping at the TU of the IASAS;
- 5. record keeping by the applicant at the applicant's request.
- (4) The sample referred to in paragraph 3, subparagraph 4 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 30.** (1) The official taking the samples shall make out a sampling protocol in the format approved by the Executive Director of the IASAS upon payment of the sampling fee in accordance with the rates referred to in Article 6(6) SPMA.
- (2) The protocol shall be signed by the person referred to in paragraph 1 and the applicant or a person authorised by the applicant and kept in the file.
- **Article 31.** Samples shall be used solely for laboratory testing and post-control purposes.

- **Article 32.** (1) In case the applicant is willing to check the usefulness of the seed prior to its final handling, samples may be drawn therefrom for laboratory testing.
- (2) The laboratory testing of the samples shall be carried out at an IASAS laboratory or a laboratory referred to in Article 7(1) SPMA, whereby the results shall be valid only for the relevant sample.
- **Article 33.** The costs incurred in the sending of samples to the relevant laboratory for laboratory testing and to the TU of the IASAS for growing trials at the TU shall be borne by the applicant.

Section V Laboratory testing of the seed usefulness

- **Article 34.** Seed samples shall be tested for analytical purity, germination and moisture content at an IASAS laboratory or a laboratory referred to in Article 7(1) SPMA, which has been approved for testing.
- **Article 35.** (1) (Amended, SG No. 87/2018, effective date 19.10.2018) Laboratory testing shall be carried out on the basis of methods approved by the Minister of Agriculture, Food and Forestry pursuant to Article 31(8) SPMA.
- (2) The laboratory which has made the tests shall issue a document with the results from the laboratory testing of the seed usefulness in the format approved by the Executive Director of the IASAS.
- (3) The document referred to in paragraph 2 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) The document referred to in paragraph 2 shall be issued within three days of the issuance of the laboratory testing document upon payment of the fee in accordance with the rates provided for in Article 6(6) SPMA.
- **Article 36.** (Amended, SG No. 87/2018, effective date 19.10.2018) Seed shall be certified provided that the results of the laboratory testing indicate that the seed satisfies the minimum conditions for analytical purity and germination in accordance with Annex No. 3 and the methods approved by the Minister of Agriculture, Food and Forestry.
- **Article 37.** (1) (Amended, SG No. 87/2018, effective date 19.10.2018) Seed shall not be certified if the results of the laboratory testing indicate that the seed does not satisfy the minimum conditions for analytical purity and germination in accordance with Annex No. 3 and the methods approved by the Minister of Agriculture, Food and Forestry.
- (2) The seed referred to in paragraph 1 shall not be marketed.
- (3) (Amended, SG No. 87/2018, effective date 19.10.2018) Seed which is not compliant with the germination requirements shall be placed on the market upon permission granted by the Minister of Agriculture, Food and Forestry or by an official authorised by the Minister of Agriculture, Food and Forestry pursuant to Article 39(1) SPMA.
- (4) Applicants my eliminate deviations from the seed germination requirements through mixing seed with other lots of the same species, variety and generation. In such cases, seed shall be resampled and re-tested.
- **Article 38.** Applicants may eliminate deviations from the requirements for seed usefulness through re-handling, after which the testing shall be re-performed.
- **Article 39.** (1) Where the applicant does not agree with the laboratory test results for the usefulness of the seed, the applicant may request, within five days of receipt of the results, an arbitration review from the Executive Director of the IASAS.
- (2) The arbitration testing shall be carried out at the central laboratory of the IASAS.
- (3) New samples shall be drawn for the purposes of arbitration.

(4) Where the arbitration review confirms the results of the initial laboratory testing, the applicant shall pay a fee in accordance with the rates referred to in Article 6(6) SPMA.

Section VI Procedure for issuing a certificate

- **Article 40.** (1) Where the seed is compliant with the requirements under this Chapter, an official authorised by the Executive Director of the IASAS shall issue a certificate.
- (2) The certificate shall be issued within five days of the completion of the laboratory testing upon payment of the fee in accordance with the rates provided for in Article 6(6) SPMA.
- (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.

Article 41. (Repealed, SG No. 87/2018, effective date 19.10.2018)

Chapter Four CONDITIONS TO BE SATISFIED BY STANDARD SEED; EXAMINATION OF STANDARD SEED

- **Article 42.** (1) (Amended, SG No. 87/2018, effective date 19.10.2018) Field inspections of standard seed shall be carried out by the standard seed producer to check the compliance with the requirements for minimum spatial isolation and varietal purity listed in Annex No. 2 in accordance with the methods approved by the Minister of Agriculture, Food and Forestry.
- (2) Standard seed produced from crops which satisfy the minimum requirements for identity and varietal purity shall be cleaned and handled in homogeneous lots pursuant to Chapter Three, Section III.
- (3) The producer's or handler's label shall be affixed on the packages of standard seed. The label shall be dark yellow in colour and shall contain the particulars listed in Annex No. 5.
- **Article 43.** Producers and handlers of standard seed shall keep records of the lots they have produced or handled. Records shall be stored for five years.
- **Article 44.** (1) Handlers of standard seed shall take samples from the lots which are already handled to carry out laboratory testing of the seed usefulness. The size and weight of the samples are listed in Annex No. 4.
- (2) (Amended, SG No. 87/2018, effective date 19.10.2018) Sampling shall be carried out on the basis of methods approved by the Minister of Agriculture, Food and Forestry pursuant to Article 31(6) SPMA.
- **Article 45.** (1) The laboratory testing of the usefulness of standard seed shall be carried out in the laboratories referred to in Article 7(3) SPMA.
- (2) (Amended, SG No. 87/2018, effective date 19.10.2018) Laboratory testing shall be carried out to check the compliance of the seed with the minimum conditions for analytical purity and germination in accordance with Annex No. 3 and the methods approved by the Minister of Agriculture, Food and Forestry.
- (3) Laboratories shall a issue a document on the laboratory testing results in two counterparts one for the applicant and one for the laboratory concerned.
- **Article 46.** (1) (Amended, SG No. 87/2018, effective date 19.10.2018) Producers and handlers of standard seed shall attest the compliance of the standard seed with the minimum conditions for varietal purity in accordance with Annex No. 2, and for analytical purity and germination in accordance with Annex No. 3 and the field inspection and laboratory testing methods approved by the Minister of Agriculture, Food and Forestry with a corporate document.
- (2) The corporate document shall contain the particulars listed in Annex No. 5, an indication of the varietal purity and the number of the laboratory testing document.

- (3) The corporate document shall be valid for one year as from the date of its issuance.
- **Article 47.** (1) Producers and handlers of standard seed, for which a corporate document has been issued, shall submit an application for post-control sampling to the TU of the IASAS at the location of the seed.
- (2) The application shall be submitted in the format approved by the Executive Director of the IASAS. The corporate document shall be attached to the application.
- (3) On the basis of the application, an official authorised by the Executive Director of the IASAS shall take samples for post-control and a sample for verification purposes, which shall be kept by the IASAS, upon payment of the fee pursuant to Aryicle 6(6) SPMA.
- (4) Standard seed may be marketed without waiting for the result of the growing trials.
- (5) Where the crop is found by growing trials that it does not satisfy the conditions for varietal purity, the seed shall not be marketed.

Chapter Five APPROVAL OF COMMERCIAL SEED

- **Article 48.** (1) Commercial seed shall be cleaned and handled in homogeneous lots pursuant to Chapter Three, Section III.
- (2) The handling, sampling, laboratory testing, packaging and labelling of commercial seed shall be carried out pursuant to Chapter Three, Sections III to V.
- (3) The label of commercial seed shall be brown in colour and shall contain the particulars listed in Annex No. 5.
- **Article 49.** (1) A document on the approval of the commercial seed, which satisfies the conditions laid down in Article 48, shall be issued in the format approved by the Executive Director of the IASAS.
- (2) The document shall be issued within five days of the completion of the laboratory testing by an official authorised by the Executive Director of the IASAS upon payment of the fee pursuant to Article 6(6) SPMA.
- (3) The document 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) The document shall be valid for one year as from the date of its issuance.

Chapter Six SUBSEQUENT REPACKAGING. SMALL PACKAGES

Section I Subsequent repackaging

- **Article 50.** (1) In the cases of subsequent repackaging of certified seed of all categories and of commercial seed, the holder of the certificate/document on the approval of the commercial seed or the trader of the seed shall submit an application to the TU of the IASAS at the location of the seed.
- (2) The application referred to in paragraph 1 shall be made out in the format approved by the Executive Director of the IASAS. A copy of the certificate/document on the approval of commercial seed shall be attached to the application.
- **Article 51.** (1) The applicant shall notify the completion of the repackaging to the TU of the IASAS.
- (2) An official authorised by the Executive Director of the IASAS shall check the repackaging on the spot.
- (3) The person referred to in paragraph 2 shall indicate the modifications and attest them with an official seal on the copy of the certificate/document on the approval of commercial seed.

- (4) The costs for the check referred to in paragraph 2 shall be borne by the applicant.
- **Article 52.** (1) Where seed remains in a single packages from the lot repackaged in small packages, the IASAS official shall seal such seed.
- (2) The seed referred to in paragraph 1 may be marketed upon re-labelling or re-packaged pursuant to the provisions of this Chapter.
- **Article 53.** (1) Any subsequent repackaging of standard seed shall be carried out by producers, handlers or traders of standard seed.
- (2) The persons referred to in paragraph 1 shall indicate the modifications and attest them with a signature and/or an official seal on the copy of the corporate document.
- (3) The persons referred to in paragraph 1 shall affix new labels on the packages after the repackaging.
- (4) Where a lot of standard seed, for which a corporate document has been issued, is repackaged subsequently, the repackaged seed shall be placed on the market after samples are taken by the IASAS for post-control purposes.

Section II Small Packages

- **Article 54.** (1) Certified seed, standard seed and commercial seed may be placed on the market in small packages.
- (2) The maximum net weight of small packages shall be up to 25 g for small-seed species and up to 500 g for large-seed species.
- (3) 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) The particulars provided for in Annex No. 5 shall be printed on the small packages in a font size of at least 12 points.
- **Article 55.** (Amended, SG No. 87/2018, effective date 19.10.2018) Seed shall be packaged in small packages by the persons referred to in Article 28(1) SPMA. The persons who carry out the packaging shall be responsible for the identity of the seed in the small packages to that of the packages it has been taken from.
- **Article 56.** (1) Certified seed and commercial seed shall be repackaged into small packages pursuant to Chapter Six, Section I.
- (2) Standard seed shall be repackaged into small packages by the producer, handler, or trader.
- (3) The person referred to in paragraph 2 shall indicate the modifications and attest them with a signature and/or a seal on the copy of the corporate document.
- **Article 57.** The certificate or the document on the approval of commercial seed or the corporate document for standard seed shall be valid for:
- 1. two years as from the date of the laboratory testing og the seed stored in packages pursuant to Article 54(3)(1);
- 1. three years as from the date of the laboratory testing og the seed stored in packages pursuant to Article 54(3)(2) and (3).

Chapter Seven MARKETING OF SEED OF MEDICINAL AND AROMATIC PLANTS

Section I Importation of seed

- **Article 58.** (1) The Executive Agency for Variety Testing, Field Inspection and Seed Control shall verify whether the imported seed matches the contents of the document on its usefulness and plant health issued by an official certification and/or controlling authority of the exporting country for the certified seed and commercial seed or the corporate quality document for standard seed.
- (2) (Amended, SG No. 87/2018, effective date 19.10.2018) For the purposes of the verification provided for in paragraph 1, an official authorised by the Executive Director of the IASAS shall draw samples in accordance with the methods approved by the Minister of Agriculture, Food and Forestry. Samples shall be used for:
- 1. laboratory testing of the usefulness of the seed;
- 2. growing trials, except for commercial seed;
- 3. storage for verification purposes.
- (3) Samples and sampling protocols shall be sent to the IASAS central laboratory and to the territorial unit of the IASAS which will carry out the growth trials.
- (4) The costs for sending the samples shall be borne by the importer.
- **Article 59.** (1) Samples drawn for laboratory testing shall be tested at the central laboratory of the IASAS on the basis of the methods provided for in Article 31(8) SPMA.
- (2) Growing trials of the samples shall be carried out in accordance with the methods laid down in Article 37(4) SPMA.
- (3) Imported seed shall not be placed on the market before the results of the laboratory testing are obtained.
- **Article 60.** (1) (Amended, SG No. 87/2018, effective date 19.10.2018) Where the results of the laboratory testing for the usefulness of the seed indicate that the seed complies with the minimum requirements for analytical purity and germination capacity laid down in Annex No. 3 and the laboratory testing methods approved by the Minister of Agriculture, Food and Forestry, a person authorised by the Executive Director of the IASAS shall issue a document on the marketing of imported seed.
- (2) The document referred to in paragraph 1 shall be issued in the format approved by the Executive Director of the IASAS within three days after the completion of the laboratory testing.
- (3) The document on the marketing of the categories of certified seed and standard seed shall be issued without waiting for the results of the growing trials.
- (4)The document referred to in paragraph 1 shall be valid for one year as from the date of its issuance.
- **Article 61.** (Amended, SG No. 87/2018, effective date 19.10.2018) Where the results of the laboratory testing indicate that the seed does not satisfy the minimum requirements for analytical purity and germination provided for in Annex No. 3 and the methods approved by the Minister of Agriculture, Food and Forestry, seed shall be exported from the country or destroyed pursuant to Article 59 SPMA.
- **Article 62.** (1) Imported seed with a marketing document shall be placed on the market in the packages and with the labels, with which it has been imported in the country, and an additional sticker in the Bulgarian language on each package, containing the particulars of the official label of the package.
- (2) Imported seed may be repackaged into small packages pursuant to Chapter Six, Section II.

Section II Documents for marketing within the country

- **Article 63.** (1) Seed of medicinal and aromatic plants shall be marketed provided that it is accompanied by a clear and legible copy of the certificate or the document on the approval of commercial seed respectively, or the corporate document for the marketing of imported seed, which is attested with the trader's signature and/or seal.
- (2) That copy shall indicate the name or company of the buyer and the seller, the quantity of the seed sold, and the date of the sale.
- (3) The details referred to in paragraph 2 shall be entered into the records provided for in Article 62(1) SPMA. The seller shall sign each entry in the records.
- (4) Where the whole lot is sold, the certificate or the documents referred to in Article 62 shall be delivered to the buyer.

Section III Export documents

- **Article 64.** (1) All categories of certified seed, commercial seed and standard seed shall be exported with the certificate, the document on the approval of commercial seed or the corporate document for standard seed or with an ISTA certificate.
- (2) For the purposes of issuing an ISTA certificate, seed exporters shall submit an application in the format approved by the Executive Director of the IASAS to the central laboratory of the IASAS.
- (3) Sampling shall be carried out pursuant to Chapter Three, Section IV for the purposes of issuing an ISTA certificate.
- (4) ISTA certificates shall be issued by the Executive Director of the IASAS or an official authorised by the Executive Director of the IASAS upon payment of the fee in accordance with the rates referred to in Article 6(6) SPMA.

Chapter Eight EXAMINATION OF THE SEED GERMINATION CAPACITY

- **Article 65.** (1) Lots of certified seed of all categories, commercial seed and standard seed shall be checked to establish its compliance with the minimum germination requirements listed in Annex No. 3.
- (2) The check shall be carried out after the expiration of the validity of the certificate or the document on the approval of commercial seed respectively or the corporate document for standard seed and the document on the marketing of imported seed by laboratory testing of the seed.
- **Article 66.** (1) Owners of lots of certified seed or commercial seed, including imported seed, shall apply for laboratory testing of its germination capacity to the territorial unit of the IASAS in the region of which the seed is located.
- (2) The application shall be submitted in the format approved by the Executive Director of the IASAS. The certificate or the document on the approval of commercial seed respectively or the document on the marketing of imported seed and the post-control document, if any, shall be attached to the application.
- **Article 67.** (1) Sampling shall be carried out in accordance with Chapter Three, Section IV for the purposes of laboratory testing.
- (2) The laboratory which has carried out the testing shall issue a document on the laboratory testing of the seed germination capacity in the format approved by the Executive Director of the IASAS upon payment of the fee in accordance with the rates referred to in Article 6(6) SPMA.

- **Article 68.** (1) Where the laboratory testing results indicate that the seed complies with the minimum germination requirements on the basis of the document referred to in Article 67(2), an official authorised by the Executive Director of the IASAS shall issue a certificate or a document on the approval of commercial seed, or a document on the marketing of imported seed.
- (2) The certificate or the document on the approval of commercial seed, or the document on the marketing of imported seed shall be issued in the format approved by the Executive Director of the IASAS within five days after the issuance of the laboratory testing document upon payment of the fee in accordance with the rates referred to in Article 6(6) SPMA.
- (3) The adhesive sticker referred to in Article 32(3) SPMA shall be affixed on the label of the package.
- **Article 69.** (1) Where the results of the laboratory testing indicate that the seed does not satisfy the minimum germination requirements, seed shall not be placed on the market.
- (2) The Executive Agency for Variety Testing, Field Inspection and Seed Control shall annul the certificate or the document on the approval of commercial seed respectively or the document on the marketing of imported seed for the seed referred to in paragraph 1.
- **Article 70.** (1) The examination of standard seed for the compliance of its germination with the requirements listed in Annex No. 3 shall be carried out in laboratories referred to in Article 7(3) SPMA.
- (2) Where it is found by laboratory testing that the seed satisfies the minimum germination requirements, the laboratory shall issue a testing document which is kept by the seed owner and made available to the controlling authority IASAS for vertification purposes.
- (3) The adhesive sticker referred to in Article 32(3) SPMA shall be affixed on the label of the package.
- (4) Where the results of the laboratory testing indicate that the seed does not satisfy the minimum germination requirements, seed shall not be placed on the market.

Chapter Nine POST-CONTROL CONDITIONS AND PROCEDURE

- **Article 71.** (1) Seed of medicinal and aromatic plants shall be subject to post-control to check its varietal purity and identity.
- (2) (Amended, SG No. 87/2018, effective date 19.10.2018) Post-control of seed of medicinal and aromatic plants shall be carried out by growing trial methods approved by the Minister of Agriculture, Food and Forestry pursuant to Article 37(4) SPMA.

Article 72. (1) Post-control shall apply to:

- 1. all lots of pre-basic seed, basic seed, and standard seed;
- 2. up to 25% of the lots of certified seed, including hybrids;
- 3. seed checked by the IASAS after placement on the retail market, except for commercial seed;
- 4. all lots of imported seed, except for commercial seed.
- (2) The percentage shall be established on an annual basis, depending on the species, in an order by the Executive Director of the IASAS.
- **Article 73.** Samples drawn for growing trials and sampling protocols shall be sent to the TU of the IASAS which will carry out the growth trials.
- **Article 74.** (1) Where the growing trial results indicate that the seed crop complies with the requirements for varietal purity and identity, an official from the TU where the growing trials have been carried out, who is authorised by the Executive Director of the IASAS, shall issue a varietal purity certificate.

- (2) The certificate referred to in paragraph 1 shall be issued in the format approved by the Executive Director of the IASAS upon payment of the fee in accordance with the rates referred to in Article 6(6) SPMA.
- (3) The certificate shall be drawn up in three counterparts: one for the TU of the IASAS which has taken the samples, one for the seed owner, and one for territorial unit which has carried out the growing trials.
- **Article 75.** Where the growing trial results indicate that pre-basic seed and basic seed does not satisfy the conditions for varietal identity and varietal purity but it satisfies the conditions provided for a lower category, the official referred to in Article 74(1) shall approve the seed in the category the conditions of which such seed satisfies.
- **Article 76.** (1) Where it is established during the growing trials that the seed crop does not comply with the requirements for varietal purity and identity, the official referred to in Article 74(1) shall notify the seed owner and the TU of the IASAS which drew the samples and, within three days of establishment of non-compliances, provide access of the owner to the seed crop. (2) The seed referred to in paragraph 1 shall not be marketed.
- **Article 77.** The results of the post-control of seed on the retail market shall apply only to the lot from which samples have been drawn.

Chapter Ten CATEGORIES OF PLANTING MATERIAL OF MEDICINAL AND AROMATIC PLANTS

- **Article 78.** (Amended, SG No. 77/2007, effective date 25.09.2007) (1) Planting material of medicinal and aromatic plants shall be marketed with a reference to the species. In such cases, the label shall indicate the plant species in a way that does not lead to confusion with the variety denominations.
- (2) Planting material of medicinal and aromatic plants shall be marketed with a reference to the variety provided that the variety is:
- 1.protected by a plant variety right in accordance with the Protection of New Varieties and Breeds Act; or
- 2. entered into the Official Variety List.
- **Article 79.** Planting material of medicinal and aromatic plants shall be produced and marketed as pre-basic planting material, basic planting material, certified planting material, and standard planting material.
- **Article 80.** (1) Pre-basic planting material shall be produced on the basis of methods and schemes to maintain the identity of the variety under the supervision of a person referred to in Article 26(1) of the Seed and Propagating Material Act, who maintains the variety.
- (2) The persons referred to in paragraph 1 shall declare in writing to the IASAS that they comply with the methods and schemes for the production of pre-basic planting material.
- (3) Pre-basic planting material shall be intended for the production of basic planting material of medicinal and aromatic plants.
- **Article 81.** (1) Pre-basic planting material of medicinal and aromatic plants shall be produced under the supervision of a person referred to in Article 26(1) SPMA, who maintains the variety.
- (2) Basic planting material shall be produced on the basis of methods and schemes for the maintenance of the varietal identity and plant health.
- (3) Basic planting material of medicinal and aromatic plants shall be intended for the production of certified planting material.

- **Article 82.** (1) Certified planting material of medicinal and aromatic plants shall be produced from basic material.
- (2) Certified planting material of medicinal and aromatic plants shall be intended for the production of medicinal and aromatic plants or for the development of stock nurseries.
- **Article 83.** Standard planting material of medicinal and aromatic plants shall be produced from certified planting material or from stock nurseries, the varietal identity and varietal purity of which is supervised by the producer.

Chapter Eleven CERTIFICATION OF PLANTING MATERIAL OF MEDICINAL AND AROMATIC PLANTS

Section I General Provisions

- **Article 84.** (1) The Executive Agency for Variety Testing, Field Inspection and Seed Control shall certify the categories of certified planting material provided that they satisfy the minimum requirements for spatial isolation, varietal purity, quality, and plant health.
- (2) The minimum distance for spatial isolation of the plants shall be 0.2 meters.
- (3) The varietal purity of crops of medicinal and aromatic plants shall be 100%.
- (4) The minimum levels of quality and plant health are laid down in Annex No. 6.
- **Article 85.** (1) Certification of planting material of medicinal and aromatic plants shall be carried out on the basis of an application submitted in the format approved by the Executive Director of the IASAS.
- (2) The following shall be attached to any such application:
- 1.(Amended, SG No. 87/2018, effective date 19.10.2018) a sketch map of the land property on which the crops are grown, which is attested by the municipal agriculture service at the location of the crops;
- 2. a certificate of the initial material;
- 3. a written declaration by the person referred to in Article 26(1) SPMA that scientific guidance will be provided in the production of pre-basic and basic planting material.
- (3) The application for certification shall be submitted by the persons referred to in Article 28(1) SPMA to the TU of the IASAS within the region of which the crops intended for the production of certified planting material of medicinal and aromatic plants are located.
- (4) The application for certification shall be submitted not later than 30 days after planting or sowing the crop and it shall be subject to registration at the TU on the date of its receipt.
- (5) An application for certification of an existing crop shall be submitted not later of 30 March of the relevant year.
- (6) The inspectors at the TU shall compile a file of the crops applied for certification of planting material of medicinal and aromatic plants within seven days of the date of the application.
- (7) (Amended, SG No. 87/2018, effective date 19.10.2018) The IASAS territorial unit shall notify the relevant Regional Food Safety Directorate *ex officio* of the application for certification within seven days of the preparation of the file.

Section II Field inspection

Article 86. (1) (Amended, SG No. 87/2018, effective date 19.10.2018) Field inspections shall be carried out to establish the compliance of the crop with the minimum requirements set out in Article 84(2) and (3), the plant health requirements, and the field inspection methods approved by the Minister of Agriculture, Food and Forestry.

- (2) Field inspections shall be carried out by IASAS inspectors through examination of the crops.
- **Article 87.** (1) Field inspection shall be carried out when the varietal characteristics of the crop are clearly visible for examination.
- (2) The applicant shall notify the examination to the TU of the IASAS at which the application for certification was submitted ten days before the beginning of the relevant plant growth phase.
- **Article 88.** (1) The results of the field inspection shall be recorded in a field inspection statement in the format approved by the Executive Director of the IASAS.
- (2) (Amended, SG No. 87/2018, effective date 19.10.2018) The statement shall be issued after the last examination by the inspector who has carried out the field inspection upon the presentation of a plant health document from the Bulgarian Food Safety Agency (BFSA) and payment of the fee in accordance with the rates referred to in Article 6(6) SPMA.
- (3) The field inspection statement shall be drawn up in two counterparts, one for the applicant and one for the file referred to in Article 85(6).
- **Article 89.** (1) Where the results of the examination indicate any non-compliance of the crops with the requirements for varietal purity but the non-compliances can be eliminated, the inspector shall prescribe a deadline for their elimination.
- (2) After the expiry of the deadline, the inspector shall re-examine the crops during the same vegetational phase, for which the applicant shall pay a fee in accordance with the rates referred to in Article 6(6) SPMA.
- **Article 90.** Where the results of the field inspection indicate any non-compliance of the crop with the requirements for varietal purity and the re-examination indicates that they have not been eliminated, the crop shall be discarded by the inspector. That fact shall be recorded in the field inspection statement.
- **Article 91.** (1) Where the applicant does not agree with the results of the field inspection, the applicant may request an arbitration review within five days of the date on which the field inspection statement was received.
- (2) The arbitration review shall be carried out by a commission appointed with an order by the Executive Director of the IASAS in the presence of the inspector who performed the field inspection and the applicant or a person authorised by the applicant.
- (3) The applicant shall not perform any additional treatments on the crops in the time between the last examination and the arbitration review.
- (4) The arbitration award shall be final. Where the arbitration review confirms the conclusions in the field inspection statement, the applicant shall pay a fee in accordance with the rates referred to in Article 6(6) SPMA.

Section III

Handling, packaging and labelling of planting material of medicinal and aromatic plants

- **Article 92.** The planting material of medicinal and aromatic plants, which is produced from the crops approved with a field inspection statement, shall be handled in homogeneous lots, packaged and labelled.
- **Article 93.** Planting material of medicinal and aromatic plants shall be packaged, depending on the species, in boxes, contained, or bundles tied with tear resistant material.
- **Article 94.** (1) A label shall be affixed on each package of planting material.
- (2) Labels shall be made out of a tear resistant material with dimensions of 70 mm x 50 mm.
- **Article 95.** The label shall contain the particulars listed in Annex No. 7 written in the Bulgarian language. These particulars shall be printed in an indelible manner.

Article 96. Depending on the category of planting material of medicinal and aromatic plants, the label shall be:

- 1. white with a diagonal violet line for pre-basic planting material;
- 2. white for basic planting material;
- 3. blue for certified planting material.
- **Article 97.** (1) Prior to the packaging and labelling, applicants shall submit an application in writing for a reference number of the lot to the TU of the IASAS within the region of which the planting material is located, stating the size and quantity of the lots of planting material and their location, and the quantity of planting material per package.
- (2) The application shall be kept in the file.
- (3) Applicants shall be assigned, on the basis of their request, a reference number of the lot concerned.

Section IV

Quality grading of planting material of medicinal and aromatic plants

- **Article 98.** (1) For the purposes of quality grading of planting material of medicinal and aromatic plants, samples shall be drawn from the lots handled pursuant to Sections III and IV. (2) Samples shall also be drawn in the case of re-handling.
- **Article 99.** (1) The sampling for quality grading purposes shall be performed by an official authorised by the Executive Director of the IASAS.
- (2) (Amended, SG No. 87/2018, effective date 19.10.2018) Samples for checking plant health shall be drawn by a representative of the BFSA.
- (3) (Amended, SG No. 87/2018, effective date 19.10.2018) Samples shall be taken in the presence of the applicant or a person authorised by the applicant on the basis of methods approved by the Minister of Agriculture, Food and Forestry.
- **Article 100.** (1) Samplers shall test the samples on the spot to check the quality and plant health of the planting material.
- (2) (Amended, SG No. 87/2018, effective date 19.10.2018) Samples taken to check the plant health may also be tested at a BFSA laboratory or a laboratory referred to in Article 8 SPMA on the basis of methods approved by the Minister of Agriculture, Food and Forestry.
- **Article 101.** (1) The IASAS official referred to in Article 99(1) shall issue a quality grading document in the format approved by the Executive Director of the IASAS on the date on which the quality grading was carried out.
- (2) The quality grading document shall be issued in two counterparts, one for the applicant and one for the TU which carried out the quality grading upon payment of the fee pursuant to Article 6(6) SPMA.
- **Article 102.** (1) Where it is found by quality grading that the planting material of medicinal and aromatic plants satisfies the minimum quality and plant health conditions listed in Annex No. 6, that planting material shall be certified.
- (1) Where it is found by quality grading that the planting material of medicinal and aromatic plants does not satisfy the minimum quality and plant health conditions listed in Annex No. 6, that planting material may be re-handled and then the quality grading may be re-performed.
- **Article 103.** (Amended, SG No. 87/2018, effective date 19.10.2018) Where the applicant does not agree with the grading results as regards quality and/or plant health, the applicant may request an arbitration review from the Executive Director of the IASAS or the Executive Director of the BFSA.

- **Article 104.** (1) (Amended, SG No. 87/2018, effective date 19.10.2018) The arbitration review shall be carried out by a commission appointed with an order by the Executive Director of the IASAS or by the Executive Director of the BFSA in the presence of the inspector who performed the quality grading.
- (2) Where the arbitration review confirms the results of the initial quality grading or the document on the plant health, the applicant shall pay a fee in accordance with the rates referred to in Article 6(6) SPMA.

Section V Procedure for issuing a certificate

- **Article 105.** (1) Where theplanting material of medicinal and aromatic plants is compliant with the requirements under this Chapter, an official authorised by the Executive Director of the IASAS shall issue a certificate.
- (2) The certificate shall be issued within five days after the completion of the quality grading procedure and upon payment of the fee pursuant to Article 6(6) SPMA.
- (4) The certificate shall be drawn up in two counterparts one for the applicant and one for the TU of the IASAS keeping the certification file.
- **Article 106.** (1) The certificate of the planting material of all categories shall be valid until the next vegetation period, depending on the species.
- (2) The certificate of the planting material of all categories, which is produced in containers, shall be valid indefinitely.

Chapter Twelve STANDARD PLANTING MATERIAL OF MEDICINAL AND AROMATIC PLANTS

- **Article 107.** (1) Standard planting material of medicinal and aromatic plants shall be produced pursuant to Article 48 SPMA.
- (2) The varietal purity and identity of the crops of medicinal and aromatic plants shall be true to the description of the variety concerned.
- **Article 108.** (1) Standard planting material of medicinal and aromatic plants shall be handled, packaged and labelled pursuant to the provisions of Articles 93, 94 and 95.
- (2) The producer's label provided for in Annex No. 7 shall be affixed on the packages of standard planting material. The colour of the label shall be dark yellow.
- **Article 109.** (1) Standard planting material of medicinal and aromatic plants shall satisfy the minimum quality and plant health conditions listed in Annex No. 6.
- (2) The quality of planting material shall be graded by the producer.
- **Article 110.** (1) The quality of standard planting material of medicinal and aromatic plants shall be attested by the producer with a corporate document containing the particulars of the label, the varietal purity and the quality indicators of the planting material.
- (2) The corporate document for standard planting material of medicinal and aromatic plants shall be valid until the next vegetation period, depending on the plant species.
- (3) The corporate document for the standard planting material, which is produced in containers, shall be valid indefinitely.

Chapter Thirteen MARKETING OF PLANTING MATERIAL OF MEDICINAL AND AROMATIC PLANTS

Section I

Importation and export of planting material of medicinal and aromatic plants

- **Article 111.** (1) The Executive Agency for Variety Testing, Field Inspection and Seed Control shall check the compliance of imported planting material of medicinal and aromatic plants with the contents of the accompanying documents.
- (2) (Amended, SG No. 87/2018, effective date 19.10.2018) For the purposes of the verification provided for in paragraph 1, an official authorised by the Executive Director of the IASAS shall draw samples for quality grading purposes in accordance with the methods approved by the Minister of Agriculture, Food and Forestry.
- (3) The person referred to in paragraph 2 shall carry out the quality grading of the planting material on the spot and shall issue a quality grading document in the format approved by the Executive Director of the IASAS.
- **Article 112.** (1) Where it is found by quality grading that the planting material of medicinal and aromatic plants satisfies the conditions set out in the importation document, an official authorised by the Executive Director of the IASAS shall issue a marketing document for the imported planting material.
- (2) The marketing document shall be issued in the format approved by the Executive Director of the IASAS within three days of the issuance of the quality document referred to in Article 111(3).
- **Article 113.** Where it is found by quality grading that the planting material of medicinal and aromatic plants does not satisfy the conditions set out in the importation document, that planting material shall be exported or destroyed, without prejudice to the provisions of Article 59 SPMA.
- **Article 114.** Imported planting material with a marketing document shall be placed on the market in the packages and with the labels, with which it has been imported in the country, and an additional sticker in the Bulgarian language on each package, containing the particulars of the official label of the package.
- **Article 115.** Planting material of medicinal and aromatic plants shall be exported with the accompanying certificate or corporate document.

Section II Marketing documents

- **Article 116.** (1) Certified and standard planting material of medicinal and aromatic plants shall be marketed provided that it is accompanied by a clear and legible copy of the certificate or the document on the marketing of imported planting material respectively, which is attested with the trader's signature and/or seal.
- (2) That copy shall indicate the name or company of the buyer and the seller, the quantity of the planting material of medicinal and aromatic plants sold, and the date of the sale.
- (3) The details referred to in paragraph 2 shall be entered into the records provided for in Article 62(1) SPMA. The trader shall sign each entry in the records.
- (4) Where the whole lot is sold, the certificate or the corporate document or the document on the marketing of imported planting material respectively shall be delivered to the buyer.

SUPPLEMENTARY PROVISIONS

- § 1. For the purposes of this Regulation:
- 1. "Growing trials" means a basic method of verification of the varietal identity and purity through field testing of the seed crop on the parcel.
- 2. "Pre-basic seed" (PB) means the following types of seed: Super Elite (SE), seed of comparative progeny testing (CPT), seed of initial propagation (SP), and others.
- 3. "Basic seed" (B) means Elite (E) seed and parental components.
- 4. "Certified seed" (C) means seed of the first generation (1G), including hybrid seed (F1).
- 5. "Standard seed" (ST) no equivalent category.
- 6. "Commercial seed" (CS) no equivalent category.

FINAL PROVISIONS

- § 2. This Regulation is issued pursuant to Article 29(6) 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. 24 OF 2004 ON THE PRODUCTION AND MARKETING OF SEED AND PLANTING MATERIAL OF MEDICINAL AND AROMATIC PLANTS

(PROMULGATED, SG No. 77/2007, EFFECTIVE DATE 25.09.2007)

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

Final Provisions

AMENDING REGULATION TO REGULATION No. 13 OF 2004
SETTING OUT THE CONDITIONS AND PROCEDURES FOR THE ISSUANCE OF
AUTHORISATION TO PRODUCERS AND HANDLERS OF SEED AND
PROPAGATING MATERIAL OR FOR REGISTRATION OF TRADERS OF SEED
AND PROPAGATING MATERIAL

(PROMULGATED, SG No. 87/2018, EFFECTIVE DATE 7.10.2018)

§ 30. Regulation No. 24 of 2004 on the production and marketing of seed and planting material
of medicinal and aromatic plants (Promulgated, SG No. 55/2004, amended, SG No. 77/2007)
shall be amended as follows:
10. The words "Minister of Agriculture and Forestry" shall be replaced by the words "Minister of

10. The words "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.

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

Annex No. 1 to Article 1(2) (Amended, SG No 77/2007, effective date 25.09.2007)

List of medicinal and aromatic plant species

- I. Annual:
- 1. Centranthus L. Red Valerian

- 2. Coriandrum sativum L. Coriander
- 3. Datura stramonium L. Thorn Apple (Jimsonweed)
- 4. Matricaria chamomilla L. Wild Chamomile
- 5. Majorana hortensis L. Marjoram
- 6. Nigella sativa L. Black Cumin
- 7. Ocimum basilicum L. Basil
- 8. Pimpinella anisum L. Anise (Aniseed)
- 9. Silibum marianum L. Milk Thistle
- II. Biennial:
- 1. Valeriana officinalis L. Common Valerian

III. Perennial:

- 1. Artemisia L. Mugwort
- 2. Atropa belladonna L. Belladonna
- 3. *Altheae officinalis* L. Marsh-mallow
- 4. Chenopodium bonus Heuricus L. Good-King-Henry
- 5. Echinacea sp. Echinacea
- 6. Glaucium flavum Grantz. Yellow Hornpoppy
- 7. Hyoscyamus niger Henbane
- 8. Hypericum perforatum L. Clamathweed (St. John's wort)
- 9. Hissopus officinalis L. Hyssop
- 10. Humulus lupulus L. Hops
- 11. Lavandula vera L. Lavender
- 12. Leucojum aestivum L. Summer Snowflake
- 13. Leuzea rhaponticum L. Maral Root
- 14. Melissa officinalis L. Balm
- 15. Mentha piperita L. Peppermint
- 16. *Monarda fistulosa* L. Bee balm (Horse Mint)
- 17. Nepeta transcaucasica L. Catmint
- 18. Origanum heracleoticum L. Oregano
- 19. Pyrethrum cinerariafolium Trev. Pyrethrum
- 20. Rosa damascena Mill. Damask Rose
- 21. Rosa rogoza L. Rosehip
- 22. Rosmarinus officinalis L. Rosemary
- 23. Salvia sclarea L. Clary Sage
- 24. Salvia officinalis L. Common Sage
- 25. Scutellaria baicalensis Gefrgi Baikal Skullcap
- 26. *Thymus* sp. Thyme
- 27. Vinca minor L. Running-myrtle

Annex No. 2 to Article 9

Minimum requirements for spatial isolation and varietal purity of crops of medicinal and aromatic plants

The spatial isolation and varietal purity of the crops of medicinal and aromatic plants indicated in the table shall be as follows:

Crop	Minimum	Varietal purity in % at least		
Слор	distance (m), all categories	Pre-basic seed (PB) and basic seed (B)	Certified seed (C)	Standard seed (ST)
Artemisia L Mugwort	1,000	98	94	90
Altheae officinalis L Marsh-mallow	1,000	99	96	92
Atropa belladonna L Belladonna	500	99	96	92
Centranthus L Red Valerian	500	99	98	94
Chenopodium bonus Heuricus L Good-King- Henry	400	98	96	92
Coriandrum sativum L Coriander	400	99	98	94
Datura stramonium L Thorn Apple (Jimsonweed)	2	99	98	94
Echinacea sp Echinacea	400	98	97	93
Glaucium flavum Grantz Yellow Hornpoppy	500	98	97	93
Hyoscyamus niger - Henbane	2	99	98	94
Hissopus officinalis L Hyssop	500	99	98	94
Hypericum perforatum L Clamathweed (St. John's wort)	300	98	97	93
<i>Lavandula vera</i> L Lavender	500	99	98	94
Leucojum aestivum L Summer Snowflake	500	99	98	94
Leuzea rhaponticum L Maral Root	500	98	97	93
<i>Majorana hortensis</i> L Marjoram	500	99	98	94
<i>Matricaria chamomilla</i> L Wild Chamomile	500	99	98	94
Melissa officinalis L Balm	500	99	98	94
Mentha piperita L Peppermint	300	99	98	94
Monarda fistulosa L Bee balm (Horse Mint)	500	99	98	94
Nepeta transcaucasica L Catmint	500	98	95	91
Nigella sativa L Black Cumin	500	98	95	91

Ocimum basilicum L Basil	500	99	98	94
Origanum heracleoticum L Oregano	300	99	98	94
Pimpinella anisum L Anise (Aniseed)	500	99	98	94
Pyrethrum cinerariafolium Trev Pyrethrum	400	99	98	94
Salvia officinalis L Common Sage	500	99	98	94
Salvia sclarea L Clary Sage	300	98	95	91
Silibum marianum L Milk Thistle	1	99	98	94
Thymus sp Thyme	500	99	98	94
Vinca minor L Running-myrtle	400	99	98	94
Valeriana officinalis L Common Valerian	500	98	95	91

Annex No. 3 to Article 9

Minimum requirements for analytical purity and germination of seed of medicinal and aromatic plants

1. Seed of medicinal and aromatic plants of the categories referred to in Article 3 shall satisfy the following conditions:

Сгор	Minimum analytical	Minimum
1	purity	germination
	(% by weight)	(% of pure seed)
Artemisia L Mugwort	95	50
Altheae officinalis L Marsh-mallow	90	40
Atropa belladonna L Belladonna	97	50
Centranthus L Red Valerian	85	50
Chenopodium bonus Heuricus L Good-King-Henry	90	50
Coriandrum sativum L Coriander	97	75
Datura stramonium L Thorn Apple (Jimsonweed)	95	60
Echinacea sp Echinacea	85	50
Glaucium flavum Grantz Yellow Hornpoppy	85	60
Hyoscyamus niger - Henbane	95	40
Hissopus officinalis L Hyssop	85	75
Hypericum perforatum L Clamathweed (St. John's wort)	85	40
Lavandula vera L Lavender	94	40
Leuzea rhaponticum L Maral Root	85	40
Majorana hortensis L Marjoram	90	50
Matricaria chamomilla L Wild Chamomile	85	50
Melissa officinalis L Balm	95	50
Mentha piperita L Peppermint	95	60
Monarda fistulosa L Bee balm (Horse Mint)	85	60
Nepeta transcaucasica L Catmint	85	40
Nigella sativa L Black Cumin	90	50
Ocimum basilicum L Basil	90	50
Origanum heracleoticum L Oregano	90	50
Pimpinella anisum L Anise (Aniseed)	95	65
Pyrethrum cinerariafolium Trev Pyrethrum	85	40

Salvia officinalis L Common Sage	95	70
Salvia sclarea L Clary Sage	90	70
Silibum marianum L Milk Thistle	92	75
Thymus sp Thyme	85	60
Vinca minor L Running-myrtle	85	50
Valeriana officinalis L Common Valerian	85	40

2. Seed of medicinal and aromatic plants of the categories referred to in Article 3, which are not indicated in the table in point 1, shall satisfy the conditions for germination and analytical purity of a crop of the same botanical family and with the closest size of the seed.

Annex No. 4 to Article 21 (2)

Size/weight of lots and samples of seed of medicinal and aromatic plants

1. Size/weight of lots and average samples drawn from a lot of seed of crops of medicinal and aromatic plants indicated in the table:

Crop	Maximum lot weight, kg	Minimum weight of a sample drawn from a lot, g
Artemisia L Mugwort	1,000	5
Altheae officinalis L Marsh-mallow	1,000	50
Atropa belladonna L Belladonna	1,000	30
Centranthus L Red Valerian	1,000	10
Chenopodium bonus Heuricus L Good-King-Henry	1,000	20
Coriandrum sativum L Coriander	5000	400
Datura stramonium L Thorn Apple (Jimsonweed)	5000	100
Echinacea sp Echinacea	5000	20
Glaucium flavum Grantz Yellow Hornpoppy	1,000	25
Hyoscyamus niger - Henbane	1,000	30
Hissopus officinalis L Hyssop	5000	10
Hypericum perforatum L Clamathweed (St. John's wort)	5000	5
Lavandula vera L Lavender	5000	10
Leuzea rhaponticum L Maral Root	1,000	100
Majorana hortensis L Marjoram	1,000	25
Matricaria chamomilla L Wild Chamomile	1,000	10
Melissa officinalis L Balm	1,000	10
Mentha piperita L Peppermint	1,000	5
Monarda fistulosa L Bee balm (Horse Mint)	1,000	10
Nepeta transcaucasica L Catmint	5000	5
Nigella sativa L Black Cumin	1,000	30
Ocimum basilicum L Basil	1,000	40
Origanum heracleoticum L Oregano	1,000	25
Pimpinella anisum L Anise (Aniseed)	5000	70
Pyrethrum cinerariafolium Trev Pyrethrum	1,000	50
Salvia officinalis L Common Sage	1,000	50
Salvia sclarea L Clary Sage	5000	20
Silibum marianum L Milk Thistle	1,000	200
Thymus sp Thyme	1,000	10
Vinca minor L Running-myrtle	5000	5
Valeriana officinalis L Common Valerian	1,000	10

- # The maximum lot weight shall not be exceeded by more than 5%.
- 2. Size/weight of average samples drawn from a lot of seed of crops of medicinal and aromatic plants which are not indicated in the table in point 1:
- (a) small-seed species at least 10 g;
- (b) large-seed species at least 50 g.

Annex No. 5 to Article 23 (1) (Amended, SG No. 87/2018, effective date 19.10.2018)

Information on the official label

- I. Categories of certified seed
- 1. (Amended, SG No. 87/2018, effective date 19.10.2018) State/institution Republic of Bulgaria, Ministry of Agriculture, Food and Forestry
- 2. Control/certification authority, address IASAS, Sofia, 125 Tsarigradsko Chausse;
- 3. Species botanical name of the species;
- 4. Variety written in the Bulgarian language;
- 5. Category;
- 6. Reference number of lot;
- 7. origin of the seed state;
- 8. Date of sampling (month and year);
- 9. Net weight or number of seeds;
- 10. Other information:
- chemical treatment;
- germination capacity trial (month and year) and "actual germination" (%). (This information is indicated on an adhesive sticker affixed on the label)

II. Commercial seed

The official label of commercial seed shall contain the information required for the official label of the categories of certified seed, except for the information on the variety. The words "commercial seed" shall be indicated instead of the indication of the category.

III. Standard seed

- 1. Name and registration number of the handler packaging and labelling standard seed;
- 2. Date of packaging and labelling of the seed (month and year);
- 3. Botanical name of the species;
- 4. Variety written in the Bulgarian language;
- 5. category standard seed (ST);
- 6. Reference number of lot;
- 7. Net weight or number of seeds.
- 8. Other information:
- chemical treatment:
- germination capacity trial (month and year) and "actual germination" (%). (This information is indicated on an adhesive sticker affixed on the label)

IV. Small packages

- 1. Name of the company responsible for the packaging of seed into small packages and its registration number (for companies registered in Bulgaria);
- 2. Validity term of the document;
- 3. Botanical name of the species;
- 4. Variety (for certified seed and standard seed) written in the Bulgarian language;
- 5. Category pre-basic seed (PB), basic seed (B), certified seed (C), standard seed (ST), commercial seed (CS);
- 6. Reference number of the seed lot packaged in small packages;
- 7. Net weight or number of seeds.
- 8. Origin of the seed state;

Annex No. 6 to Article 84 (4)

Conditions to be satisfied by planting material of medicinal and aromatic plants as regards quality and plant health

1. Planting material of Damask rose obtained from herbaceous cuttings

E	\mathcal{E}
Indicators	Characteristics and standards
1	2
1. Root system	W. II. 1 . 1 . 1
(a) length of roots (cm), at least	Well developed, fibrous type 5
2. Diameter of the conditional rot collar at 1 cm above the top roots (mm), at least	3
3. Total length of the above ground part measured from the topmost	11
root, together with new shoots (cm), at least	11
4. Plant health	Не се допуска нападение от ръжда, черни
	листни петна и акари
2. Planting material of lavender from cuttings	
Indicators	Characteristics and standards
1. Length of the above ground part (cm)	10
2. Length of the root system (cm)	8
Diameter of the root collar (mm) Plant health	4
4. Plant nearth	Free of damage from fungi, pests, rodents and hailstone on the above ground part Root system -
	no mechanical damage or browning; free from
	diseases and pests
3. Planting material of lavender from seed	1
Indicators	Characteristics and standards
1. Length of the above ground part (cm), at least	8
2. Length of the root system (cm), at least	10
3. Diameter of the root collar (mm), at least 4. Plant health	<u>5</u>
4. Plant nealth	Free of damage from fungi, pests, rodents and hailstone on the above ground part Root system -
	no mechanical damage or browning; free from
	diseases and pests
	discuses and pests
4. Planting material of rosehip	
Indicators	Characteristics and standards
1. Root system	
(a) length of the main root (cm), at least	Well developed 12
2. Diameter of the root collar (mm), at least	6
3. Above ground part	W. H. 1. 105
(a) length of main branch (cm), at least 4. Plant health	Well shaped 25
4. Flant nearm	Healthy plants, (completely) free from canker, Agrylus and other diseases and pests
5. Damage	Single surface damages to the crown and the root
J. Damage	system shall be permissible
5 Dianting material of nonnamint whiteamer	
5. Planting material of peppermint - rhizomes	
Indicators	Characteristics and standards
1. Age	Annual, from single crop harvesting
2. Appearance	Fresh rzhizomes - underground (white) and above
	ground (rambling stems), no shoots, all dry and
	damaged parts of the plant removed, soil thoroughly removed No admixtures of wild mint,
	other mint species, or Bermuda grass
3. Root system	At least 3 healthy internodes
4. Plant health	Healthy planting material No signs of presence of
	mint acari, viral diseases, leaf curl, or verticillium
	mint acari, viral diseases, leaf curl, or verticillium wilt
6. Planting material of peppermint - rhizomes	
	wilt
6. Planting material of peppermint - rhizomes Indicators	wilt Characteristics and standards
	Characteristics and standards Healthy and fresh plants, well developed above
Indicators 1. Appearance	Characteristics and standards Healthy and fresh plants, well developed above ground part and roots
Indicators	Characteristics and standards Healthy and fresh plants, well developed above

4. Root system	At least four or five radicles at the base of the rhizome	
5. Plant health	No damage from fungi (white rust, verticillium wilt, powdery mildew), no damage from rodents hailstone on the above ground part Root system without any mechanical damage or damage caus by diseases or pests	
7. Planting material of balm		
Indicators	Characteristics and standards	
1. Appearance	Healthy and fresh plants, well developed above ground part and root system	
2. Height (cm), at least	8	
3. Leaves (number), at least	6	
4. Length of the root system (fibrous type) (cm), at least	4	
5. Plant health	Healthy plants, without substantial damage from diseases and pests	
6. Mechanical damage	No broken or crushed leaves or main root debarking	
8. Planting material of valeriana		
Indicators	Characteristics and standards	
1. Appearance	Healthy and fresh plants, well developed root system and preserved plant top	
2. Leaf rosette		
(a) basal leaves, number, at least	2	
(b) length of rosette leaves (cm), at least	3	
3. Root system (a) number of root ramifications, at least	2	
(a) number of root ramifications, at least (b) length of root ramifications (cm), at least	<u>3</u> 4	
4. Plant health	No damage from diseases, pests or rodents and no mechanical damage	
9. Planting material of common sage		
Indicators	Characteristics and standards	
1. Appearance Healthy and fresh plants with well d system and above ground part		
2. Height of the above ground part (cm), at least	12	
3. Diameter of the root collar (mm), at least	3	
4. Length of main roots (cm), at least	8	
5. Plant health	Healthy, no damage from fungi, pests or rodents	
10. Planting material of bee balm		
Indicators	Characteristics and standards	
1. Appearance	Healthy and fresh plants with well developed root	
2. Height of the above ground part (cm), at least	system and above ground part	
3. Number of leaves, at least	6	
4. Number of root ramifications, at least	3	
5. Length of main roots (cm), at least	4	
6. Plant health	No signs of powdery mildew, verticillium wilt, or other diseases No damage from pests or rodents	
7. Mechanical damage	No broken or crushed leaves or main root debarking	
11. Planting material of hyssop		
Indicators	Characteristics and standards	
1. Appearance	Healthy and fresh plants with well developed root system and above ground part	
2. Height of the above ground part (cm), at least	8	
3. Number of root ramifications, at least	5	
4. Diameter of the root collar (mm), at least	3	
5. Length of main roots (cm), at least	10	
6. Plant health	Healthy, no damage from fungi, pests or rodents	
7. Mechanical damage	No broken or crushed leaves or main root	

12. Planting material of catmint

Indicators	Characteristics and standards	
1. Appearance	Healthy and fresh plants with well developed root	
	system and above ground part	
2. Height of the above ground part (cm), at least	10	
3. Number of leaves, at least	8	
4. Length of the root system (fibrous type) (cm), at least	4	
5. Plant health	Healthy plants, without substantial damage from	
	diseases and pests	
13. Planting material of rosemary		
Indicators	Characteristics and standards	
1. Appearance	Healthy and fresh plants with well developed root	
	system and above ground part	
2. Above ground part:		
(a) height (cm), at least	15	
(b) number of shoots	1 to 3	
3. Root system:		
(a) diameter of the root collar (mm), at least	4	
(b) length of main roots (cm), at least	8	
4. Plant health	Healthy plants, without substantial damage from	
	fungi and pests	
5. Mechanical damage	No broken or crushed leaves or main root	
	debarking	
14. Planting material of catmint		
Indicators	Characteristics and standards	
1. Appearance	Healthy and fresh plants, well developed above	
••	ground part and root system	
2. Length of the above ground part (cm), at least	8	
3. Shoots (number), at least	1	
4. Length of the root system (cm), at least	8	
5. Diameter of the branching node (mm), at least	2	
15. Planting material of summer snowflake		
Clusters of hulbs depending on the size	Indicators	

Clusters of bulbs, depending on the size	Indicators
I	Flowering bulbs with at least two inseparable daughter bulbs
II	Flowering bulbs with at least one inseparable daughter bulb
III	Flowering bulbs without any visible daughter bulbs with diameter
	above 1.5 cm
IV	Bulbs with diameter below 1.5 cm - to be further grown

^(*) The diameter of a bulb shall be measured at the widest cross section.

Annex No. 7 to Article 95

Label

- I. Information on the label of the categories of certified planting material of medicinal and aromatic plants
- 1. Initials and address of the certification authority IASAS, Sofia, 125 Tsarigradsko Chausse;
- 2. Reference number of lot;
- 3. Botanical name of the species;
- 4. Denomination of the variety in the Bulgarian language;
- 5. Quantity number or net weight of the package;
- 6. Origin of the planting material state.
- II. Information on the label of standard planting material of medicinal and aromatic plants
- 1. Name of the producer/handler packaging and labelling the planting material of medicinal and aromatic plants, and its registration number
- 2. Lot number assigned by the producer;

- 3. Botanical name of the species;4. Denomination of the variety in the Bulgarian language;5. Quantity number or net weight of the package;6. Origin of the planting material state.