 REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY	STANDARD OPERATING PROCEDURE	Code: SOP PPFFC Version: 03 Page: 1 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

*Annex No1 to Order No RD 11-26/11.01.2022
of the BFSA Executive Director*


I. OBJECTIVE OF THE PROCEDURE

The procedure determines the order and the rules, regulates the responsibilities and the necessary documentation for carrying out the activities for registration and issuance of a certificate for placing on the market and use of fertilisers, soil improvers, biologically active substances and nutrient substrates.

II. RESPONSIBILITIES AND RIGHTS

1. Fertilisers, soil improvers, biologically active substances and nutrient substrates are placed on the market and used after registration and issuance of a certificate for placing on the market and use, when they are effective and do not adversely affect humans, animals or the environment in conditions of use prescribed by the manufacturer.
2. The Executive Director of the Bulgarian Food Safety Agency (BFSA) by an order registers a fertiliser, soil improver, biologically active substance or nutrient substrate and issues a certificate for placing on the market and use by a model (Annex No 6) or reasonably refuses registration when the product does not comply with the requirements in p. 1.
3. According to Art. 132 of the Plant Protection Act (PPA), the Executive Director of the BFSA establishes an Expert Commission on fertilisers, soil improvers, biologically active substances and nutrient substrates, hereinafter referred to the "Expert Commission", which is a permanent advisory body on fertilisers, soil improvers, biologically active substances and nutrient substrates. The composition of the Expert Commission is determined by an order of the Minister of Agriculture and includes representatives of the Ministry of Agriculture, the Ministry of Health, the Ministry of Environment and Water and the Bulgarian Food Safety Agency.

Compiled, date: Sofia Apostolova, Expert in CPPP Signature:..... Violeta Yordanova, Expert in APPPF Signature:.....	Checked: 04.01.2022 Petya Grigorova, Head of APPPF Signature:	Coordinated: 04.01.2022 r. Dobrinka Pavlova, Director of PPPFC Signature:	Applied from: 11.01.2022 All pages 28
---	--	--	--


 REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY	STANDARD OPERATING PROCEDURE	Code: SOP PPPFC Version: 03 Page: 2 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

III. REFERENCE

1. Plant Protection Act (PPA), Art. 130-136;
2. Regulation No. 21 of 23.11.2016 regarding the conditions and order of registration, labeling and control of fertilisers, soil improvers, biologically active substances and nutrient substrates.

IV. DEFINITIONS

1. "Microbial fertilisers" are fertilisers containing microorganisms (bacteria, fungi, yeasts) and have a beneficial effect on plant development or improve the absorption of nutrients when applied to plants, seeds and soils.
2. "Mineral fertilisers" are fertilisers in which declared nutrients are in form of non-organic salts obtained as non-metallic minerals by an industrial and/or chemical process.
3. "Product sample" is a quantity of up to 1 liter or kilogram of a product, in a well sealed package bearing Bulgarian language label, which indicates: trade name, importer, date of manufacture and expiry date.
4. "Organic fertilisers" are carbon-containing products, mainly of vegetable and/or animal origin, added to the soil for plant nutrition.
5. "Organo-mineral fertilisers" are organic fertilisers with added macro and/or micro elements.
6. "Fertilisers" are materials with main function to supply the plants with nutrients.
7. "EC FERTILISERS" is a mark affixed by the manufacturer of the product and ensures that the mineral fertiliser complies with the requirements of Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers.
8. "Soil improvers" are materials which added to soil have the main function to improve the physical and/or chemical properties and/or biological activity of soils.
9. "Biologically active substances" are substances or mixtures, other than nutrients and plant protection products, which when applied to plants, seeds, soil or nutrient substrates, change the physiological processes in plants in a way that creates conditions for improved growth, development, yield, quality or resistance to abiotic stress factors.

 REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY	STANDARD OPERATING PROCEDURE	Code: SOP PPPFC Version: 03 Page: 3 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

10. "Nutrient substrates" are products which provide a favorable environment and nutrients for growth and development of the plants.
11. "Product group" means the products produced by one manufacturer with the same raw materials but with a different proportion of the nutrients.
12. "Fertilisers, soil improvers, biologically active substances and nutrient substrates intended for use only in potted plants" are products intended for flowers and decorative plants which are grown in pots.
13. "Placing on the market" is any delivery against payment or free of charge or storage for the purposes of delivery. Imports on the territory of the country are considered to be placed on the market.

V. PROCEDURE SCOPE


This procedure applies to the registration and issue of a certificate for placing on the market and use of fertilisers, soil improvers, biologically active substances and nutrient substrates based on Article 130, paragraph 1, Art. 132, paragraph 1 and Art. 133, paragraph 1 and paragraph 3.

All fertilisers, soil improvers, biologically active substances and nutrient substrates are subject of registration, **with the exception** of the products referred to in Article 131, paragraph 1 of PPA, namely:

- Manure within the meaning of Article 3(20) of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 establishing health rules concerning animal products and derived products not intended for human consumption and repealing Regulation No 1774/2002 (Other animal products Regulation) (OB, L 300/1 of 14 November 2009);
- Fertilisers, soil improvers, biologically active substances and nutrient substrates intended for use only in potted plants;
- Inorganic fertilisers that meet the requirements of Regulation (EC) No 2003/2003 and are labeled "EC FERTILISERS" – types of fertilisers listed in Annex No 1 of the Regulation.

VI. DOCUMENTS REQUIRED

The applicant (natural or juridical person registered under the Commerce Act — producers, importers or distributors of fertilisers) submits an application to the Executive Director of the BFSa, in accordance with an approved template (Annex No 1 to the procedure), published on

 <p>REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY</p>	STANDARD OPERATING PROCEDURE	<p>Code: SOP PPFC Version: 03 Page: 4 of 28</p>
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

the BFSA website. Foreign producers submit an application through an authorised representative registered under the Commerce Act.

A. Required documents for the registration of fertilisers, soil improvers, biologically active substances and nutrient substrates which are **not placed on the market** in a Member State:

1. Application for registration of fertilisers, soil improvers, biologically active substances and nutrient substrates in accordance with a template (Annex No 1 to the procedure) submitted in Bulgarian in one copy, in paper and electronic form.

2. Administrative Product File — a set of documents needed to register the product or group of products. The administrative file contains:


2.1. A declaration in accordance with a template (Annex No 2 to the procedure) by the manufacturer for the place of manufacture of the product;

2.2. Original Power of attorney when the applicant acts through an authorised representative; the date, content and signature of the power of attorney must be certified by an official competent authority.

3. Technical Product File - a set of documents required for the registration of the product or group of products. The technical file contains the following documents:

3.1. Safety data sheet in Bulgarian in accordance with Article 31 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006. The safety data sheet is dated and contains the following headings:

- 3.1.1 Name of the substance/preparation and the company/enterprise;
- 3.1.2. Hazard identification;
- 3.1.3. Composition/information on the ingredients;
- 3.1.4. First aid measures;
- 3.1.5. Fire-fighting measures;
- 3.1.6. Emergency release arrangements;
- 3.1.7. Operation and storage;
- 3.1.8. Exposure control/personal protective equipment;
- 3.1.9. Physical and chemical properties;
- 3.1.10. Stability and reactivity;
- 3.1.11. Toxicological information;
- 3.1.12. Environmental information;
- 3.1.13. Waste disposal;
- 3.1.14. Transport information;

 REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY	STANDARD OPERATING PROCEDURE	Code: SOP PPPFC Version: 03 Page: 5 or 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

3.1.15. Information according to the current legislation;

3.1.16. Other information.

3.2. Draft label in accordance with Article 9 of Regulation No 21 of 23 November 2016. On the label is indicated:

3.2.1. Type and trade name of the product;

3.2.2. Declared nutrient content as a percentage and nutrient form;

3.2.3. Storage conditions;

3.2.4. Recommended dose and/or method of use;

3.2.5. Name and registered address of the manufacturer;

3.2.6. Name and address of the person placing the product on the market;

3.2.7. Partid number and date of manufacture;

3.2.8. Expiry date;

3.2.9. Specific precautions for use;

3.2.10. Number of the certificate for placing on the market and use;

3.2.11. Instructions for preventing accidents;

3.2.12. Weight or packaging capacity;

3.2.13. Percentage content of organic matter and total nitrogen, the origin of the product for the organic and the organo-mineral fertilisers;

3.2.14. Type of useful microorganisms — for the microbial fertilisers;


3.2.15. Percentage content of calcium oxide and/or magnesium oxide or other substances improving the physico-mechanical and/or chemical properties of the soil - for the soil improvers;

3.2.16. Active substance, the recorded dose for use of the final product, the crop and the development phase for application - for the biologically active substances;

3.2.17. When the organic fertilisers or soil improvers contain components of animal origin, the packaging and/or labels shall also indicate material category (2 or 3) and the information required in points (b), (ix) and (c) of Chapter II of Annex No 8 to Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules for animal by-products and derived products, not intended for human consumption and implementing Council Directive 97/78/EC regarding certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54/1 of 26 February 2011).

3.3. Technical specification of the product or group of products

3.4. Certificate for laboratory testing by the manufacturer or a test report for laboratory analysis by an accredited laboratory pursuant to Regulation (EC) No 765/2008 of the European

 REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY	STANDARD OPERATING PROCEDURE	Code: SOP PPPFC Version: 03 Page: 6 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218/30 of 13 August 2008) issued no later than 12 months before the date of submission of the application for registration, which, depending on the nature of the product, certifies:

3.4.1. Every indicator in the draft label.

3.4.2. Heavy metals content - Arsenic (As), Cadmium (Cd), Chromium (Cr), Nickel (Ni), Mercury (Hg), Lead (Pb).

3.4.3. Absence of harmful microorganisms — Enterococcus, Escherichia coli, Clostridium perfringens, Salmonella, Staphylococcus aureus, yeasts and molds with confirmation of Aspergillus, eggs, larvae and cysts of nematodes.

3.5. Documents certifying the origin, species, material category (2 or 3) and method/parameters for the processing of derived products within the meaning of Article 3(2) of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules regarding animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300/1 of 14 November 2009), when the products contain such ingredients.

3.6. Declaration that the product or products do not have an adverse effect on humans, animals or the environment under the stated conditions of use.


3.7. Documents or scientific publications for tests performed proving the main effect of the requested products and contain detailed results for the obtained yields and quality of the crops.

4. Sample of the product.

B. Required documents for the registration of fertilisers, soil improvers, biologically active substances and nutrient substrates **placed on the market** in a Member State:

1. Application for registration of fertilisers, soil improvers, biologically active substances and nutrient substrates in accordance with a template (Annex No 1 to the procedure) submitted in Bulgarian in one copy, in paper and electronic form.

2. Certified copies of the documents on the basis of which the product was placed on the market in the Member State or other evidence that the product has been placed on the market; documents shall also be presented in an official translation into Bulgarian.


 <p> <i>REPUBLIC OF BULGARIA</i> <i>MINISTRY OF AGRICULTURE</i> <i>BULGARIAN FOOD SAFETY AGENCY</i> </p>	STANDARD OPERATING PROCEDURE	Code: SOP PPFFC Version: 03 Page: 7 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

3. Safety data sheet in Bulgarian in accordance with Article 31 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006. The safety data sheet is dated and contains the following headings:

- 3.1.1 Name of the substance/preparation and the company/enterprise;
- 3.1.2. Hazard identification;
- 3.1.3. Composition/information on the ingredients;
- 3.1.4. First aid measures;
- 3.1.5. Fire-fighting measures;
- 3.1.6. Emergency release arrangements;
- 3.1.7. Operation and storage;
- 3.1.8. Exposure control/personal protective equipment;
- 3.1.9. Physical and chemical properties;
- 3.1.10. Stability and reactivity;
- 3.1.11. Toxicological information;
- 3.1.12. Environmental information;
- 3.1.13. Waste disposal;
- 3.1.14. Transport information;
- 3.1.15. Information according to the current legislation;
- 3.1.16. Other information.

4. Draft label in accordance with Article 9 of Regulation No 21 of 23 November 2016. On the label is indicated:

- 3.2.1. Type and trade name of the product;
- 3.2.2. Declared nutrient content as a percentage and nutrient form;
- 3.2.3. Storage conditions;
- 3.2.4. Recommended dose and/or method of use;
- 3.2.5. Name and registered address of the manufacturer;
- 3.2.6. Name and address of the person placing the product on the market;
- 3.2.7. Partid number and date of manufacture;
- 3.2.8. Expiry date;
- 3.2.9. Specific precautions for use;
- 3.2.10. Number of the certificate for placing on the market and use;
- 3.2.11. Instructions for preventing accidents;
- 3.2.12. Weight or packaging capacity;
- 3.2.13. Percentage content of organic matter and total nitrogen, the origin of the product for the organic and the organo-mineral fertilisers;
- 3.2.14. Type of useful microorganisms — for the microbial fertilisers;

 REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY	STANDARD OPERATING PROCEDURE	Code: SOP PPPFC Version: 03 Page: 8 or 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

3.2.15. Percentage content of calcium oxide and/or magnesium oxide or other substances improving the physico-mechanical and/or chemical properties of the soil - for the soil improvers;

3.2.16. Active substance, the recorded dose for use of the final product, the crop and the development phase for application - for the biologically active substances;

3.2.17. When the organic fertilisers or soil improvers contain components of animal origin, the packaging and/or labels shall also indicate material category (2 or 3) and the information required in points (b), (ix) and (c) of Chapter II of Annex No 8 to Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules for animal by-products and derived products, not intended for human consumption and implementing Council Directive 97/78/EC regarding certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54/1 of 26 February 2011).

5. Original Power of attorney when the applicant acts through an authorised representative; the date, content and signature of the power of attorney must be certified by an official competent authority.

VII. PROCESS OF THE PROCEDURE


1. The application with the required documents, shall be submitted for incoming number to the BFSFA Records Keeping Office in paper and electronic form in Bulgarian with the signature of the applicant. The documents attached to the application shall be submitted in an official translation into Bulgarian in paper and/or electronic form.

2. Within 14 days of the submission of the application and the documents referred to in point 1, the BFSFA checks their fullness by completing a checklist (Annex No 4 or Annex No 5).


3. If any incompleteness and inconsistencies are identified, the Executive Director of the BFSFA or an official authorised person by him shall inform the applicant in writing and set a deadline of one month for their correction. Until the incompleteness and inconsistencies have been resolved, the registration period for products shall be suspended.

4. If the incompleteness and inconsistencies are not corrected within the set deadline, the application shall be left unexamined, which shall be notified in writing to the applicant.

A. When the product is not placed on the market in a Member State:

 <i>REPUBLIC OF BULGARIA</i> <i>MINISTRY OF AGRICULTURE</i> <i>BULGARIAN FOOD SAFETY AGENCY</i>	STANDARD OPERATING PROCEDURE	Code: SOP PPFC Version: 03 Page: 9 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

1. When the documents are complete, the BFSA submits them to the Expert Commission for review.
2. The Expert Commission makes decisions at face-to-face meetings by voting and makes proposal to the Executive Director of the BFSA for:
 - 2.1. Registration of fertilisers, soil improvers, biologically active substances and nutrient substrates which are not placed on the market in a Member State or refusal;
 - 2.2. Change in the registration of fertilisers, soil improvers, biologically active substances and nutrient substrates, or refusal;
 - 2.3. Cancellation of registration of fertilisers, soil improvers, biologically active substances and nutrient substrates.
3. A protocol for the meetings of the Expert Commission shall be drawn up on the reviewed products signed by the members of the Commission.
4. On the basis of the protocol referred to in point 3, the Head of the Expert Commission on fertilisers, soil improvers, biologically active substances and nutrient substrates makes a proposal to the Executive Director of the BFSA for issuing the relevant orders.
5. Within three months of the submission of the application the Executive Director of the BFSA on the basis of the proposal register by an order a fertiliser, soil improver, biologically active substance or nutrient substrate and issue a certificate for placing on the market and use in accordance with the template (Annex No 6 of the procedure) or reasonably refuse the registration if the product does not comply with any of the requirements of Section II point 1 of this procedure and cancel the certificate for placing on the market and use.
6. Before issuing the order for registration of fertilisers, soil improvers, biologically active substances and nutrient substrates by the Executive Director of the BFSA, the applicant shall be informed of the fee due under Article 8, p. 1 of the Tariff for fees collected by the BFSA. The certificate of placing on the market and use is issued after the payment of the fee.
7. Within 14 days of receipt of the order, the holder of the registration certificate shall submit to the Central Office of the BFSA a model of the label with which the fertiliser, soil improver, biologically active substance or nutrient substrate will be placed on the market and used and receive the issued certificate.

 <p> REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY </p>	STANDARD OPERATING PROCEDURE	Code: SOP PPFFC Version: 03 Page: 10 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

B. When the product is placed on the market in a Member State:


1. When registering a product placed on the market in a Member State, the documents are not examined by the Expert Commission.
2. When a product which is placed on the market in a Member State is requested for registration, the order and the certificate is issued on a proposal from the responsible Deputy Executive Director of the BFSA within 30 days of the submission of the application.
3. Before issuing the order for registration of fertilisers, soil improvers, biologically active substances and nutrient substrates by the Executive Director of the BFSA, the applicant shall be informed of the fee due under Article 8, p. 1 of the Tariff for fees collected by the BFSA. The certificate of placing on the market and use is issued after the payment of the fee.
4. Within 14 days of receipt of the order, the holder of the registration certificate shall submit to the Central Office of the BFSA a model of the label with which the fertiliser, soil improver, biologically active substance or nutrient substrate will be placed on the market and used and receive the issued certificate.

C. Change of registration

1. In case of a change in the registration of a fertiliser, soil improver, biologically active substance or nutrient substrate, the relevant documents certifying the change shall be attached to the application.
2. Where the change relates to the composition, the action or the method of use of the products, the submitted documents are examined by the Expert Commission and the change of registration is made on its proposal.
3. Before issuing the order for registration of fertilisers, soil improvers, biologically active substances and nutrient substrates by the Executive Director of the BFSA, the applicant shall be informed of the fee due under Article 8, p. 1 of the Tariff for fees collected by the BFSA. The certificate of placing on the market and use is issued after the payment of the fee.

D. Cancellation of the registration

1. The registration of a fertiliser, soil improver, biologically active substance or nutrient substrate shall be canceled and the certificate of placing on the market and use shall be invalidated under the conditions and in accordance with the procedure laid down in Article 136 of the Plant Protection Act:
 - 1.1. With a written request from the certificate holder;
 - 1.2. When the fertiliser, soil improver, biologically active substance or nutrient substrate:

 REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY	STANDARD OPERATING PROCEDURE	Code: SOP PPFC Version: 03 Page: 11 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

- no longer meets the conditions under which it is registered;
- is registered on the basis of an incorrected data;
- it is not effective or has an adverse effect on humans, animals or the environment.

2. Within 14 days of receipt of the written request or the proposal of the Expert Commission, the Executive Director of the BFSA by an order cancels the registration and invalidates the certificate. The order shall set a time limit for the use of existing quantities of the fertiliser, soil improver, biologically active substance or nutrient substrate.

3. The order is announced to the certificate holder and may be appealed under the Administrative Procedure Code.

4. The cancellation of the registration or the invalidation of the certificate is entered in the public electronic register of registered fertilisers, soil improvers, biologically active substances and nutrient substrates.

VIII. PAYMENT OF SERVICES


For the registration and the issuance of a certificate for the placing on the market and use of fertilisers, soil improvers, biologically active substances and nutrient substrates, a fee shall be paid in accordance with Article 8 of the Tariff for the fees collected by the BFSA as follows:

Number by order	Activity	Measure	BGN
1.	For product registration and issuance of a certificate under Article 130(1) PPA *	For one product	1000,00
1.1.		For a group of two products	1600,00
1.2.		For each subsequent product	700
2.	For product registration and issuance of a certificate under Article 133(3) PPA **	For one product	500,00
2.1.		For a group of two products	800,00
2.2.		For each subsequent product	300,00
3.	Registering changes in the registration and the issuing of a new certificate	For one product	20,00

* For products not placed on the market in a Member State.

** For products placed on the market in a Member State.

The certificate(s) shall be provided to the applicant after the presentation of a payment of the fee.

 REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY	STANDARD OPERATING PROCEDURE	Code: SOP PPPFC Version: 03 Page: 12 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

Transit account for the payment for registration of fertilisers, soil improvers, biologically active substances and nutrient substrates:

Budget account (transit) — in BGN:

BG 45 UBBS 8888 3127 1983 01

BIC UBBSBGSF

UBB AD

Millennium Center, 89B Vitosha Blvd., 1463, Bulgaria

IX. PERIOD OF VALIDITY


The registration of products is **open-ended** from the date of issuance of the certificate.

X. RIGHTS AND OBLIGATIONS OF THE CERTIFICATE HOLDERS

1. Within 14 days of receipt of the written request or the proposal of the Expert Commission, the Executive Director of the BFSA by an order cancels the registration and invalidates the certificate. The order shall set a time limit for the use of existing quantities of the fertiliser, soil improver, biologically active substance or nutrient substrate.
2. Producers or importers of fertilisers are obliged to inform the Bulgarian Food Safety Agency for the emergence of new facts about the effects of the products related to their safety for humans, animals or the environment.
3. Applicants for the registration of products are obliged to notify the BFSA in writing for any change in the data referred to in the application for registration as soon as they occur by applying for a change in circumstances in Annex No 3 to this procedure.
4. Natural and juridical persons trading with fertilisers, soil improvers, biologically active substances and nutrient substrates are obliged to provide data on the quantities sold in active substance at the request of the BFSA.

XI. TEMPLATES AND ANNEXES

1. Template of application for registration of fertilisers, soil improvers, biologically active substances and nutrient substrates and issuing of a certificate for placing on the market and use, available on the BFSA website, **Annex No 1** to this procedure.
2. Template of manufacturer's declaration, **Annex No 2** to this procedure.
3. Template of application for change of circumstances, **Annex No 3** to this procedure.

 REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY	STANDARD OPERATING PROCEDURE	Code: SOP PPFFC Version: 03 Page: 13 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

4. Checklist for completeness of documents for products not placed on the market in a Member State, **Annex No 4** to this procedure.
5. Checklist for completeness of documents for products placed on the market in a Member State, **Annex No 5** to this procedure.
6. Template of certificate for placing on the market and use of fertilisers, soil improvers, biologically active substances and nutrient substrates, **Annex No 6** to this procedure.

XII. ARCHIVING OF DOCUMENTS

A copy of the certificate for placing on the market and use of fertilisers, soil improvers, biologically active substances and nutrient substrates, the submitted application and the accompanying documents are archived to the “Plant Protection Products, Fertilisers and Control” Directorate of the Central Office of the BFSA.

Fertilisers, soil improvers, biologically active substances and nutrient substrates, for which a certificate for placing on the market and use has been issued, are entered in the public register of registered fertilisers under Article 6(1)(14) of the PPA.

XIII. VERSION REGISTER

Date of issue	Version	Changed pages No.	Type of change
Order No RD 11-95/21.03.2011	01		
Order No RD 1-2312/07.11.2017	02	1 to 16	Update
	03	1 to 28	Update



REPUBLIC OF BULGARIA
 MINISTRY OF AGRICULTURE
 BULGARIAN FOOD SAFETY AGENCY

STANDARD OPERATING PROCEDURE

**PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL
 IMPROVERS, BIOLOGICALLY
 ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES**

**Code: SOP
 PPPFC
 Version: 03
 Page: 14 of 28**

Annex No 1

APPLICATION

**FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE
 SUBSTANCES AND NUTRIENT SUBSTRATES AND ISSUING OF A CERTIFICATE FOR PLACING
 ON THE MARKET AND USE**

1. Identification of the applicant

Name, address for correspondence, contact phone:

UIC/BULSTAT of the applicant company

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Name of the person/trader placing the product on the market:

Name and surname of the official responsible for the application:

2. Identification of the manufacturer

Name, address for correspondence, contact phone:

UIC/BULSTAT of the company manufacturer

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Name and surname of the company manager:

3. Placed on the market in a Member State of the European Union

YES NO

EU Member State in which it is placed on the market:

4. Production

4.1. Trade name of the product in Cyrillic/Latin:.....

4.2. Place of production:.....

4.3. Type of product:

- Microbial fertiliser; Organic fertiliser; Organo-mineral fertiliser; Inorganic fertiliser;
 Soil improver; Biologically active substance; Nutrient substrate.

4.4. Raw materials:

Type*	Name	Production quantity per 100 kg/litre	Geographical origin of production

- *The type of raw material can be: nutrient, microorganism inoculate, diluent, solvent, binder, complexing agent, preservative, emulsifier, anti-evaporator, antifoam, colorant.*
- *Consider water as a diluent and/or a solvent.*

4.5. Manufacturing technology

Description:

.....

.....

.....

Patent No (if the product is patented):.....

5. Final product

5.1. Ingredients in 100 kg/litre of the final product

Type	Name and chemical formula	Quantity in %

5.2 Physical and physico-chemical characteristics:

Physical state: Solid; Suspension; Emulsion; Solution; Gas; Gel; Porridge

Wetness: Yes; No

Granulation by: Grinding Crystallisation Aggregation Compaction Encapsulation



Granulometric composition:

Particle size (millimeters)								
% in the final product								

Volumetric mass (20°C), solution, suspension kg/l..... solubility in water g/l 20°C.....

Dry substance %.....

Inorganic substance %.....

Organic substance %.....

pH.....

5.3. Content of heavy metals in mg/kg — quantity in the final product

(As) Arsenic.....

(CD) Cadmium.....

(CR) Chromium.....

(NI) Nickel.....

(Hg) Mercury.....

(PB) Lead.....

5.4. Biological and/or biochemical characteristics

Presence of living organisms: No Yes:

1. Algae; 2. Mushrooms; 3. Bacteria; 4. Yeast; 5. Virus; 6. Other

Class.....

Genus, species, biovariety..... Activity.....

Strain..... Storage.....

CFU/g*.....

* CFU/g (Colony forming Unites): Colonies-forming units in 1 g product — COE/g

6. Microbiological characteristic

Type	Result	Type	Result
Aerobic mesophilic microorganisms (g)		Staphylococcus aureus (g)	
Faecal coliforms (g)		Eggs, larvae and cysts of nematodes (at 25 g)	
Salmonella spp. (pcs/25 g)		Clostridium perfringens (pcs/25 g)	



7. Expected effect:

.....
.....
.....
.....

8. Crops, doses, mode of use

8.1. Method of import

- | | | |
|---|--|---|
| <input type="checkbox"/> Superficially | <input type="checkbox"/> Locally | <input type="checkbox"/> Spraying |
| <input type="checkbox"/> Watering | <input type="checkbox"/> Dusting | <input type="checkbox"/> Pelleting |
| <input type="checkbox"/> Injection | <input type="checkbox"/> Drip irrigation | <input type="checkbox"/> Flowing solution |
| <input type="checkbox"/> By mixing the soil | <input type="checkbox"/> Seed treatment | <input type="checkbox"/> Other |

8.2. Import into:

- | | | | |
|--|---|---|---------------------------------------|
| <input type="checkbox"/> Soil | <input type="checkbox"/> Nutrient substrate | <input type="checkbox"/> Seed | <input type="checkbox"/> Plant - leaf |
| <input type="checkbox"/> Plant - fruit | <input type="checkbox"/> Plant — wood | <input type="checkbox"/> Plant - root (nutrient solution) | |

8.3. Recommended crops

Crop	Dose ml/da; g/da or g/100 kg of seeds.		Number of applications per year		Consumption of working solution/da		Spray concentration		Term for treatment
	Min	Max	Min	Max	Min	Max	%min	%Max	

8.4. Crop development phase at the time of import: describe the development phase reached for more than 50 % of the plants at the time of application, in the order shown in Table 8.3.

.....
.....
.....

9. Toxicological data

Toxicity	Type	Strain	Carrier	Method	Result
Oral					
Skin					
Inhalation					
Skin (irritation)					



REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE
BULGARIAN FOOD SAFETY AGENCY

STANDARD OPERATING PROCEDURE

PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL
IMPROVERS, BIOLOGICALLY
ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES

Code: SOP
PPPFC
Version: 03
Page: 18 of 28

Skin (sensitivity)					
Eyes					
Fish					
Water fleas					
Birds					

10. Special precautions

Possible mixes:.....
 Mixtures not recommended:.....
 Climatic conditions not recommended:.....
 Soil conditions not recommended.....
 Treatment is prohibited on the following crops:.....

11. Precautions for operation

Storage:.....
 Transport:.....
 Fire:.....
 Measures in case of human accident:.....
 Measures in case of unintended spreading:.....
 Possibility of deactivation:.....

12. Risk phrases

Enclosed:
 1.
 2.
 3.
 4.

The applicant expressed his wish to receive the individual administrative act:
 Through a licensed postal operator at this address:

 declaring that the postage is at his expense, payable upon receipt for domestic postal items, and
 agreeing the documents to be transported for official purposes. Send the individual
 administrative act:
 As internal registered post
 As internal courier shipment
 As international registered post
 Personally from the administrative service unit

Applicant:
 (name, surname) (signature, date)

* Copies of documents should be certified with the marking “true with the original”.



REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE
BULGARIAN FOOD SAFETY AGENCY

STANDARD OPERATING PROCEDURE

PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL
IMPROVERS, BIOLOGICALLY
ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES

Code: SOP
PPFC
Version: 03
Page: 19 of 28

Annex No 2

DECLARATION

Of.....
(name of legal entity or ET)

with UIC/BULSTAT:

represented by:
(name, surname)

I hereby ensure that the place of manufacture of the product(s):

.....

is located at the following address:

.....

Date:.....

Signature:.....



REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE
BULGARIAN FOOD SAFETY AGENCY

STANDARD OPERATING PROCEDURE

PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL
IMPROVERS, BIOLOGICALLY
ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES

Code: SOP
PPFC
Version: 03
Page: 20 of 28

Annex No 3

APPLICATION

**FOR A CHANGE IN CIRCUMSTANCES RELATED TO THE REGISTRATION OF FERTILISERS,
SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES AND
ISSUING A CERTIFICATE FOR PLACING ON THE MARKET AND USE**

Details of the applicant:

.....
(name of the juridical or ET)

with UIC/BULSTAT:
represented by:
(name, surname)

in his capacity as:.....

address for correspondence:
(if different from the registered office)

tel./fax: GSM: E-mail:

To registrate a **change in Certificate No...../.....**, concerning:

1.
 2.
 3.
- (specify the type of changed circumstance)

The applicant expressed his wish to receive the individual administrative act:


Through a licensed postal operator at this address:

.....
declaring that the postage is at his expense, payable upon receipt for domestic postal items, and
agreeing the documents to be transported for official purposes. Send the individual
administrative act:

- As internal registered post
- As internal courier shipment
- As international registered post
- Personally from the administrative service unit

Attached certified copies of documents certifying the change:

1.
2.
3.

 REPUBLIC OF BULGARIA MINISTRY OF AGRICULTURE BULGARIAN FOOD SAFETY AGENCY	STANDARD OPERATING PROCEDURE	Code: SOP PPFC Version: 03 Page: 21 of 28
	PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES	

4.

5. Document for the fee paid according to the Tariff for fees collected by the Bulgarian Food Safety Agency when the payment is not made electronically.

Applicant:
(name, surname) (signature, date)

* Copies of documents should be certified with the marking “true with the original”.



REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE
BULGARIAN FOOD SAFETY AGENCY

STANDARD OPERATING PROCEDURE

PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL
IMPROVERS, BIOLOGICALLY
ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES

Code: SOP
PPFFC
Version: 03
Page: 22 of 28

Annex No 4

**CHECKLIST FOR COMPLETENESS OF REGISTRATION DOCUMENTS FOR
FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND
NUTRIENT SUBSTRATES FOR AN EXPERT COMMISSION**

NO	DOCUMENT	YES	NO	NOT APPLIC ABLE	REMARK
1.	Application for registration of fertilisers, soil improvers, biologically active substances and nutrient substrates in accordance with a template (Annex No 1 to the procedure) submitted in Bulgarian in one copy, in paper and electronic form.				
2.	Declaration in accordance with a template (Annex No 2 to the procedure) by the manufacturer for the place of manufacture of the product.				
3.	Original Power of attorney when the applicant acts through an authorised representative; the date, content and signature of the power of attorney must be certified by an official competent authority.				
4.	Safety Data Sheet in Bulgarian in accordance with Article 31 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.				
5.	Draft label in accordance with Article 9 of Regulation No 21 of 23 November 2016.				
6.	Technical specification of the product or group of products.				



REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE
BULGARIAN FOOD SAFETY AGENCY

STANDARD OPERATING PROCEDURE

PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL
IMPROVERS, BIOLOGICALLY
ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES

Code: SOP
PPPFC
Version: 03
Page: 23 of 28

7.	Certificate for laboratory testing by the manufacturer or a test report for laboratory analysis by an accredited laboratory pursuant to Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218/30 of 13 August 2008) issued no later than 12 months before the date of submission of the application for registration, which, depending on the nature of the product, certifies:				
7.1.	Every indicator in the draft label.				
7.2	Heavy metals content - Arsenic (As), Cadmium (Cd), Chromium (Cr), Nickel (Ni), Mercury (Hg), Lead (Pb).				
7.3	Absence of harmful microorganisms — Enterococcus, Escherichia coli, Clostridium perfringens, Salmonella, Staphylococcus aureus, yeasts and molds with confirmation of Aspergillus, eggs, larvae and cysts of nematodes				
8.	Documents certifying the origin, species, material category (2 or 3) and method/parameters for the processing of derived products within the meaning of Article 3(2) of Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules regarding animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300/1 of 14 November 2009), when the products contain such ingredients.				
8.1	Registration certificate of the respective Regional Directorate of Food Safety (RDFS) for the production site as a processing animal by-products (ABP) establishment in accordance with Article 229 of the Veterinary Activities Act and Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 on ABP.				



REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE
BULGARIAN FOOD SAFETY AGENCY

STANDARD OPERATING PROCEDURE

PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL
IMPROVERS, BIOLOGICALLY
ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES

Code: SOP
PPFC
Version: 03
Page: 24 of 28

8.2	Document certifying the registration of the livestock establishment generating manure in accordance with Article 137 of the Veterinary Activities Act.				
9.	Declaration that the product or products do not have an adverse effect on humans, animals or the environment under the stated conditions of use.				
10.	Documents or scientific publications for tests performed proving the main effect of the requested products and contain detailed results for the obtained yields and quality of the crops.				
11.	Sample of the product.				



REPUBLIC OF BULGARIA
MINISTRY OF AGRICULTURE
BULGARIAN FOOD SAFETY AGENCY

STANDARD OPERATING PROCEDURE

PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL
IMPROVERS, BIOLOGICALLY
ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES

Code: SOP
PPFC
Version: 03
Page: 25 of 28

Annex No 5

**CHECKLIST FOR COMPLETENESS OF REGISTRATION DOCUMENTS FOR
FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND
NUTRIENT SUBSTRATES PLACED ON THE MARKET IN A MEMBER STATE**

NO	DOCUMENT	YES	NO	NOT APPLICABLE	REMARK
1.	Application for registration of fertilisers, soil improvers, biologically active substances and nutrient substrates in accordance with a template (Annex No 1 to the procedure) submitted in Bulgarian in one copy, in paper and electronic form.				
2.	Certified copies of the documents on the basis of which the product was placed on the market in the Member State or other evidence that the product has been placed on the market; documents shall also be presented in an official translation into Bulgarian.				
3.	Safety Data Sheet in Bulgarian in accordance with Article 31 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.				
4.	Draft label in accordance with Article 9 of Regulation No 21 of 23 November 2016.				
5.	Original Power of attorney when the applicant acts through an authorised representative; the date, content and signature of the power of attorney must be certified by an official competent authority.				



REPUBLIC OF BULGARIA
 MINISTRY OF AGRICULTURE
 BULGARIAN FOOD SAFETY AGENCY

STANDARD OPERATING PROCEDURE

PROCEDURE FOR REGISTRATION OF FERTILISERS, SOIL IMPROVERS, BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES

Code: SOP
 PPPFC
 Version: 03
 Page: 26 of 28

Annex No 6

CERTIFICATE

**FOR THE PLACING ON THE MARKET AND USE OF FERTILISERS, SOIL IMPROVERS,
 BIOLOGICALLY ACTIVE SUBSTANCES AND NUTRIENT SUBSTRATES**

Reg. No.....

Sofia,.....

Product name:

Manufacturer:

Type of product:

Composition:.....

.....

.....

pH.....

Application of the product:

.....

.....

.....

.....

The certificate is issued in accordance with Article 134(1)/ Article 134(6) of the Plant Protection Act and Order No..... of the Executive Director of the BFSA in connection with an application under ref. No..... at the BFSA of the company

.....

In accordance with Article 134(2) of the Plant Protection Act, the validity of the registration and the certificate is indefinite.

.....
EXECUTIVE DIRECTOR

Pursuant to Article 6(1)(14) of the Plant Protection Act, the Bulgarian Food Safety Agency maintain and update a public register on the website: <http://www.babh.government.bg> with registered fertilisers, soil improvers, biologically active substances and nutrient substrates authorised for placing on the market and use.