Ministry of Agriculture and Food	**PROCEDURE FOR THE DESIGNATION OF OFFICIAL LABORATORIES FOR THE PURPOSE OF ORGANIC PRODUCTION PURSUANT TO ART. 37 OF REGULATION (EU) 2017/625 AND FOR THE IMPLEMENTATION OF ART. 39(1) OF REGULATION (EU) 2017/625** Approved by Order No. RD 09 – 63 of 22.01.2026 of the Minister of Agriculture and Food	Version: 03 Page: 1 of 10

I. OBJECTIVE:

The purpose of the procedure is to regulate the rules for the designation of official laboratories for the performance of laboratory analyses of samples taken during official controls of organic production, in accordance with Art. 37 of Regulation (EU) 2017/625.

The procedure also regulates the conditions for the application of Art. 39(1) of Regulation (EU) 2017/625 on the possibility to carry out audits/inspections of official laboratories.

II. LEGAL FRAMEWORK:

1. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities carried out to ensure the enforcement of food and feed law, animal health and animal welfare rules, plant health and plant protection products, amending Regulations (EC) No. 999/2001, (EC) No. 396/2005, (EC) No. 1069/2009, (EC) No. 1107/2009, (EU) No. 1151/2012, (EU) No. 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No. 1/2005 and (EC) No. 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (the Official Controls Regulation);

2. Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labeling of organic products and repealing Regulation (EU) No. 834/2007 (Regulation (EU) 2018/848);

3. Act on the implementation of the Common Organization of Agricultural Markets of the European Union;

4. Ordinance No. 5 of 2018 on the application of the rules of organic production, labeling and control, and on the authorization of control activities for compliance with the rules of organic production, as well as on the subsequent official supervision of controllers (Ordinance No. 5 of 2018);

5. Rules for the designation of official laboratories for the performance of laboratory analyses of samples taken during official control of organic production, approved by Order No. RD 09-233/02.03.2020 of the Minister of Agriculture, Food and Forestry (the Rules);

6. Order No. RD 09-7/05.01.2024 of the Minister of Agriculture and Food on the designation of National Reference Laboratories, including for the purposes of organic production.

III. ORGANIZATION OF THE PROCESS FOR THE DESIGNATION OF OFFICIAL LABORATORIES:

1. Submission of an application by an accredited laboratory for designation as official for the purpose of official control of organic production in accordance with Art. 37 of Regulation (EU) 2017/625.

2. Appointment of Committee for the verification of the applications submitted under point 1.

3. Verification of documents on the basis of the Rules for the designation of official laboratories for the performance of laboratory analyses of samples taken during official control of organic production.

4. Preparation of a "Verification Results Protocol" based on the verification and submission of the Report to the Minister of Agriculture and Food.

5. Issuance of an order to the Minister of Agriculture and Food designating official laboratories pursuant to Art. 37 of Regulation (EU) 2017/625.

6. Inclusion of the designated official laboratory(ies) in a public "List of Official Laboratories for the purpose of Organic Production pursuant to Art. 37 of Regulation (EU) 2017/625" and its maintenance on the website of the Ministry of Agriculture (MoA).

IV. SUBMISSION OF APPLICATION. DEADLINES.

1. An accredited laboratory may apply for designation as an official laboratory within the meaning of Art. 37 of Regulation (EU) 2017/625 for the purposes of organic production if it is:

1.1. Located on the territory of the Republic of Bulgaria;

1.2. Located in another Member State or in a third country, provided that the laboratory has already been designated as official by the relevant competent authority on whose territory it is located and the necessary arrangements have been made to carry out the audits/inspections referred to in Art. 39(1) of Regulation (EU) 2017/625.

2. The accredited laboratory applying for designation as official shall submit a written application (template) to the Ministry of Agriculture. The application template specifies all the documents to be provided by the applicant.

3. In case the applicant laboratory has already been designated as an official laboratory pursuant to Art. 37(2) of Regulation (EU) 2017/625, the Application shall be accompanied by:

3.1. A certified copy ("true copy") of the current document(s) of the relevant competent authority designating it as official in accordance with Art. 37 of Regulation (EU) 2017/625;

3.2. A certified copy ("true copy") of the latest audit report, as referred to in Art. 39(1) of Regulation (EU) 2017/625, issued by the competent authority that designated the laboratory as official. (if available).

4. The Application and the attached documents shall be submitted electronically or on paper to the Ministry of Agriculture.

Documents that are not in Bulgarian must be provided by the Applicant with a translation into English.

4.1. On paper: The documents shall be submitted to the Administrative Service Center, "Registry" Desk, Republic of Bulgaria, Sofia 1040, 55 "Hristo Botev" Blvd. by handing it over the counter or by postal courier services.

4.2. Electronically:

4.2.1. to the e-mail address edelovodstvo@mzh.government.bg;

4.2.2. through the secure electronic delivery system (SEDS): https://edelivery.egov.bg/

4.2.3. on document portal: https://www.mzh.government.bg/bg/uslugi/dokumenten-portal/ if an electronic signature is available.

5. For each calendar year, the period for submission and receipt of applications shall be from the 1st of January to the 31st of March.

Applicants' documents shall be examined and verified within three months of the end of the admission period.

V. COMMITTEE FOR VERIFICATION OF APPLICATIONS REGISTERED WITH THE MINISTRY OF AGRICULTURE WITH THE ACCOMPANYING DOCUMENTS

1. Composition of the Committee.

When an application(s) is/are received, an order of the Minister of Agriculture shall appoint a named Committee for the examination of the applications and the accompanying documents (the Committee).

1.1. The Committee shall consist of a Chairperson, a Vice-Chairperson, a Secretary and members.

The Chairperson of the Committee is the Director of the Directorate of Organic Production (OP) in the Ministry of Agriculture, the Vice-Chairperson is the Head of Department in the OP Directorate and the Secretary is an expert from the same Directorate.

The Committee members are the heads and one expert each from the National Reference Laboratories for organic production, designated by Order No. RD 09-7/05.01.2024 of the Minister of Agriculture and Food, an expert from the Ministry of Agriculture with competence in the field of GMOs and an expert from the Directorate of Organic Production.

1.2 The Chairperson of the Committee:

1.2.1. Shall schedule and chair Committee meetings;

1.2.2. Shall be responsible for communication with applicant laboratories;

1.2.3. Shall inform the responsible Deputy Minister for Agriculture and Food of the results of the Committee's inspection;

1.2.4. Shall submit to the Minister of Agriculture and Food a report with a "Verification Results Protocol" for approval.

1. 3. In the absence of the Chairperson, the Deputy Chairperson of the Committee shall perform his/her duties.

1. 4. The Secretary of the Committee:

1.4.1. Shall organize and participate in the preparation and conduct of meetings;

1.4.2. Shall draw up a report on the results of the Committee's examination;

1.4.3. Shall organize the reception, storage and archiving of documents;

1.4.4. Shall perform such other functions as may be assigned by the Chairperson of the Committee.

2. Organization of the Committee's work.

Meetings of the Committee for the examination of the application(s) received shall be convened by the Chairperson and shall be deemed to be regular when at least 2/3 of its members are present. Meetings may also be held remotely by video conference and/or exchange of information by e-mail.

The Committee shall take decisions by a majority of at least 2/3 of its members.

The Chairperson, the Deputy Chairperson, the Secretary and the members of the Committee shall perform their duties conscientiously, objectively and impartially and shall keep

secret the circumstances which have come to their knowledge in connection with the activities of the Committee.

After reading the applications received, the Committee members shall sign a "Declaration of confidentiality and absence of conflict of interest" (form). The declarations shall be kept with the records of the meetings.

In the event of any circumstances giving rise to doubt as to the objectivity of a member of the Committee, the same shall inform the Chairperson, who shall take action to amend the order of the Minister determining the composition of the Committee, in order to replace the examiner concerned by another expert (in accordance with the area of competence).

External experts may be involved in the work of the Committee by decision of the Chairperson of the Committee in cases where additional expertise is required for the decision-making of the Committee. The external experts shall provide the Committee with their opinions in writing, which shall be annexed to the applicant's file.

3. Scope of the Committee's activities.

The Committee shall check the application together with the attached documents for completeness and, if no deficiencies are found, shall proceed to the examination of the documentation, in accordance with the criteria in the Rules for the designation of official laboratories for the performance of laboratory analyses of samples taken during official control of organic production (the Rules).

Where the completeness check reveals incompleteness of the documents submitted, the Committee shall inform the applicant in writing by sending a notification letter by e-mail. The letter shall indicate the relevant deficiencies and shall allow the applicant a period of not more than 7 working days from the date of the electronic transmission to remedy the deficiencies. The additional documents submitted within the specified time limit shall be examined by the Committee in accordance with the criteria in the Rules.

In case the applicant fails to submit a response and additional information to the notification letter sent within the specified time limit, further processing of the application shall be terminated.

The work of the Committee shall be documented and concluded with the preparation of a "Verification Results Protocol", which shall be submitted together with a report to the relevant Deputy Minister of Agriculture for information and to the Minister of Agriculture for approval.

The Verification Results Protocol shall contain at least the following information:

- A description of the applications received by the Ministry of Agriculture from laboratories;
- Results of the completeness check;
- Additional information requested (where applicable);
- Consideration of additional information provided in a timely manner (where applicable);
- Verification of applications in accordance with the Rules;
- Result of the verification;
- Result of the vote of the Committee (pursuant to item 2);
- Reasons in case of refusal to designate the laboratory as official (where applicable);
- Signatures of the members of the Committee.

On the basis of the approved Verification Results Protocol, the Directorate of Organic Production shall prepare an order of the Minister of Agriculture and Food designating the laboratories as official laboratories in accordance with Art. 37 of Regulation (EU) 2017/625.

For each designated official laboratory, the order shall specify - which areas of research are covered by the designation, the tasks it performs in its official capacity, the conditions under which it performs the tasks, the measures necessary for efficient and effective coordination and cooperation between it and the competent authority (Art. 37(3) of Regulation (EU) 2017/625) and the duration of its designation.

If the designated official laboratory does not perform analyses of samples sent by the controllers carrying out control activities on the territory of the Republic of Bulgaria for a period of one year from the date of issue of the order, the Minister of Agriculture and Food shall, by order, withdraw its designation as an official laboratory.

VI. NOTIFICATION OF THE APPLICANT LABORATORIES AND PUBLICATION OF THE "LIST OF OFFICIAL LABORATORIES FOR ORGANIC PRODUCTION PURPOSES ACCORDING TO ART. 37 OF REGULATION (EU) 2017/625".

The designated official laboratory(ies) shall be notified in writing by sending a copy of the order to the Minister for Agriculture and Food electronically.

The other laboratories that have submitted an application shall also be notified of the result of the inspection by e-mail.

The Order, together with the "List of official laboratories for organic production purposes

pursuant to Art. 37 of Regulation (EU) 2017/625", shall be published on the website of the Ministry of Agriculture under the heading "Organic production", under the sub-heading "Laboratories".

VII. EXCHANGE OF INFORMATION IN RELATION TO ART. 37(2)(A) AND THE APPLICATION OF ART. 39(1) OF REGULATION (EU) 2017/625.

1. In relation to the requirement of Art. 37(2)(a) and Art. 39(1) of Regulation (EU) 2017/625, the Minister of Agriculture and Food shall exchange information with the competent authorities of the Member State or third country on:

1.1. The performance of audits/inspections of official laboratories and their results;

1.2. The accreditation of laboratories and the results of accreditation assessments, particularly where the host Member State relies on accreditation assessments;

1.3. Designation as an official laboratory under Art. 39(2) of Regulation (EU) 2017/625, in particular withdrawal by the competent authority in the Member State where the laboratory is located.

2. The competent authority, the Minister of Agriculture and Food, may delegate by official letter the performance of audits/inspections under Art. 39 of Regulation (EU) No. 2017/625 of designated official laboratories located in the territory of another Member State or third country to the relevant competent authority that made the designation.

3. The competent authority, the Minister of Agriculture and Food, may organize audits/inspections under Art. 39 of Regulation (EU) 2017/625 of the designated official laboratories located in the territory of the Republic of Bulgaria for compliance with the conditions of Art. 37(4) and (5) of Regulation (EU) 2017/625, taking into account the volume of samples tested, the number of non-compliant results and compliance with the obligations laid down in Art. 38 of Regulation (EU) 2017/625.

3.1. For the purpose of the audits/inspections, the Minister of Agriculture and Food shall issue an order for a Committee to verify the requirements under item 3. The Committee shall be composed of experts from the Directorate for Organic Production, an expert from the MoA with competence in the field of GMOs (if applicable) and an expert from the relevant National Reference Laboratory. The Committee members shall sign a "Declaration of confidentiality and

absence of conflict of interest" (form). The declarations shall be kept with the audit/inspection documents.

3.2. The official laboratory to be inspected shall be informed of the period of the forthcoming audit/inspection electronically within 3 working days of the issue of the order referred to in point 3.1.

3.3. The results of the audits/inspections shall be documented in a report which shall be submitted to the relevant Deputy Minister for information and to the Minister for Agriculture and Food for approval.

3.4. Within 5 working days after approval of the report, it shall be sent electronically to the laboratory. In case of weaknesses identified as a result of the audit/inspection, the laboratory shall take appropriate and timely action to remedy the weaknesses in accordance with Art. 39(2) of Regulation (EU) No. 2017/625 within one month of receipt of the report.

3.5. The Minister for Agriculture and Food may, by order, revoke, in whole or in part, the designation as an official laboratory when the laboratory fails to take appropriate measures in a timely manner where breaches of the conditions of Art. 37(4) and (5) and Art. 38 of Regulation (EU) No. 2017/625 are identified.

VIII. ARCHIVING THE APPLICATION AND AUDIT/VERIFICATION DOCUMENTS.

The application and all documents accompanying it shall be completed in a file and kept at the Directorate of Organic Production at the Ministry of Agriculture for a period of three years.

The records of the audit/verification carried out in accordance with Art. 39(1) of Regulation (EU) No. 2017/625 shall be kept at the Directorate for Organic Production of the Ministry of Agriculture for a period of three years.

IX. MONITORING.

When legislation and other administrative documents relating to the designation and operation of official laboratories and the performance of audits/inspections are amended, the Directorate for Biological Production shall take action to update this procedure and its templates.

When amendments are made to the procedure, the following information shall be provided:

Amended document	Description of amendment	Version of amendment	Date of amendment
Version 01	Section V "COMMITTEE FOR VERIFICATION OF APPLICATIONS REGISTERED WITH THE MINISTRY OF AGRICULTURE WITH THE ACCOMPANYING DOCUMENTS", Section 1 "Composition of the Committee", Section 1.1. the words "representative of the BFSA Head Office" are replaced by "expert from the MoA with competence in the field of GMOs".	Version 01	01/03/2021
Version 01	The terms and conditions for the application of Art. 39(1) of Regulation (EU) 2017/625, concerning the possibility to carry out audits/inspections of official laboratories, are laid down.	Version 02	31/10/2022
Version 02	Conditions are created for the submission of applications electronically through the secure electronic delivery system (SEDS). It is stipulated that documents that are not in Bulgarian must be provided by the Applicant with a translation into English.	Version 03	22/01/2026

X. ATTACHMENTS:

1. Annex No. 1 - Form of the "Application for designation of an official laboratory for the purpose of organic production according to Art. 37 of Regulation (EU) 2017/625" (in Bulgarian and English).

2. Annex No. 2 - Form of Declaration of confidentiality and absence of conflict of interest *(in relation to Art. 37 of Regulation (EU) 2017/625)*.

3. Annex No. 3 - Form of Declaration of confidentiality and absence of conflict of interest *(in relation to Art. 39(1) of Regulation (EU) 2017/625)*.