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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to the cases and conditions under which competent authorities may designate official laboratories which do not fulfil the conditions in relation to all the methods they use for official controls or other official activities

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2017/625 of the European Parliament and of the Council establishes rules on the performance of official controls by the competent authorities of the Member States. It provides that laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities are to be performed by official laboratories, which have been designated as such by the competent authority of the Member State.

These official laboratories need to comply with certain accreditation criteria based on international standards. In addition, all methods used by those laboratories in the context of official controls and other official activities have to fall within the scope of the accreditation.

Based on Article 41 of Regulation (EU) 2017/625, this draft Delegated Regulation specifies cases where and conditions under which competent authorities may designate as official laboratories, laboratories which do not fulfil the conditions of that Regulation in relation to all the methods they use for official controls and other official activities.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission's Expert Group "official controls" (E00911) and stakeholders, mainly European Union reference laboratories and national reference laboratories were consulted through a specific questionnaire and in specific discussions during their annual meetings.

The informal discussions contributed to the preparation of a draft which did not present controversial issues.

No impact assessment has been carried out, as the Delegated Regulation is not expected to have significant impacts. It will further improve the flexibility already foreseen in Regulation (EU) 2017/625and should reduce the administrative and financial burden.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis for the Delegated Regulation is Article 41 of Regulation (EU) 2017/625, which places an obligation on the Commission to act.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, 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 Regulation (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 (Official Controls Regulation)[1], and in particular Article 41 thereof,

Whereas:

(1) Regulation (EU) 2017/625 provides that laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities are to be performed by official laboratories, which have been designated as such by the competent authorities of the Member States.

(2) In accordance with Article 37(4), point (e) of Regulation (EU) 2017/625, official laboratories need to comply with, *inter alia*, certain accreditation criteria based on international standards. Article 37(5) provides that the scope of this accreditation shall include the methods of laboratory analysis, test or diagnosis required to be used during official laboratory operations.

(3) The purpose of the obligation to have laboratories and methods accredited is to ensure the competence of official laboratories to produce reliable and reproducible results as a basis for harmonised official controls and other official activities within the Union.

(4) At the same time, the accreditation process requires considerable time and resources.

(5) Article 41 of Regulation (EU) 2017/625 therefore empowers the Commission to adopt delegated acts specifying the cases where and the conditions under which competent

[1] OJ L 93, 7.4.2017, p. 3.

authorities may designate as official laboratories, laboratories which do not fulfil the conditions of Article 37(4), point (e) of that Regulation in relation to all the methods they use for official controls and other official activities. Such laboratories may be designated according to the conditions stipulated under that empowerment provided they fulfil the criteria established in Article 41, points (a) and (b) of Regulation (EU) 2017/625.

(6) In the areas of plant health, food contact materials, food additives, food enzymes, flavourings and feed additives further efforts are needed to complete the process of accreditation. The related tasks are complex since the potential number of substances to be verified in a given matrix or the various matrix/analyte combinations implies a broad range and high number of testing methods. Accrediting all the potential combinations poses a disproportionate burden in terms of time and resources on laboratories in these areas.

(7) Competent authorities should therefore be able to designate as official laboratories those laboratories that are not accredited for all the methods they use for official controls and other official activities provided that such laboratories have a quality assurance scheme in place and make use of methods characterised by the relevant criteria set out in Annex III to Regulation (EU) 2017/625, as well as by the modalities for the application of those criteria.

(8) In the area of plant health competent authorities should be able to designate as official laboratories those laboratories that wish to use a method for which they do not have accreditation and that are already accredited for at least one method for use on a pest from the same organism group, namely nematodes, bacteria, fungi and oomycetes, viruses, viroids and phytoplasmas, insects and mites, as the pest for which the non-accredited method is used.

(9) In accordance with Article 167(2) of Regulation (EU) 2017/625, in the area of plant health, Article 37(4), point (e) and Article 37(5) of that Regulation apply from 29 April 2022. With respect to the designation of official laboratories in the area of plant health, this Regulation should therefore also apply from 29 April 2022,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes the cases where, and the conditions under which, laboratories which do not fulfil the conditions of accreditation laid down in Article 37(4), point (e) of Regulation (EU) 2017/625 in relation to all the methods they use for official controls or other official activities may be designated as official laboratories by the competent authorities.

Article 2

Official laboratories in the areas of food contact materials, food additives, food enzymes, flavourings and feed additives

The competent authorities may designate laboratories which do not fulfil the conditions referred to in Article 37(4), point (e) of Regulation (EU) 2017/625 in relation to all the methods of laboratory analysis, test or diagnosis they use for official controls or other official activities, as official laboratories in the areas of food contact materials, food additives, food enzymes, flavourings and feed additives provided that:

(a) those laboratories have a quality assurance system in place to ensure that reliable results are obtained from the use of methods of laboratory analysis, test or diagnosis outside the scope of their accreditation and

(b) the non-accredited methods used by those laboratories are characterised by the relevant criteria to the areas covered under this article set out in Annex III to Regulation (EC) 2017/625.

Article 3

Official laboratories in the areas of plant health

The competent authorities may designate laboratories which do not fulfil the conditions referred to in Article 37(4), point (e) of Regulation (EU) 2017/625 in relation to all the methods of laboratory analysis, test or diagnosis they use for official controls or other official activities, as official laboratories in the areas of plant health provided that:

(a) those laboratories have a quality assurance system in place to ensure that reliable results are obtained from the use of methods of laboratory analysis, test or diagnosis outside the scope of their accreditation;

(b) the non-accredited methods used by those laboratories are characterised by the relevant criteria to the area of plant health set out in Annex III to Regulation (EC) 2017/625, and

(c) the laboratory is already accredited for at least one of the methods listed in the categories referred to in the Annex for use on a pest from the same organism group as the pest for which the non-accredited method is used.

Article 4

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 3 shall apply from 29 April 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN