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COMMISSION DELEGATED REGULATION (EU) .../...

of 7.2.2018

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by establishing European Union reference laboratories for pests of plants

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 92(4) of Regulation (EU) 2017/625 of the European Parliament and the Council 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 (Official Controls Regulation)¹, sets out that the Commission shall supplement that Regulation by adopting the decision to establish European Union reference laboratories by means of a delegated act in accordance with its Article 144.

Effectiveness of official controls and other official activities is of primary importance for the competent authorities to take adequate and timely measures against quarantine pests of plants within the meaning of Article 3 of Regulation (EU) 2016/2031 on protective measures against pests of plants², as well as against pests which are not included in the list of Union quarantine pests but which may, in accordance with Article 30(1) of that Regulation, fulfil the conditions for inclusion in that list. This effectiveness depends also on quality, uniformity and reliability of the methods of analysis, test or diagnosis used by official laboratories and of the results thereof. The methods used must moreover remain updated and, where necessary, be improved to achieve the above-mentioned objective.

European Union reference laboratories (EURLs) should thus be established to contribute to the improvement of the methods of analysis, test or diagnosis for pests, to the development of validated methods, to co-ordinate and provide assistance to official laboratories and to promote uniform practices in the development or use of those methods.

In order to ensure the appropriate specialisation, EURLs should be established for specific categories of pests. Those categories should take into account the nature and biology of the pests, as well as their categorisation as set out in Annex I, Part A and Annex II, Part A to Directive 2000/29/EC³. In this view, EURLs should be established for the following pest categories: insects and mites, nematodes, bacteria, fungi and oomycetes, and viruses, viroids and phytoplasmas (which is an updated term for 'mycoplasmas', as referred to in that Directive).

¹ 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 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 (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

² Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

³ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

This draft delegated act was subject to consultation of the general public between 12 December 2017 and 9 January 2018 via the Better Regulation Portal. A total of 3 responses were received which are publicly available and were considered⁴.

The Commission consulted the Official Controls Expert Group on 29 May 2017 and on 15 December 2017.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The Delegated Act establishes European Union reference laboratories for plant pests in accordance with Article 92(4) of Regulation (EU) 2017/625.

⁴ https://ec.europa.eu/info/law/better-regulation/have-your-say_en

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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 the Council 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 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 (Official Controls Regulation)⁵, and in particular Article 92(4) thereof,

Whereas:

- (1) Competent authorities are required to take adequate and timely measures against quarantine pests within the meaning of Article 3 of Regulation (EU) 2016/2031⁶ of the European Parliament and of the Council, as well as against pests which are not included in the list of Union quarantine pests but which may, in accordance with Article 30(1) of that Regulation, fulfil the conditions for inclusion in that list. The effectiveness of official controls and other official activities ensuring compliance with Union legislation is of primary importance in this regard.
- (2) That effectiveness depends on the quality, uniformity and reliability of the methods of analysis, test or diagnosis employed by the official laboratories designated in accordance with Article 37(1) of Regulation (EU) 2017/625, and of the results of the analyses, tests and diagnoses performed by those official laboratories.
- (3) Those methods are to remain updated and, where necessary, improved in order to ensure the quality, uniformity and reliability of analytical, testing and diagnostic data generated by them.
- (4) The measures taken for previous infestations indicate that official laboratories designated in accordance with Article 37 of Regulation (EU) 2017/625 would benefit from coordination and assistance to improve and promote uniform practices in the

⁵ OJ L 95, 7.4.2017, p. 1.

⁶ Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

development or use of the methods of analysis, test or diagnosis employed by those official laboratories, and in the interpretation of results.

- (5) European Union reference laboratories should therefore be established to contribute to the improvement and harmonisation of the methods of analysis, test or diagnosis, the development of validated methods and the co-ordinated assistance to those official laboratories.
- (6) In order to ensure the appropriate specialisation, one specific European Union reference laboratory should be established for each of the specific categories of pests. Those categories should take into account the nature and biology of the pests, as reflected in their categorisation set out in Annex I, Part A and Annex II, Part A to Council Directive 2000/29/EC⁷. In this view, European Union reference laboratories should be established for the following categories of pests: insects and mites, nematodes, bacteria, fungi and oomycetes, and viruses, viroids and phytoplasmas (which is an updated term for 'mycoplasmas', as referred to in that Directive).

HAS ADOPTED THIS REGULATION:

Article 1

European Union reference laboratories are hereby established as regards quarantine pests provided for in Article 3 of Regulation (EU) 2016/2031 of the European Parliament and of the Council and as regards pests which are not included in the list of Union quarantine pests but which may, in accordance with Article 30(1) of that Regulation, fulfil the conditions for inclusion in that list, and on the basis of the categorisation set out in Council Directive 2000/29/EC:

- (a) a European Union reference laboratory for insects and mites;
- (b) a European Union reference laboratory for nematodes;
- (c) a European Union reference laboratory for bacteria;
- (d) a European Union reference laboratory for fungi and oomycetes;
- (e) a European Union reference laboratory for viruses, viroids, and phytoplasmas.

Article 2

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

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

Done at Brussels, 7.2.2018

For the Commission
The President
Jean-Claude JUNCKER

⁷ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1).