Discussion paper for the expert group on the establishment of European Reference Laboratories for Plant Health

Concept paper

The objective of this paper is to introduce the legal basis to the Expert Group and discuss the content of a Commission Delegated Act concerning the establishment of a European Union reference laboratory (EURL) for the purpose of plant health.

Legal bases for the establishment and designation of EURLs

Regulation (EU) 2017/625 on official controls (Official Controls Regulation) has been adopted on 15 March 2017. It regulates several different areas, including the area of plant health. It will become applicable on the same date as the new Plant Health Regulation (EU) 2031/2016 (14 December 2019) to ensure consistency between those two inter-connected legal regimes.

The provisions of the Official Controls Regulation concerning the establishment and designation of EURLs, with relevance to plant health, are set out in Articles 92, 93 and 94. They shall apply from 29 April 2018 (see Article 167(3) of that Regulation).

Legal basis:

Regulation (EU) 2017/625

Article 92:

"Decision to establish a European Union reference laboratory

1. In the areas governed by the rules referred to in Article 1(2), a European Union reference laboratory shall be established where the effectiveness of official controls and other official activities also depends on the quality, uniformity and reliability of:

(a) the methods of analysis, test or diagnosis employed by the official laboratories designated in accordance with Article 37 (1); and

(b) the results of the analyses, tests and diagnoses performed by those official laboratories.

2. A European Union reference laboratory shall be established where there is a recognised need to promote uniform practices in relation to the development or use of the methods referred to in point (a) of paragraph 1.

[….]

4. The Commission shall supplement this Regulation by adopting the decision to establish a European Union reference laboratory by means of a delegated act in accordance with Article 144."

As there is a need for the establishment of a EURL in the area of plant health, the Commission intends to adopt the respective delegated act referred to in Article 92(4) of the Official Controls Regulation. The designation of the individual EURLs would then follow through the adoption of an implementing act pursuant to Article 93(1) of that Regulation.

Responsibilities of EURLs

As stipulated in Article 94(1) of that Regulation, the responsibility of the EURLs is to "contribute to the improvement and harmonisation of methods of analysis, test or diagnosis to be used by official laboratories and of the analytical, testing and diagnostic data generated by them". That responsibility will also apply in the area of Plant Health.

Tasks of EURLs

As stipulated in article 94(2) of that Regulation, the tasks are included in annual or multiannual work programmes established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission and are listed below:

"(a) providing national reference laboratories with details and guidance on the methods of laboratory analysis, testing or diagnosis, including reference methods;

(b) providing reference materials to national reference laboratories;

(c) coordinating the application by the national reference laboratories and, if necessary, by other official laboratories of the methods referred to in point (a), in particular, by organising regular inter-laboratory comparative testing or proficiency tests and by ensuring appropriate follow-up of such comparative testing or proficiency tests in accordance, where available, with internationally accepted protocols, and informing the Commission and the Member States of the results and follow-up to the inter-laboratory comparative testing or proficiency tests;

(d) coordinating practical arrangements necessary to apply new methods of laboratory analysis, testing or diagnosis, and informing national reference laboratories of advances in this field;

(e) conducting training courses for staff from national reference laboratories and, if needed, from other official laboratories, as well as of experts from third countries;

(f) providing scientific and technical assistance to the Commission within the scope of their mission;

(g) providing information on relevant national, Union and international research activities to national reference laboratories;

(h) collaborating within the scope of their mission with laboratories in third countries and with the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC);

(i) assisting actively in the diagnosis of outbreaks in Member States of foodborne, zoonotic or animal diseases, or of pests of plants, by carrying out confirmatory diagnosis, characterisation and taxonomic or epizootic studies on pathogen isolates or pest specimens;

(j) coordinating or performing tests for the verification of the quality of reagents and lots of reagents used for the diagnosis of foodborne, zoonotic or animal diseases and pests of plants;

(k) where relevant for their area of competence, establishing and maintaining:

(i) reference collections of pests of plants and/or reference strains of pathogenic agents;

(ii) reference collections of materials intended to come into contact with food used to calibrate analytical equipment and provide samples thereof to national reference laboratories;

(iii) up-to-date lists of available reference substances and reagents and of manufacturers and suppliers of such substances and reagents; and

(l) where relevant for their area of competence, cooperate among themselves and with the Commission, as appropriate, to develop methods of analysis, testing or diagnosis of high standards.

As regards point (i) of point (k), the European Union reference laboratory may establish and maintain those reference collections and reference strains by contractual outsourcing to other official laboratories and to scientific organisations."

Specificities

We are faced with the following specificities when planning the set-up of EURLs for Plant Health purposes:

a) Over 250 pests are regulated in the Annexes to Directive 2000/29/EC and measures adopted pursuant to Article 16(3) of that Directive. Those pests are going to be relisted as Union quarantine pests, protected zone quarantine pests or regulated non-quarantine pests under the new Plant Health Regulation (Regulation (EU) 2016/2031) which is going to replace and repeal Directive 2000/29/EC on 14 December 2019;

b) Often different host plants, plant products or other objects exist for the same pest;

c) The current range of technologies underlying diagnostic methods are diverse, for example conventional (morphological, as well as microscopy), immunological (e.g. ELISA) and molecular (e.g. PCR, both conventional and derivatives, RealTime PCR, LAMP, sequencing, etc.);

(d) The diagnosis of certain pests is amenable or only technically possible with limited technical approaches;

(e) Not all pests referred to in point (a) have been subject to the development of a validated diagnostic protocol.

Set-up of EURLs

When deciding on the way the EURLs for Plant Health are to be set up, the specificities and constraints are taken into account. A number of options exist to address the large number of regulated pests falling under the scope of the future EURLs for Plant Health, while taking into account the various host-pest combinations. Following options could be therefore considered.

Option 1:

To organise the EURLs, following a similar grouping of harmful organisms as in the annexes of Directive 2000/29/EC, "the harmful organism approach" e.g.:

I. Insects, mites and nematodes;

II. Bacteria (and phytoplasmas);

III. Fungi;

IV. Viruses (and viroids).

Option 2:

To organise the EURLs on the basis of commodities only, "the commodity approach" e.g.:

a) Agricultural crops;

b) Fruits and Vegetables;

c) Forest trees;

d) Ornamentals.

Option 3:

To organise the EURLs following a similar grouping of harmful organisms as in the annexes of Directive 2000/29/EC and the possible host combinations, "the harmful organism – commodity approach" e.g.:

	a) Agricultural crops	b) Fruits and Vegetables	c) Forest trees	d) Ornamentals
I. Insects, mites and nematodes				
II. Bacteria (and phytoplasmas)				
III. Fungi				
IV. Viruses (and viroids)				

The members of the Expert Group are invited to reflect upon those three options and discuss them at the first meeting scheduled for this purpose on 29 May 2017.