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New regulation on official controls: what changes for official laboratories, and for national and EU reference laboratories?

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Introduction

In May 2013, the European Commission put forward three new regulations concerning animal health, plant health, and controls and other official activities. The regulation on transmissible animal diseases, called the “Animal Health Law”, was published on 31 March 2016 (Regulation (EU) 2016/429) [EU, 2016a]. The regulation on organisms harmful to plants, called the “Plant Health Law”, was published on 23 November 2016 (Regulation (EU) 2016/2031) [EU, 2016b]. And the regulation on “official controls” intended to replace Regulation (EC) No 882/2004, was agreed on politically in June 2016 under the Dutch presidency of the Council. The final text has been adopted by the European Parliament and the Council in March 2017. This text will be applicable at the same time as the plant health regulation (“Plant Health Law”), *i.e.* as of 14 December 2019, will change the obligations of official laboratories, and will set up a framework for European Union Reference Laboratories (EURLs) and National Reference Laboratories (NRLs). Concerning the EURLs and NRLs, the provisions will be applicable one year after publication of the “official controls” regulation.

The main principles underpinning Regulation (EU) No 882/2004 are maintained but the new text will provide new information and clarifications.

Keywords

- European Union
- Official controls
- Laboratories
- Revision of regulation

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■ Official laboratories: clarity on the accreditation obligation

The competent authorities in each Member State in charge of official controls and other official activities will, as is currently the case, appoint official laboratories tasked with carrying out official analyses. These appointments will indicate the expected tasks and the framework of cooperation with the competent authority of the Member State. In addition to requirements concerning equipment and personnel, the official laboratory will need to guarantee its impartiality, and the absence of any conflicts of interest when carrying out official analyses. It will need to be accredited for the analytical methods implemented as part of official analyses [ISO/IEC 17025:2005]. However, exemptions to this obligation of accreditation are planned, specifically:

- for the detection of Trichinella in meat, for laboratories that perform only this analysis;

- for the cases that will be indicated subsequently by delegated act of the European Commission;

- temporarily, when replacing analytical methods, when the method itself is changed, or in emergency situations.

These exemptions are only possible if the laboratory provides guarantees, *i.e.* depending on the case: accreditation for similar methods, satisfactory results in inter-laboratory proficiency testing, or supervision by the competent authorities of the Member States.

Lastly, the new regulation will strengthen the requirements for the competent authorities of the Member States to check that the conditions for appointment as an official laboratory are still complied with. If necessary, the competent authorities are required to withdraw the appointment.

■ European reference activities are reinforced for reference missions in animal protection and food fraud. The EURL-NRL system is maintained and generalised for analytical activities

The regulation also provides for the possibility of appointing European reference centres in animal protection as well as European reference centres on the authenticity and integrity of the food chain.

Concerning analytical laboratories, the EURL and NRL system is maintained for the areas of animal health and food safety, and expanded to include plant health. The European Commission will firstly need to establish the need for a reference laboratory at the European level in a specific regulation (established by delegated act). The new text provides for appointment of European Union Reference Laboratories via a public selection process with regular review of mandates. However, a laboratory will need to be appointed as the EURL for a minimum period of 5 years. The new text is supplemented with appointment conditions and obligations, such as the absence of conflicts of interest or the availability of personnel and equipment. The work programme, including in particular the activities related to analytical methods, inter-laboratory proficiency testing, and reagents and reference materials, will need to be established on the basis of the scope of competence and the missions identified by the European Commission.

The obligation for the Member States to appoint a National Reference Laboratory (NRL) for each EURL is maintained. The same obligations as those of the EURLs, for instance in terms of conflicts of interest and availability of personnel and equipment, will apply.

The improvement and distribution of analytical methods, as well as consistency in their implementation, will continue to rely on a system bringing together European Union Reference Laboratories, National Reference Laboratories, and official analysis laboratories, specifically through the organisation of inter-laboratory proficiency testing.

The text will be published in the next few weeks, with early implementation, *i.e.* one year and 20 days after publication for the articles regarding EURLs and NRLs, while the remainder of the text will widely come into force at the same time as the Plant Health Law.

References

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ISO/IEC 17025:2005 - General requirements for the competence of testing and calibration laboratories, 28 pp. www.iso.org