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[...] (2024) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

laying down analytical methods applicable to official controls performed for the verification of compliance of food business operators with Regulation (EC) No 2073/2005

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

laying down analytical methods applicable to official controls performed for the verification of compliance of food business operators with Regulation (EC) No 2073/2005

(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 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)¹, and in particular Article 34(6), first subparagraph, point (a), thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States to verify compliance with Union legislation, among others, in the area of food safety at all stages of production, processing and distribution. Article 37 of that Regulation provides for the competent authorities to designate official laboratories to carry out the laboratory analyses, tests and diagnoses on samples taken during official controls and other official activities.
- (2) Commission Regulation (EC) No 2073/2005² lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators in respect of the general and specific hygiene requirements referred to in Article 4 of Regulation (EC) No 852/2004 of the European Parliament and of the Council³. The competent authorities of the Member States verify compliance of food business operators with the rules and criteria laid down in Regulation (EC) No 2073/2005 by, among other things, taking samples during official controls and other

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¹ OJ L 95, 7.4.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/625/oj>.

² Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/2073/oj>).

³ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1, ELI: <http://data.europa.eu/eli/reg/2004/852/oj>).

official activities ('official samples') in the premises of food business operators and sending them for analyses to designated official laboratories.

- (3) There are no Union rules regarding the specific methods of laboratory analyses to be used during official controls aimed to verify compliance with the rules and criteria laid down in Regulation (EC) No 2073/2005. This situation could be detrimental to the quality of official controls of foodstuffs placed on the market and create distortion of competition. To ensure greater uniformity, reliability and consistency of official controls, Union requirements should therefore be set for the analytical methods to be used by official laboratories when they analyse official samples against criteria laid down in Regulation (EC) No 2073/2005.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. When analysing samples taken during official controls performed to verify compliance with the rules and criteria laid down in Regulation (EC) No 2073/2005, official laboratories designated by the competent authorities in accordance with Article 37 of Regulation (EU) 2017/625 shall use the analytical reference methods referred to in Annex I to Regulation (EC) No 2073/2005.
2. By way of derogation from paragraph 1, the competent authorities may authorise designated official laboratories to use alternative analytical methods, including proprietary methods, provided these alternative analytical methods are validated against the analytical reference methods referred to in Annex I to Regulation (EC) No 2073/2005 in accordance with the protocol set out in standard EN ISO 16140-2 and are validated either for the food category specified in the relevant microbiological criterion set in Annex I to Regulation (EC) No 2073/2005 or for a broad range of food as referred to in standard EN ISO 16140-2. The competent authorities may also authorise designated official laboratories to use alternative analytical methods if these alternative analytical methods are validated against other internationally accepted scientific protocols.
3. When alternative methods referred to in paragraph 2 are proprietary methods, they shall be certified by an independent certification body. The certification shall include a summary of or a reference to the validation results of the proprietary method and a statement on the quality management of the production process of the method. The certification shall show that the production process assurance of the manufacturer was evaluated and be subject, at least every 5 years, to reassessment through renewal procedures.

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,

For the Commission
The President
Ursula VON DER LEYEN

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