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

of **XXX**

**on the methods of sampling and analysis, and on the interpretation of results for the
official control of pesticide residues in and on food and feed of plant and animal origin,
and repealing Directive 2002/63/EC**

(Text with EEA relevance)

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

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on the methods of sampling and analysis, and on the interpretation of results for the official control of pesticide residues in and on food and feed of plant and animal origin, and repealing Directive 2002/63/EC

(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) 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 Member States to check compliance with Union legislation, among others in the area of food and feed safety at all stages of production, processing and distribution. It provides for specific rules on official controls in relation to substances whose use may result in residues in food and feed and sets general requirements for the methods to be used for sampling, laboratory analyses and tests during official controls and other official activities.
- (2) Articles 34, 35 and 36 of Regulation (EU) No 2017/625 and Commission Delegated Regulation (EU) 2021/2244² provide for general rules with regard to sampling and analysis.
- (3) Regulation (EC) No 396/2005 of the European Parliament and of the Council³ establishes maximum residue levels ('MRLs') of pesticides in or on food and feed of plant and animal origin.

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

² Commission Delegated Regulation (EU) 2021/2244 of 7 October 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific rules on official controls as regards sampling procedures for pesticides residues in food and feed (OJ L 453, 17.12.2021, p. 1, ELI: http://data.europa.eu/eli/reg_del/2021/2244/oj).

³ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending

- (4) Commission Directive 2002/63/EC⁴ provides for the methods of sampling for the official control of pesticide residues in and on products of plant and animal origin.
- (5) However, Directive 2002/63/EC no longer reflects best practices in the field of pesticide residues in and on products of plant and animal origin.
- (6) More clarity is necessary for the sampling rules of some product categories listed in Annex I to Regulation (EC) No 396/2005, in particular the categories ‘Honey and other apicultural products’, ‘Amphibians and Reptiles’, ‘Terrestrial invertebrate animals’, ‘Wild terrestrial vertebrate animals’ and ‘Fish, fish products and any other marine and freshwater food products’. In addition, the clarification of sampling requirements is necessary for products of high value, for products of very large size and for certain processed food as well as food supplements.
- (7) The European Union Reference Laboratories in the field of pesticide residues have elaborated a ‘Guidance Document on Analytical Quality Control and Validation Procedures for pesticide residues analysis in food and feed’⁵. As that Guidance Document contains the best up to date technological knowledge, its principles on reporting and interpretation of results should become binding to ensure uniform enforcement action by Member States.
- (8) Commission Regulation (EC) No 152/2009⁶ establishes methods of sampling and analysis for the official control of feed. As regards the collection of samples and the preparation of samples for analysis for the purpose of control of pesticides residues in feed, the rules of Regulation (EC) No 152/2009 are not affected by this Regulation. As regards the method for laboratory analyses, the measurement uncertainty and the interpretation of the analytical results for the purpose of control of pesticide residues in feed, specific rules are necessary and should therefore be established in this Regulation.
- (9) It is therefore appropriate to update the specific provisions on sampling laid down in Directive 2002/63/EC, and to provide for rules on analysis for the control of pesticide residues in and on food and feed of plant and animal origin.
- (10) For the purposes of clarity and legibility, Directive 2002/63/EC should be repealed and replaced by this Regulation.
- (11) In view of the time and resources necessary for Member States to adapt to the new rules, it is appropriate that this Regulation applies from 1 January 2027.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/oj>).

⁴ Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC (OJ L 187, 16.7.2002, p. 30, ELI: <http://data.europa.eu/eli/dir/2002/63/oj>).

⁵ Analytical Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed. Available online: https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/guidelines-maximum-residue-levels_en.

⁶ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/152/oj>).

HAS ADOPTED THIS REGULATION:

Article 1
Subject matter

This Regulation lays down rules on:

- the methods for sampling and the preparation of samples for analysis for food;
- the methods for laboratory analyses, the measurement uncertainty and the interpretation of the analytical results for food and feed;

for the purpose of verifying compliance with maximum residue levels of pesticides in or on food and feed of plant and animal origin established in Regulation (EC) No 396/2005.

Article 2
Definitions

In addition to the definitions of Article 3 of Regulation (EC) No 396/2005, the following definitions apply for the purposes of this Regulation:

- (1) ‘lot’ means an identifiable quantity of food and feed delivered at one time and determined by the sampling officer to have common characteristics (such as origin, producer, variety, species, catchment area, packer, type of packing, markings, hour of production or consignor);
- (2) ‘sublot’ means a part of a lot that is designated to be sampled in accordance with section B.1 of the Annex;
- (3) ‘suspect lot’ means a lot which, for any reason, is suspected to contain pesticide residues exceeding the respective MRLs set out in Regulation (EC) 396/2005;
- (4) ‘non-suspect lot’ means a lot for which there is no indication that it may contain pesticide residues exceeding MRLs set out in Regulation (EC) No 396/2005;
- (5) ‘sampling’ means the selection of a sample intended for laboratory analysis;
- (6) ‘sampling officer’ means a person designated by the competent authorities to take samples for pesticide residues of food and feed;
- (7) ‘sample’ means one or more units selected from a population of units, or a portion of material selected from a larger quantity of material;
- (8) ‘incremental (primary) sample’ means a quantity taken from a specific place in the lot or sublot;
- (9) ‘unit’ means the smallest distinct portion in a lot or sublot, withdrawn to form the whole or part of an incremental sample;
- (10) ‘aggregate sample’ means the combined total of all the incremental samples taken from the lot or sublots;
- (11) ‘reduced sample’ is a part of the aggregate sample, obtained from the latter by a process of representative reduction;
- (12) ‘replicate sample’ means a sample taken from an aggregate sample for enforcement, defence and reference purposes in accordance with Article 35 of Regulation (EU) 2017/625;

- (13) ‘laboratory sample’ means a sample sent to, or received by, the laboratory that constitutes a representative quantity of material removed from the aggregate sample;
- (14) ‘analytical sample’ means material prepared for analysis from the laboratory sample;
- (15) ‘analytical portion’ means a representative quantity of material removed from the analytical sample, of proper size for measurement of the residue concentration;
- (16) ‘measurement uncertainty’ means a non-negative parameter associated with the result of measurement, which characterises the dispersion of values that could reasonably be attributed to the particular quantity subject to measurement;
- (17) ‘limit of quantification’ means the lowest concentration or mass of the analyte that has been validated with acceptable accuracy by applying the complete analytical method and identification criteria;
- (18) ‘expanded measurement uncertainty’ represents the uncertainty in a measurement by giving a confidence range, typically calculated by multiplying the range of values within which the true value of the measurement is expected to lie by a coverage factor;
- (19) ‘coverage factor (k)’ is a multiplier used in the calculation of expanded uncertainty, which provides a range within which the true value of a measurement is expected to lie.

Article 3

Methods of sampling and preparation of samples for analysis for food

Samples of food shall be collected and prepared in accordance with Parts A and B of the Annex.

Article 4

Methods of analysis, measurement uncertainty and interpretation of results for food and feed

The analysis of the samples, the calculation of the measurement uncertainty and the interpretation of the results of such analysis, shall be carried out in accordance with Part C of the Annex to this Regulation for food and, by way of derogation from Articles 2 and 3 of Regulation (EC) 152/2009, for feed.

Article 5

Repeal

Directive 2002/63/EC is repealed.

References to the repealed Directive shall be construed as references to this Regulation.

Article 6

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*.

It shall apply from 1 January 2027.

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