

Brussels, XXX PLAN/2023/636 Rev.12 [...](2025) XXX draft

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

of XXX

on the methods of sampling and analysis for the 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)

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on the methods of sampling and analysis for the 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)<sup>1</sup>, 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) 2021/2244<sup>2</sup> provide for general rules with regard to sampling and analysis.
- (3) Regulation (EC) No 396/2005 of the European Parliament and of the Council<sup>3</sup> establishes maximum residue levels ('MRLs') of pesticides in or on food and feed of plant and animal origin.

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

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: <a href="http://data.europa.eu/eli/reg\_del/2021/2244/oj">http://data.europa.eu/eli/reg\_del/2021/2244/oj</a>).

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/EC<sup>4</sup> provides for the methods of sampling for the official control of pesticide residues in and on products of plant and animal origin.
- (5) 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, clarification is also 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'<sup>5</sup>. As that Guidance Document contains the best up to date technological knowledge, its main? principles on reporting and interpretation of results serves as a solid basis for binding rules for sampling and analysis to ensure uniform enforcement action by Member States. It is therefore appropriate to take over the specific sampling provisions laid down until now in Directive 2002/63/EC, to update and expand them and to provide also for rules on analysis for the control of pesticide residues in and on food and feed of plant and animal origin.
- (8) In order to facilitate sampling in cases where feed is sampled for multiple purposes (e.g. for both contaminants and pesticides residues), it is appropriate to allow Commission Regulation (EC) No 152/2009<sup>6</sup> to be used as an alternative sampling method as it provides for equally adequate requirements to ensure results are representative for the sampled lot.
- (9) Directive 2002/63/EC should therefore be repealed and replaced by this Regulation for the purpose of clarity and legibility and align the requirements with Regulation (EU) No 2017/625.
- (10) 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.
- (11) 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: <a href="http://data.europa.eu/eli/reg/2005/396/oj">http://data.europa.eu/eli/reg/2005/396/oj</a>).

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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: <a href="http://data.europa.eu/eli/reg/2009/152/oj">http://data.europa.eu/eli/reg/2009/152/oj</a>).

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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: <a href="http://data.europa.eu/eli/dir/2002/63/oi">http://data.europa.eu/eli/dir/2002/63/oi</a>).

Analytical Quality Control and Method Validation Procedures for Pesticide Residues Analysis in Food and Feed
<a href="https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/guidelines-maximum-residu

#### HAS ADOPTED THIS REGULATION:

## Article 1 Subject matter

This Regulation lays down rules on the methods for sampling, the method for laboratory analyses, measurement of uncertainty and the interpretation of the analytical results 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 (EU) 2017/625 and 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 and trained in sampling procedures;
- (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) 'size of sample' means the number of units, or quantity of material, constituting the sample;
- (9) 'representative sample' means a sample that is representative of the lot and sublot, in respect of its pesticide residue content;
- (10) 'incremental (primary) sample' means a quantity of material taken from a specific place in the lot or sublot;
- (11) 'unit' means the smallest distinct portion in a lot or sublot, withdrawn to form the whole or part of an incremental sample;
- (12) 'aggregate sample' means the combined total of all the incremental samples taken from the lot or sublots;
- (13) 'reduced sample' is a part of the aggregate sample, obtained from the latter by a process of representative reduction;

- '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;
- (15) 'laboratory sample' means a sample sent to, or received by, the laboratory that constitutes a representative quantity of material removed from the aggregate sample;
- (16) 'analytical sample' means material prepared for analysis from the laboratory sample;
- (17) 'analytical portion' means a representative quantity of material removed from the analytical sample, of proper size for measurement of the residue concentration;
- (18) '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;
- '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. The limit of quantification is referred to in Regulation (EC) No 396/2005 as the limit of determination (LOD).
- (20) 'expanded measurement uncertainty' means the measurement uncertainty adjusted with a coverage factor (k);
- (21) 'coverage factor (k)' means a number which expresses the desired level of confidence and is associated with the expanded measurement uncertainty.

# Article 3 Methods of sampling

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

In cases where feed is sampled for multiple purposes (e.g. for both contaminants and pesticides), sampling may be carried out in accordance with Annex I to Regulation (EC) No 152/2009. In these cases the methods of sampling of this Regulation do not apply.

# Article 4 Methods of analysis analytical uncertainty and interpretation of results

The analysis of the samples, the measurement of uncertainty and the interpretation of the results of such analysis, shall be made in accordance with Part C of the Annex.

Article 5 Repeal

Directive 2002/63/EC is repealed.

### 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