

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

on the methods of sampling and analysis for the control of pesticide residues in and on products 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]](#footnote-1), and in particular Article 34(6),

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 inter alia in the area of food 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 (EC) No 2017/625 and Commission Delegated Regulation (EU) 2021/2244 provide for general rules with regard to sampling and analysis.
3. Commission Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 establishes maximum residue levels (‘MRLs’) of pesticides in or on food and feed of plant and animal origin[[2]](#footnote-2).
4. Directive 2002/63/EC provides for the methods of sampling for the official control of pesticide residues in and on products of plant and animal origin[[3]](#footnote-3).
5. The experience of Member States has evolved since the entry into force of Directive 2002/63/EC. Therefore, that Directive no longer reflects best practices.
6. Furthermore, more clarity is needed for the sampling rules of more product categories listed in Annex I to Regulation (EC) No 396/2005 and specifically for 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 needed for products of high value, for products of very large size and for certain processed food as well as food supplements.
7. On the basis of the best available scientific information, 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’[[4]](#footnote-4). As this Guidance Document contains the best up to date technological knowledge, its conclusions should be reflected in the rules for sampling and analysis as well as on the criteria for compliance decisions. As those elements form the basis of risk management decisions, they should be integrated in an Implementing Regulation to ensure harmonised enforcement action by Member States.
8. It is therefore appropriate to update and expand the specific sampling provisions as currently laid down in Directive 2002/63/EC.
9. Furthermore, it is appropriate to ensure that food business operators applying the controls performed within the framework of Article 4 of Regulation (EC) No 852/2004 of the European Parliament and of the Council[[5]](#footnote-5) apply sampling procedures equivalent to the sampling procedures provided for by this Regulation in order to ensure that samples taken for those controls are representative.
10. It is therefore appropriate to supplement Article 34 of Regulation (EU) 2017/625 by laying down rules for the performance of the official controls as regards the relevant procedures for sampling and analysis for pesticide residues in products of plant and animal origin.
11. Directive 2002/63/EC should therefore be repealed and replaced by this Regulation.
12. 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

*Subject matter and scope*

This Regulation lays down rules for the sampling and analysis to determine the level of residues of pesticides in and on products of plant and animal origin, as those are listed in Annex I to Regulation (EC) 396/2005.

These rules apply without prejudice to the provisions of Regulation (EC) No 152/2009 as regards the methods of sampling for the official control of feed[[6]](#footnote-6).

It also lays down rules with regard to the expression and the interpretation of results of laboratory analyses in view of verifying compliance with MRLs.

The rules apply equally to samples collected in the framework of official controls and to samples taken by food business operators. Food business operators may use other sampling rules if they can demonstrate to the competent authority that these rules provide at least equivalent guarantees.

Article 2

*Definitions*

For the purposes of this Regulation, the definitions in Article 3 of Regulation (EU) 2017/625 and in Article 3 of Regulation (EC) No 396/2005 shall apply.



The following definitions shall also apply:

1. ‘aggregate sample’ the combined total of all the incremental samples taken from the lot or sublots; aggregate samples shall be considered as representative of the lots or sublots from which they are taken;.
2. ‘analytical portion’ means a representative quantity of material removed from the analytical sample, of proper size for measurement of the residue concentration. A device may be used to withdraw the analytical portion;
3. ‘analytical sample’ means the material prepared for analysis from the laboratory sample;
4. ‘coverage factor (k)’ means a number which expresses the desired level of confidence and is associated with the expanded measurement uncertainty;
5. ‘consignment’ means as defined in Article 3 of Regulation (EU) 2017/625;
6. ‘expanded measurement uncertainty’, means the measurement uncertainty adjusted with a coverage factor (k);
7. ‘laboratory sample’ means the sample sent to, or received by, the laboratory and concerns a representative quantity of material removed from the aggregate sample;
8. ‘lot’ means an identifiable quantity of food 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);
9. ‘measurand’ means the particular quantity subject to measurement;
10. ‘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 measurand, based on the information used.
11. ‘non-suspect lot’ means a lot for which there is no indication to suspect that it may contain pesticide residues exceeding MRLs set out in the Regulation (EC) 396/2005.
12. ‘incremental (primary) sample’ means a quantity of material taken from a single place in the lot or sublot.
13. ‘reduced sample’ is a part of the aggregate sample, obtained by the latter by a process of representative reduction.
14. ‘sample’ means one or more units selected from a population of units, or a portion of material selected from a larger quantity of material.

'replicate sample’ means a sample to be taken from an aggregate sample for enforcement, defence and reference purposes, unless such procedure conflicts with Member States’ rules as regards the rights of the food business operator. The replicate sampleshall be taken from the ~~homogenised~~ aggregate sample, unless such procedure conflicts with Member States’ rules ~~as regards the rights of the food business operator.~~ It shall be taken to ensure a second expert opinion as specified in Article 35 of Regulation (EU) 2017/625.

1. ‘sampling’ means the procedure used to draw and constitute a sample intended for laboratory analysis.
2. ‘authorised person for sampling means a person trained in sampling procedures and, where required, authorised by the appropriate authorities to take samples. The officer is responsible for procedures including preparation, packing and shipping of the laboratory sample(s) and ensures consistent adherence to the specified sampling procedures. The sampling officer completes documentation for samples, and collaborates closely with the laboratory.
3. ‘sample size’ means the number of units, or quantity of material, constituting the sample.
4. ‘sublot’ means a designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separated and identifiable.
5. ‘suspect lot’ means a lot which, for any reason, is suspected to contain pesticide residues exceeding MRLs set out in the Regulation (EC) 396/2005.
6. ‘unit’ is the smallest discrete portion in a lot or sublot, which should be withdrawn to form the whole or part of an incremental sample.

‘Article 3

*Methods for sampling and analysis and quality control*

Member States shall ensure that samples are collected and analysed in accordance with Article 34 paragraphs (1) to (5), Article 35 (1), (2) and (3) as applicable, and Article 36 paragraphs (1) and (2) of Regulation (EU) 2017/625 and with the more specific sampling methods described in Parts A and B of the Annex to this Regulation.

Methods of analysis shall be supported by quality control data and shall be validated for the specific substance/commodity group combination in accordance with the procedures detailed in the most updated version of the ‘Guidance Document on Analytical Quality Control and Validation Procedures for pesticide residues analysis in food and feed’.

Article 4

*Interpretation of results*

Member States shall ensure that the interpretation of results is in accordance with the requirements listed in the Part C of the Annex to this Regulation.

Article 5

*Repeals and transitional measures*

Directive 2002/63/EC is repealed from the date of entry into force of this Regulation.

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

Article 6

*Entry into force*

This Regulation shall enter into force [*6 months 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

1. OJ L 95, 7.4.2017, p. 1. [↑](#footnote-ref-1)
2. OJ L 070 16.3.2015, p. 1 [↑](#footnote-ref-2)
3. OJ L 187, 16.7.2002, p.30 [↑](#footnote-ref-3)
4. <https://food.ec.europa.eu/plants/pesticides/maximum-residue-levels/guidelines-maximum-residue-levels_en> [↑](#footnote-ref-4)
5. OJ L 139, 30.4.2004, p. 1 [↑](#footnote-ref-5)
6. OJ L 54, 26.2.2009, p.1 [↑](#footnote-ref-6)