COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

laying down the methods of sampling and analysis for the control of the levels of mycotoxins in food and repealing Regulation (EC) No 401/2006

(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) thereof,

Whereas:

1. Commission Regulation (EU) 2023/915[[2]](#footnote-2) sets maximum levels for certain mycotoxins and ergot sclerotia in foods.
2. Commission Regulation (EC) No 401/2006[[3]](#footnote-3) lays down the methods of sampling and analysis to be used for the official control of the levels of mycotoxins in foodstuffs.
3. The sampling methods provided for in Regulation (EC) No 401/2006 for the different foods should apply to the control of all mycotoxins instead of specifically mentioned mycotoxins, in those foods. It is furthermore appropriate to update the sampling method for food supplements and to provide for a sampling method for dried herbs, herbal infusions and teas.
4. Official controls can be performed on foods for which no specific maximum level has been established for mycotoxins and for which no specific sampling procedure has been established. It is therefore appropriate to provide criteria to determine which sampling procedure should be applied in such cases.
5. On the basis of the best available scientific information, the European Union Reference Laboratory on mycotoxins and plant toxins have updated the analytical performance criteria for mycotoxins. It is therefore appropriate to modify the criteria as laid down in Regulation (EC) No 401/2006.
6. It is necessary to provide sufficient time for control laboratories to implement the new requirements introduced by this Regulation. Therefore, it is appropriate to provide for a reasonable time until this Regulation applies.
7. In order to ensure continuity in the performance of official controls and other regulatory activities on maximum levels of mycotoxins and to allow enough time for methods of analysis to be re-validated, it is appropriate to provide that methods of analysis which have been validated before the date of application of this Regulation may remain in use for a defined period, subject to the specific requirements provided for in point 4.2 in Annex II to Regulation (EC) No 401/2006
8. Since the modifications to Regulation (EC) No 401/2006 are substantial, it is appropriate, for reasons of clarity, to repeal and replace that Regulation.
9. 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

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘lot’ means an identifiable quantity of a food commodity delivered at one time and determined by the competent authority to have common characteristics, such as origin, variety, type of package, packer, consignor or markings;

(2) ‘sublot’ means a physically separate and identifiable part of a large lot designated to apply the sampling method;

(3) ‘incremental sample’ means a quantity of material taken from a single place in the lot or sublot;

(4) ‘aggregate sample’ means the combined total of all the incremental samples taken from the lot or sublot;

(5) ‘subsample’ means a quantity of material taken from the aggregate sample for control of ergot sclerotia by visual examination;

(6) ‘laboratory sample’ means a representative part or quantity of the aggregate sample intended for the laboratory;

(7) ‘recovery (Rec, %)’ means the percentage obtained by applying the following formula x/xref × 100% where

x = measured concentration (for spiked samples corrected for background concentration if not blank), and

xref = reference concentration (concentration of a Certified Reference Material (CRM), Proficiency Test material, or spiked sample);

(8) ‘bias’ means the difference between the measured value and the reference concentration

(9) ‘repeatability relative standard deviation(RSDr)’ means the relative standard deviation (%) calculated from results generated under repeatability conditions (repeatability precision): using the same method on the same sample material in one laboratory by the same operator, with the same instrument, within a short interval of time (1 day or 1 sequence);

(10) ‘within-laboratory reproducibility relative standard deviation (RSDwR)’ means the relative standard deviation (%) calculated from results generated under within-laboratory reproducibility conditions (intermediate precision): using the same method on the same sample material in one laboratory but different days (preferably a longer time interval), and may include other conditions, such as involving different operators and/or different (equivalent) instruments;

(11) ‘reproducibility relative standard deviation (RSDR)’ means the relative standard deviation (%) calculated from results generated under reproducibility conditions (interlaboratory precision), meaning the same material is analysed by different laboratories. The RSDR may be derived from, in particular, collaborative studies and proficiency tests;

(12) ‘limit of Quantification (LOQ)’ means the lowest content of the analyte which can be measured with reasonable statistical certainty. In the context of this regulation this means the lowest successfully validated level: the lowest tested concentration of analyte in a sample material, for which it has been demonstrated that the criteria for recovery, precision, and identification are met[[4]](#footnote-4);

(13) ‘screening target concentration (STC)’ means the concentration of interest for detection of the mycotoxin in a sample. When the aim is to test compliance with regulatory limits, the STC is equal to the applicable maximum level. For other purposes or in case no maximum level has been established, the STC is predefined by the laboratory;

(14) ‘screening method’ means the method used for selection of those samples with levels of mycotoxins that exceed the screening target concentration (STC), with a given certainty. For the purpose of mycotoxin screening, a certainty of 95% is considered fit-for-purpose. The result of the screening analysis is either ‘negative’ or ‘suspect’. Screening methods shall allow a cost-effective high sample-throughput, thus increasing the chance to discover new incidents with high exposure and health risks to consumers. These methods shall be based on bio-analytical, LC-MS or HPLC methods. Results from samples exceeding the cut-off value shall be verified by a full re-analysis from the original sample by a confirmatory method;

(15) 'negative sample' means the mycotoxin content in the sample is < STC with a certainty of 95% (i.e. there is a 5% chance that samples will be incorrectly reported as negative);

(16) 'false negative sample' means the mycotoxin content in the sample is >STC but it has been identified as negative;

(17) 'suspect sample' (screen positive) means the sample exceeds the cut-off level and may contain the mycotoxin at a level higher than the STC.;

(18) 'false suspect sample' means a negative sample that has been identified as suspect;

(19) 'confirmatory methods' means methods that provide full or complementary information enabling the mycotoxin to be identified and quantified unequivocally at the level of interest;

(20) ‘cut-off level’ means the response, signal, or concentration, obtained with the screening method, above which the sample is classified as ‘suspect’. The cut-off is determined during the validation and takes the variability of the measurement into account;

(21) ‘negative control (blank matrix) sample’ means a sample known to be free of the mycotoxin to be screened for, by previous determination using a confirmatory method of sufficient sensitivity or by other method or, where such sample cannot be obtained, material with the lowest obtainable level as long as the level allows the conclusion that the screening method is fit for that purpose;

(22) ‘sample known to be free’ means a sample where the amount present of the analyte does not exceed more than 1/5th of the STC. If the level can be quantified with a confirmatory method, the level shall be taken into consideration for the validation assessment.

(23) ‘positive control sample’ means a sample containing the mycotoxin at the screening target concentration, such as a certified reference material, a material of known content (e.g. test material of proficiency tests) or otherwise sufficiently characterised by a confirmatory method. In the absence of any of the above, a blend of samples with different levels of contamination or a spiked sample prepared within laboratory and sufficiently characterised can be used, provided it can be proven that the contamination level has been verified.

Article 2

1. Sampling for the control of the levels of mycotoxins in foods shall be carried out in accordance with the methods set out in Annex I.
2. In case of a food that cannot be classified in a food category for which a sampling procedure has been established in Annex I, the sampling procedure shall be determined having regard to the particle size of that food or the similarity of that food with a product that can be classified in one of the food categories in Annex I.
3. In case of a foods that cannot be classified in any food category listed in Annex I and provided that there is evidence that the mycotoxin is homogeneously distributed in such a food, the food shall be sampled using the sample procedure laid down in Part B of the Annex to Regulation (EC) No 333/2007[[5]](#footnote-5) .

Article 3

Sample preparation and methods of analysis used for the control of the levels of mycotoxins in foodstuffs shall comply with the criteria set out in Annex II.

Article 4

Regulation (EC) No 401/2006 is hereby repealed. References to the repealed Regulation shall be construed as references to this Implementing Regulation.

However, until 1 January 2029, the specific requirements provided for in point 4.3 in Annex II to Regulation (EC) No 401/2006 shall continue to apply to methods which have been validated before the entry into application of this Regulation.

Article 5

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 April 2024.

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. Commission Regulation (EU) No 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.53.2023, p. 103). [↑](#footnote-ref-2)
3. Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 070 9.3.2006, p. 12). [↑](#footnote-ref-3)
4. For risk assessment, fit-for-purpose LOQs are generally lower compared to what is required for official control for checking compliance with a ML, as the aim is to generate numerical data for the major part of the samples analysed (i.e. avoid left-censored data) in order to be able to perform accurate exposure assessments. For monitoring purposes, it can be acceptable to report levels below the LOQ as defined in the context of this Regulation. [↑](#footnote-ref-4)
5. Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs (OJ L 88, 29.3.2007, p. 29). [↑](#footnote-ref-5)