



Brussels, **XXX**
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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

on the monitoring and reporting of molecular analytical data within the frame of epidemiological investigations of food-borne outbreaks in accordance with Article 8 of Directive 2003/99/EC of the European Parliament and of the Council

(Text with EEA relevance)

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

of **XXX**

on the monitoring and reporting of molecular analytical data within the frame of epidemiological investigations of food-borne outbreaks in accordance with Article 8 of Directive 2003/99/EC of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC¹, and in particular Article 8(3) thereof,

After consulting the Standing Committee on Plants, Animals, Food and Feed,

Whereas:

- (1) Article 8(2) of Directive 2003/99/EC requires the competent authority of Member States designated pursuant to Article 3(2) of this Directive to investigate food-borne outbreaks in cooperation with the competent authorities responsible for addressing serious cross-border threats to human health and the consequences thereof referred to in Article 1 of Regulation (EU) 2022/2371 of the European Parliament and of the Council². This investigation is to provide data on the epidemiological profile, the foodstuffs potentially implicated, the potential causes of the outbreak and microbiological studies.
- (2) The efficiency and the cross-sectorial cooperation between public health and food safety authorities in such investigation is essential to limit the public health impact of an outbreak and minimize the economic impact linked to recalls and withdrawal of unsafe or potentially unsafe food. A quick and reliable identification of batches, lots or consignments containing this food and the cause of the outbreak is therefore necessary.
- (3) Whole genome sequencing (WGS) is a modern molecular analytical technique which facilitates greatly the swift identification of causes of an outbreak and the batches, lots or consignments of unsafe food since it enables to establish links between different isolates recovered from humans, food, animals, feed and the related environment during the outbreak investigation.

¹ OJ L 325, 12.12.2003, p. 31.

² Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26)

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- (4) The European Food Safety Authority (EFSA) has developed a molecular typing system (EFSA One Health WGS System) for the collection of WGS data of isolates of *Salmonella enterica*, *Listeria monocytogenes* and *Escherichia coli* recovered from food, animals, feed and related environment. The European Centre for Disease Prevention and Control (ECDC) has developed and integrated a Molecular Typing system in EpiPulse for the collection of where WGS data and epidemiological data of isolates recovered from patients.
- (5) The EFSA and ECDC have developed a joint One Health system that allows for a joint analysis of WGS data submitted by Member States from both sectors. The system can detect microbiological clusters of human and non-human food-borne pathogens isolates for *Salmonella enterica*, *Listeria monocytogenes* and *Escherichia coli* and support detection and assessment of multi-country foodborne outbreaks. So far, WGS data for pathogens recovered from food, animals, feed and related environment are submitted by Member States to the system on a voluntary basis only.
- (6) ECDC is already able to collect also WGS data of isolates of *Campylobacter jejuni* and *Campylobacter coli*. EFSA will be able to collect WGS data of these pathogens from 1 January 2026 on.
- (7) Article 13(3)(d) of Regulation (EU) 2022/2371 requires that the national competent authorities referred to in paragraph 1 shall communicate molecular pathogen data, if required for detecting or investigating serious cross-border threats to health, to the participating authorities of the network for epidemiological surveillance.
- (8) Article 8(3) of Directive 2003/99/EC empowers the Commission to lay down detailed rules concerning the investigation of food-borne outbreaks. To substantially facilitate food-borne outbreak investigations at Union level and timely find the cause of such outbreaks, Member States should be required to collect *Salmonella enterica*, *Listeria monocytogenes*, *Escherichia coli*, *Campylobacter jejuni* and *Campylobacter coli* isolates derived from food, animal, feed or related environmental samples, from food business operators and official controls where suspected to be associated with a food-borne outbreak and to carry out WGS on these *Salmonella enterica*, *Listeria monocytogenes*, *Escherichia coli*, *Campylobacter jejuni* and *Campylobacter coli* isolates. Isolates from humans, affected or suspected to be affected by the food-borne outbreak are often analysed by WGS. Together with the results from WGS on human isolates collected in accordance with Article 13(3)(d) of Regulation (EU) 2022/2371, this will allow EFSA and ECDC to compare the results from WGS in isolates from humans, food, animals, feed and the related environment and to assess a possible link.
- (9) The submission by the Member States of the results from WGS in isolates from food, animals, feed and the related environment to EFSA for further analysis should be made mandatory. When submitting the results from WGS to the EFSA One Health WGS System associated data, needed for detection and assessment of foodborne outbreaks, should be included while respecting the protection of private data. The associated epidemiological data submitted with the results from WGS should therefore cover to what is essential for the foodborne outbreak investigation and be anonymized.
- (10) It is appropriate to provide Member States with sufficient time to adapt to the new requirements on collecting, WGS analysis and reporting in order to foresee the necessary technical and financial means. The requirements in this Regulation should

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therefore apply 12 months from the date of entry into force of this Regulation. In addition, the WGS analysis and reporting of *Campylobacter jejuni* and *Campylobacter coli* isolates should only become mandatory when EFSA One Health WGS System is ready to collect this information.

- (11) 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 detailed rules on the food-borne outbreak investigations in relation to the Whole Genome Sequencing (WGS) of isolates of food-borne pathogens from food, animals, feed and the related environment and submission of results thereof in accordance with Article 8(2) of Directive 2003/99/EC.

Article 2

Collection and analysis of isolates from food, animals, feed and related environment, associated with food-borne outbreaks and WGS of such isolates.

1. The competent authority responsible for the investigation of food-borne outbreak investigations in accordance with Article 8 of Directive 2003/99/EC, shall collect without undue delay isolates of *Salmonella enterica*, *Listeria monocytogenes*, *Escherichia coli*, *Campylobacter jejuni* and *Campylobacter coli*, where associated or suspected to be associated with an outbreak and derived from relevant food, animals, feed and related environment samples. Food and feed business operators shall provide such isolates or the results from WGS on such isolates, together with the associated data requested in Article 4(3)(a) of this Regulation, at the request of the competent authority.
2. The competent authority shall carry out WGS on the collected isolates of *Salmonella enterica*, *Listeria monocytogenes*, *Escherichia coli*, *Campylobacter jejuni* and *Campylobacter coli* in official laboratories referred to in Article 37 of Regulation (EU) 2017/625 of the European Parliament and of the Council³.

³ 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)(OJ L 95, 7.4.2017, p. 1)

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Article 3

Submission of results from WGS of isolates, associated with food-borne outbreaks, to EFSA

1. The competent authority responsible for the investigation of food-borne outbreak in accordance with Article 8 of Directive 2003/99/EC, shall submit to EFSA without undue delay the results of WGS and the associated data related to isolates of *Salmonella enterica*, *Listeria monocytogenes*, *Escherichia coli*, *Campylobacter jejuni* and *Campylobacter coli*, where associated or suspected to be associated with an outbreak strain and derived from relevant food, animals, feed and related environment.
2. The results for WGS referred to in paragraph 1, shall be accompanied by the following associated data:
 - a) a unique reference number of the sequence, isolate from which the sequence has been generated and of the sample from which the isolate was obtained;
 - b) the pathogen species;
 - c) the description of the specific food, animal species, feed or environment the isolate was derived from;
 - d) the date of sampling;
 - e) the country of sampling;
 - f) the reference to the notification in the Rapid Alert System for Food and Feed (RASFF), associated with the isolate.

Article 4

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 apply from ... [12 months from the date of entry into force of this Regulation].

The requirements laid down in this Regulation as regards *Campylobacter jejuni* and *Campylobacter coli* shall only apply from 1 January 2026 on.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
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