



2025/179

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COMMISSION IMPLEMENTING REGULATION (EU) 2025/179

of 31 January 2025

on the collection and transmission of molecular analytical data within the frame of epidemiological investigations of food-borne outbreaks in accordance with 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/EEC ⁽¹⁾, and in particular Article 8(3) thereof,

Whereas:

- (1) Article 8(2) of Directive 2003/99/EC requires the competent authority of the respective Member State 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 pursuant to Decision No 2119/98/EC of the European Parliament and of the Council ⁽²⁾. That Decision was repealed by Decision No 1082/2013/EU of the European Parliament and of the Council ⁽³⁾, which was later repealed and replaced by Regulation (EU) 2022/2371 of the European Parliament and of the Council ⁽⁴⁾. Those investigations are to provide data on the epidemiological profile, the foodstuffs potentially implicated, the potential causes of the outbreaks, as well as to include adequate epidemiological and microbiological studies.
- (2) The efficiency and the cross-sectorial cooperation between public health and food safety authorities in such investigations is essential to limit the public health impact of an outbreak and to minimize the economic impact linked to recalls and withdrawal of unsafe or potentially unsafe food. For this purpose, the quick and reliable identification of batches and lots or consignments containing contaminated food and the cause of the outbreak is necessary.
- (3) Whole genome sequencing (WGS) is a modern molecular analytical technique for microbiological studies which facilitates greatly the swift identification of clusters of microorganisms, supporting the epidemiological investigations. It enables to establish links between isolates of food-borne pathogens recovered from humans, food, animals, feed and the related environment during the outbreak investigation.
- (4) To substantially facilitate food-borne outbreak investigations and the timely detection of the sources of those 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 and related environmental samples from food and feed business operators and during official controls, where those isolates are associated or suspected to be associated with a food-borne outbreak. Member States should also be required to carry out WGS on those isolates.

⁽¹⁾ OJ L 325, 12.12.2003, p. 31, ELI: <http://data.europa.eu/eli/dir/2003/99/oj>.

⁽²⁾ Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p. 1, ELI: <http://data.europa.eu/eli/dec/1998/2119/oj>).

⁽³⁾ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1, ELI: <http://data.europa.eu/eli/dec/2013/1082/oj>).

⁽⁴⁾ 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, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>).

- (5) The Member States should transmit the results from WGS on isolates of those pathogens from food, animals, feed and the related environment to the European Food Safety Authority (the 'Authority') that developed a joint One Health system together with the European Centre for Disease Prevention and Control (ECDC). Within the joint One Health system, the Authority can compare the results from WGS on isolates of those pathogens collected in accordance with this Regulation with the results from WGS in human isolates communicated to ECDC in accordance with Article 13(3), point (d), of Regulation (EU) 2022/2371. Such comparison allows the identification of the source of an outbreak and of the affected consignments when used in combination with data from epidemiological investigations. When transmitting the results of the WGS to the EFSA Authority, additional related data, essential for the investigation of foodborne outbreaks, should be included.
- (6) It is appropriate to grant to Member States and the Authority sufficient time to adapt to the new requirements on collecting isolates derived from food, animal, feed and related environmental samples, the WGS of those isolates and the transmission of the related data in order to provide for the necessary technical applications and financial means. The requirements in this Regulation should therefore start to apply 18 months from the date of entry into force of this Regulation.
- (7) 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

Collection and Whole Genome Sequencing (WGS) of isolates of food-borne pathogens associated with food-borne outbreaks

1. The competent authority responsible for the investigation of food-borne outbreaks pursuant to 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 those pathogens are associated or suspected to be associated with a food-borne outbreak, based on the available analytical or epidemiological information, in the Member State of that competent authority or in another Member State and they were derived from samples taken from the suspected food, animals, feed or the related environment during foodborne outbreak investigations.
2. The competent authority shall carry out WGS on at least one isolate of each serovar, biotype or molecular type of the collected isolates referred to in paragraph 1 of this Article in an official laboratory which is referred to in Article 37 of Regulation (EU) 2017/625 of the European Parliament and of the Council⁽⁵⁾ and which is accredited for this method according to ISO 17025.
3. Where available, food and feed business operators shall submit to the competent authority, upon its request, the isolates of the pathogens referred to in paragraph 1 and the related results from WGS from their own investigations when associated or suspected to be associated with an outbreak, together with the associated data referred to in Article 2(2).

⁽⁵⁾ 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 (OJ L 95, 7.4.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/625/oj>).

*Article 2***Transmission of the results from the WGS**

1. The competent authority referred to in Article 1 shall transmit, without undue delay, to the Authority the results of the WGS carried out on the isolates of *Salmonella enterica*, *Listeria monocytogenes*, *Escherichia coli*, *Campylobacter jejuni* and *Campylobacter coli*, referred to in Article 1(1).
2. The data referred to in paragraph 1 shall be accompanied by the following associated data:
 - (a) a unique reference number of the genome sequence of the isolate from which the sequence has been generated;
 - (b) a unique reference number of the sample from which the pathogen has been isolated;
 - (c) the pathogen species;
 - (d) the description of the food, animal species, feed or environment the isolate was derived from;
 - (e) the date of sampling;
 - (f) the Member State of sampling;
 - (g) if notified in the Rapid Alert System for Food and Feed (RASFF), the reference to the notification associated with the isolate;
 - (h) a unique reference number of the foodborne outbreak investigated at national level.

*Article 3***Entry into force and date of 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 23 August 2026.

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

Done at Brussels, 31 January 2025.

For the Commission
The President
Ursula VON DER LEYEN