EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND ANIMAL WELFARE

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Whole genome sequencing within the frame of foodborne outbreak investigations (implementation of Regulation (EU) 2025/179)

Frequently asked questions

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1. WHAT ARE THE MAIN REQUIREMENTS OF THE NEW COMMISSION IMPLEMENTING REGULATION (EU) 2025/179?

Commission Implementing Regulation (EU) 2025/179([1]) aims to facilitate the swift identification of causes of a foodborne outbreak and the related batches, lots or consignments of potentially unsafe food by making mandatory WGS analysis and reporting to EFSA WGS system of at least one bacterial isolate from pathogens obtained from animals, feed, food or feed/food production environments, and associated or suspected to be associated with a foodborne outbreak. The pathogens concerned are *Salmonella enterica*, *Campylobacter jejuni/coli, Listeria monocytogenes* and *Escherichia coli.*

2. WHAT IS A FOODBORNE OUTBREAK?

A food-borne outbreak means an incidence, observed under given circumstances, of two or more human cases of the same disease and/or infection, or a situation in which the observed number of cases exceeds the expected number and where the cases are linked, or are probably linked, to the same food source ([2]).

3. HOW THE TERMS "*SUSPECTED TO BE ASSOCIATED WITH A FOODBORNE OUTBREAK*" SHOULD BE INTERPRETED IN THE IMPLEMENTING REGULATION 2025/179?

A foodborne outbreak starts with the detection of a pathogen in at least one of two or more human cases of the same disease and/or infection. Food ("matrix") become suspicious when there is an epidemiological link between at least two of the human cases and matrix where the same pathogen was found. An epidemiological link is established through investigations conducted by competent authorities (e.g. patient interview assessing exposure history, food data analysis (e.g. tracing back the food), etc…). The link can be a joint meal, food eaten in the same place or bought from the same consignment, food derived from the same establishment or flock/holding of animals. More conventional methods (e.g. serotyping, verification of virulence genes, …) may then be first applied to compare human and other isolates and in this way confirm the suspicion (further WGS required) or exclude it (no WGS required).

4. IN CASE OF A MULTINATIONAL OUTBREAK, WHICH MEMBER STATE(S) (COMPETENT AUTHORITY) NEEDS TO IMPLEMENT REGULATION (EU) 2025/179?

The competent authority of each Member State where an isolate was detected from food, animals, feed or the related environment, and where this isolate is associated or suspected to be associated with an outbreak are responsible for carrying out WGS. Article 8(2) of Directive 2003/99/EC obliges Member States to investigate foodborne outbreaks,

([1]) 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 (OJ L, 2025/179, 3.2.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/179/oj)

([2]) Definition in Article 2(2)(d) of Directive 2003/99/EC, the zoonosis monitoring Directive.

including carrying out microbiological studies. This includes the pro-active obligation to take samples whenever possible when a consignment is potentially associated with an outbreak based on public health investigations and traceability findings in another Member State or third country, indicating an outbreak. Implementing Regulation (EU) 2025/179 must then be applied when an isolate is detected in such samples indicating an analytical link e.g. same serovar. When the initial analysis is not very specific (e.g. detection of *Campylobacter jejuni*), a pro-active approach to carry out WGS should again be taken because of the obligation to investigate foodborne outbreaks.

5. DOES THE COMMISSION IMPLEMENTING REGULATION (EU) 2025/179 IMPOSE WGS TO FOOD BUSINESSES?

No, the text only requests to make results of WGS analysis available if WGS has been carried out by businesses at their own initiative; however they shall submit the isolates to competent authorities for WGS upon its request. It is however in the interest of the food business to fully cooperate in foodborne outbreak investigations to limit the possible impact of such outbreak, also for their own business by contributing to finding of the specific source and affected consignments. The use of WGS facilitates greatly the food-borne investigations and voluntary submissions of any available WGS data are very much welcomed. Furthermore, Article 15 of Regulation 2017/625 ([3]) stipulates that they are required to assist and cooperate with the personnel of the competent authorities during official controls and other official activities, and this could be clarified further.

6. WHAT WILL HAPPEN IF THE WGS PROFILE OF A HUMAN ISOLATE DURING AN OUTBREAK CORRESPONDS WITH THE WGS PROFILE OF A CERTAIN FOOD ISOLATE PRESENT IN THE EFSA WGS SYSTEM? WILL THE FOOD BE CONSIDERED AS THE SOURCE OF THE OUTBREAK?

A genetic match of WGS profiles between a human isolate and a food isolate alone does not confirm the food as the outbreak source. Additional epidemiological investigations, such as patient interviews, exposure history, and traceback analysis, are required to establish a link. The WGS data from human and food isolates must be combined with epidemiological investigations to confirm the food source. Common WGS profiles between human isolates and a matrix without (initial) epidemiological evidence, may be sufficient to be considered as a suspicion requesting further investigations e.g. when the production period of a food corresponds to the consumption period of the human cases.

([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, 07/04/2017, p. 1)

7. CAN A FOOD SOURCE BE CONFIRMED IF NO SAMPLE WAS ANALYSED IN THE FOOD CHAIN OR THE SAME WGS PROFILE WAS NOT DEMONSTRATED YET?

When a foodborne outbreak with a certain pathogen is detected in humans, it might not be easy to sample and confirm that the pathogen with the same WGS profile was present in a suspected food source. The suspected consignment might no longer be available since time passes between the production/placing on the market of a food and the detection of the outbreak in humans. Where the consignment is still available, sampling and analysis take time while exposure of humans might continue. In such cases, a food source can already be considered as confirmed (and corrective action taken if possible) if the results from epidemiological investigations are sufficiently robust (e.g. when other evidence shows that a producer represents the only common point of manufacturing of the contaminated products).

8. ASSUMING THAT EPIDEMIOLOGICAL INVESTIGATIONS DEMONSTRATE A LINK BETWEEN HUMAN OUTBREAK CASES AND A CERTAIN FOOD WHERE THE SAME WGS PROFILE WAS FOUND, WILL THIS THEN BE PUBLISHED?

The communication strategy laid down in Article 21 of Decision (EU) 2019/300 ([4]) is generally applied for all multi country outbreaks: information is first distributed through dedicated networks such as RASFF and the Commission crisis coordinators network to allow coordinated communication within responsibility of the different involved actors. In addition, the Member States shall immediately inform the affected food business operators, when reliable evidence on the possible source of an outbreak has been collected, in line with Decision 2019/300.

9. WHAT'S THE SENSE OF STORING WGS IN THE EFSA WGS SYSTEM FOR SEVERAL YEARS SINCE THEY DO NOT HAVE AN EPIDEMIOLOGICAL LINK WITH A RECENT OUTBREAK?

Historical data are often used to give an orientation to required outbreak investigations: some strains are more commonly present in certain food or from certain origin (e.g. from imports of certain parts of the world). Investigations can therefore be better targeted. Historical data can also provide information on the persistence in the food production environment of certain food-borne bacterial isolates with specific virulence or antimicrobial resistance factors: when found again in certain food, this might provide information if urgent action is needed.

10. WHAT SPECIFIC DATA MUST BE TRANSMITTED ALONG WITH THE WGS SEQUENCES TO EFSA?

Article 2(2) of Implementing Regulation (EU) 2025/179 lists the data to be submitted. While some are straightforward and EFSA provides a specific format for introducing (e.g.

([4]) Commission Implementing Decision (EU) 2019/300 of 19 February 2019 establishing a general plan for crisis management in the field of the safety of food and feed (OJ L 50, 21.2.2019, p. 55). ELI: http://data.europa.eu/eli/dec_impl/2019/300/oj

reference numbers, pathogen species, date and Member State of samplings), others are more descriptive e.g. the description of the food, animal species, feed or environment the isolate was derived from. A FoodEx2 catalogue of EFSA is available for the submission of the sample matrix data and should be used maximally to provide information on the sample, allowing a statistical evaluation of the data. In addition to using the FoodEx2 catalogue, the submission of additional details on the sample is also required, and this is done using a free text in any EU language. e.g. the FoodEx2 catalogue contains terms such as "Chocolate/cocoa-based products" or "Cheese" but in outbreak investigation it is relevant to be more specific and to indicate for example respectively "Mousse au chocolat" or "red culture soft cheese".

11. SHOULD OTHER WGS RESULTS (E.G. FROM ROUTINE SAMPLING, NOT SUSPECTED OF BEING ASSOCIATED WITH A FOODBORNE OUTBREAK) BE SUBMITTED TO THE EFSA WGS SYSTEM?

The Implementing Regulation (EU) 2025/179 doesn't cover the submission of the results of WGS coming from other monitoring activities. However, MS are strongly encouraged to share any WGS results available in the country to populate the database for enhancing the capacity of the system to detect and to support the investigation of foodborne outbreaks at EU level e.g; by giving an orientation to public health investigations when the same WGS profile is detected at a later stage in human outbreak isolates.

12. THE NEW IMPLEMENTING REGULATION (EU) 2025/179 REQUESTS THE COMPETENT AUTHORITY TO TRANSMIT, WITHOUT UNDUE DELAY, TO THE EUROPEAN FOOD SAFETY AUTHORITY THE RESULTS OF THE WGS. WHAT DOES "WITHOUT UNDUE DELAY" MEAN?

The term 'without undue delay' means that WGS results should be transmitted to EFSA as soon as they are available. This includes ensuring that sequencing, data analysis, and transmission occur without unnecessary delays. The goal is to enable timely outbreak investigations, minimize the impact on health risks and allow to take the necessary risk mitigating measures.

13. THE NEW IMPLEMENTING REGULATION (EU) 2025/179 ALSO IMPOSES ACCREDITATION OF THE OFFICIAL LABORATORY FOR CARRYING OUT WGS ACCORDING TO ISO 17025. WHY IS THIS NEEDED? WHAT IS EXACTLY EXPECTED?

Accreditation according to ISO 17025 ensures that official laboratories designated by the competent authorities to carry out WGS possess expertise, equipment, infrastructure and staff to carry out such tasks to the highest standards. Sound and reliable results are essential in foodborne outbreak investigations. A dedicated working group of EU Reference Laboratories is preparing guidelines on what is expected by official laboratories to be accredited for WGS. Those guidelines will be made available by the end of 2025. Official laboratories will then have until mid-2028 to become accredited.

14. WHAT BENEFIT HAVE COMPETENT AUTHORITIES AND FOOD BUSINESSES IN COLLABORATING WITH THIS COLLECTION OF DATA ON WGS PROFILES OF FOODBORNE PATHOGENS?

The advantage for competent authorities and food businesses would be the capacity to contextualize the national investigations at EU level, in order to identify potential links across countries and sectors, therefore helping the investigation of the foodborne outbreaks also at national level. In certain conditions, this might result in early identification of clusters of interest in the food sector which might accelerate the identification of foodborne outbreaks and the application of effective control measure at an early stage, minimising the risk of unnecessary withdrawals/recalls of food. Once the database is well populated with WGS profiles of food-borne bacterial isolates from both human and food, feed, animal and related environment, the information related to the comparison of such WGS profiles helps to decide on the need for control measures differentiating for example between highly pathogenic *Listeria monocytogenes*, *Campylobacter* or VTEC strains and less-pathogenic ones.

Additional FAQs on the EFSA WGS System and Data bases