Implementing Regulation 2025/179

Milestones

2023 — **September**

Together with the Inter-EURL working group on Next Generation Sequencing, EFSA organises the conference "Science meets policy": Using Next Generation Sequencing to tackle foodborne threats". The conference advances discussions on data sharing methodologies and standards, identifying areas for action with a view to a stakeholder-conceived roadmap while also addressing legal barriers and solutions related to food safety.

2022 — **July**

EFSA launches a platform for the collection and analysis of Whole Genome Sequencing (WGS) data on *Salmonella*, *Listeria monocytogenes*, and *Escherichia coli* in food and animals, following a request from the European Commission. The platform is accessible to national competent organisations in the field of food safety, which will be uploading data that come from the annual monitoring of foodborne diseases. It will interact with the equivalent ECDC data collection system.

The platform will support the work of EFSA and ECDC on rapid outbreak assessments, and ultimately help protect European consumers.

2019 — **December**

Experts evaluate the possible use of whole genome sequencing and metagenomics to investigate foodborne outbreaks, in source attribution analysis and microbiological *risk assessment*. They also analyse the advantages and limitations of next generation sequencing-based methodologies for characterising *Salmonella* and STEC and detecting *antimicrobial resistance* genes in bacteria.

May

Following a request from the Commission, EFSA and the European Centre for Disease Prevention and Control (ECDC) provide technical support for the collection and analysis of whole genome sequencing (WGS) data. Experts assess the state of the art of existing tools and identify needs and requirements for the joint EFSA-ECDC data collection system.

Whole genome sequencing in foodborne outbreaks

Last reviewed date: 26 March 2025
| 7 minutes read

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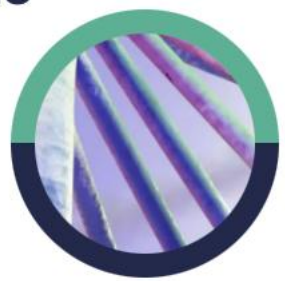

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3.2.2025

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)

- **Mandatory whole genome sequencing on isolates within foodborne outbreaks:**
  - **From feed, animals, food, related environment**
  - ***Salmonella enterica, Listeria monocytogenes, Escherichia coli, Campylobacter jejuni and Campylobacter coli***
  - ***WGS on at least one isolate of each serovar, biotype or molecular type***
- **Mandatory collection of isolates from businesses if available**
- **Mandatory submission of results to EFSA One Health WGS system**

Published in 3 February 2025

Applicable on 23 August 2026

Commission Implementing Regulation (EU) 2025/179: complementary initiatives

- INTER-EURL working group for WGS
- FAQs on WGS within foodborne outbreak investigations
  - https://food.ec.europa.eu/document/download/bb6b197a-cce2-4ebf-aca2-ebb6696c803f_en?filename=diseases_foodborne_zoonoses_reg-2025-179_faqs.pdf
  - Focus on data sharing and interest for food business operators

From the FAQs

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 mandatory for food business to fully cooperate in foodborne outbreak investigations…

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?

… a food source can already be considered as confirmed (and corrective action taken if needed) 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).

From the FAQs

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.**

Ref. Ares(2025)7724078 - 16/09/2025

European Commission

CALL FOR EVIDENCE
FOR AN INITIATIVE (without an impact assessment)

TITLE OF THE INITIATIVE	Food and feed safety – simplification omnibus
LEAD DG – RESPONSIBLE UNIT	DG SANTE E.4, R.1
LIKELY TYPE OF INITIATIVE	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 1107/2009, Regulation (EC) No 396/2005, Regulation (EU) No 528/2012, Regulation (EC) 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, Regulation 1099/2009, Regulation (EC) No 999/2001, Regulation (EC) No 1069/2009, Regulation (EU) 2017/625, Directive 98/58/EC and Directive 2009/128/EC as regards simplifying and strengthening food and feed safety requirements
INDICATIVE TIMING	Q4 2025
ADDITIONAL INFORMATION	--

This document is for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described, including its timing, are subject to change.

Problem the initiative aims to tackle

Among others…

Official Controls Regulation: currently, border control posts cannot release the compli another part still needs further checks. This often leads to unnecessary delays, especi made up of different batches with varying control requirements. Also, **the accreditation laboratories are too rigid and do not consider the specific needs** of areas like plant p ongoing compliance issues.

B. What does the initiative aim to achieve and how

Under the **Official Controls Regulation**, the initiative aims to allow partial clearance o and plant products at border control posts. This responds to practical challenges in cas certificates cover diverse batches requiring different types of checks; Member States ha flexibility to avoid trade delays when only part of a consignment is held up. **The propos a limited derogation from accreditation requirements for reference laboratories. This wo issues, better reflect technical specificities**, and respond to repeated requests from Me European Commission's Joint Research Centre, while preserving the integrity of EU rules.

One Proposal from the EC

the idea that the EC has is mind is to provide more flexibility as regards accreditation of laboratories carrying out **further testing on isolates (e.g. WGS) of foodborne pathogens.** The accreditation today is according to EN ISO/IEC 17025 (’General requirements for the competence of testing and calibration laboratories’) while **the intention would be to allow for this specific purpose also accreditation according to EN ISO 15189** (’Requirements for quality and competence of medical laboratories’). In this way a laboratory carrying out these tests (e.g. WGS) on human isolates and accredited according to EN ISO 15189, would also be allowed to carry out these test on isolates derived from non-human sources **without the need for an additional accreditation according to EN ISO/IEC 17025.**