COLLABORATION AGREEMENT

on cross-sectoral sharing and use of Whole Genome Sequencing and related data of foodborne pathogens for public health purposes between ECDC and EFSA

Annex III.
EU protocol for response to cross-border foodborne outbreaks

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Abbreviations

cgMLST	core genome Multilocus Sequence Typing
CO	Country Officer
DG SANTE	Directorate-General for Health and Food Safety
DP	Data Provider
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFSA	European Food Safety Agency
EpiPulse	European Surveillance portal for Infectious Diseases
EU	European Union
EURL	European Union Reference Laboratories
EURL-PH	European Union Reference Laboratories for public health
EURL-PH-FWDB	European Union Reference Laboratories for public health for food- and waterborne diseases bacteria
FS	Food Safety
FWD	Food- and Waterborne Diseases
FWD-Net	Food- and Waterborne Diseases Network
MTT	Molecular Typing Tool
NFP	National Focal Point
OCP	Operational Contact Point
PH	Public Health
RASFF	Rapid Alert System for Food and Feed
STEC	Shiga toxin-producing *Escherichia coli*
WGS	Whole Genome Sequencing

Introduction

Since 2007, the European Centre for Disease Prevention and Control (ECDC) has been collecting data on human infectious diseases, including salmonellosis, campylobacteriosis, listeriosis and Shiga toxin-producing *Escherichia coli* (STEC) infections. These diseases pose a significant public health burden within the EU/EEA. Surveillance at the EU level is conducted in accordance with EU legislation, which provides clear guidelines for the classification and reporting of cases.

The EU legislation on the monitoring of zoonoses and zoonotic agents mandates the European Food Safety Agency (EFSA) to collect and analyse zoonotic disease and zoonotic agent data from EU Member States annually in collaboration with ECDC, which is responsible for collecting and monitoring human communicable diseases surveillance data. The joint effort aims to support veterinary and food safety authorities in planning actions that reduce the occurrence of zoonotic diseases and agents in animals, food, and in the related environment (non-human sector), ultimately lowering the number of human zoonotic disease cases.

As genome sequencing techniques have advanced and countries' capacities to sequence bacterial isolates have increased. ECDC and EFSA established a joint One Health Whole Genome Sequencing (OH WGS) system for the collection and analysis of WGS data from both the public health and food safety sector to enhance the detection and assessment of cross-border foodborne outbreaks at the EU level.

The joint ECDC-EFSA One Health WGS System became operational in July 2022, and it has been designed for cluster analyses of *Salmonella* (*S.*) *enterica, Listeria* (*L.*) *monocytogenes* and *Escherichia* (*E.*) *coli* including STEC, and later extended to *Campylobacter* (*C.*) *coli* and *C. jejuni* to comply with the legislative requirements of Commission Implementing Regulation (EU) 2025/179. This system is composed of two interconnected sector-specific platforms (i.e. ECDC WGS system and EFSA WGS system), each comprising databases of core genome MLST profiles and/ or sequencing data, and associated metadata. WGS data provide remarkable added value to the detection and investigation of foodborne outbreaks both at the national and EU level.

While the processes of data collection, analysis, and risk assessment between ECDC and EFSA have been well established, there is a recognised need for standardising monitoring and response procedures for cross-border foodborne outbreaks. The response process involves multiple stakeholders in both sectors at the national and EU level. Figure 1 outlines the main steps of the cross-sectoral collaboration for the detection of microbiological clusters and outbreaks, and for the response to multi-country foodborne outbreaks.

To facilitate a smooth and effective preparedness and response to cross-border foodborne outbreaks, ECDC and EFSA have prepared this protocol under the framework of a Collaboration Agreement on the management and sharing of molecular typing data of isolates from human, food, feed, animal, and the related environment for public health purposes (hereafter "Collaboration Agreement'')[1] between ECDC and EFSA, finalised with input from EU/EEA countries representatives.

Purpose of the protocol

Within the scope of this protocol: This document outlines the steps for the cross-sectoral collaboration for routine microbiological cluster and outbreak detection for *S. enterica, L. monocytogenes, E. coli* (including STEC) and *Campylobacter* spp., and response to multi-country foodborne outbreaks in the EU, starting with WGS data reported to ECDC and EFSA WGS systems by countries in both sectors. The document identifies the roles and contributions of the involved public health and food safety authorities/institutes including laboratories and the coordination role of ECDC and EFSA. It covers routine follow up of events and signals, joint cluster searches using WGS data, as well as the monitoring and response to multi-country foodborne events. This activity may result in the production of joint outbreak assessment reports.

[1] Collaboration Agreement on the management and sharing of molecular typing data of isolates from human, food, feed, animal, and the related environment for public health purposes

Out of scope of this protocol: The decision on the approach to be used to assess and communicate the multi-country foodborne outbreak is out of scope of this protocol. If events of unusual character or circumstances occur, an *ad hoc* response where a different approach for assessing and communicating events other than what is described in this protocol may be applied. This document also does not apply to food/feed crisis situations under the Commission Implementing Decision (EU) 2019/300, establishing a general plan for crisis management in the field of the safety of food and feed, and Regulation (EU) 2022/2371 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. The protocol does not describe the bioinformatics analysis pipelines used within the ECDC and EFSA WGS systems, nor the automated data exchanges between the two platforms. These technical aspects are detailed in the technical specifications (Annex II of the collaboration agreement).

Legal framework

This protocol has been developed considering the following EU legislation:

- 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 (Art 8)
- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 on ECDC's updated mandate to collect pathogen data, including at molecular level, if required for epidemiological surveillance and for detecting or investigating serious cross-border threats to health
- 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
- EC Mandate (Ref. Ares (2013)2576387) on the 'Request for scientific assistance of EFSA in the investigation of multinational foodborne outbreaks' https://open.efsa.europa.eu/study-inventory/EFSA-Q-2024-00213
- EC Mandate (Ref. Ares (2019)8634353) on 'Request for the implementation of an 'One Health' system for the collection and analysis of whole genome sequencing (WGS) data from human and food/animal isolates' https://open.efsa.europa.eu/question/EFSA-Q-2020-00101
- 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 foodborne outbreaks in accordance with Directive 2003/99/EC of the European Parliament and of the Council

Platforms and users

Public health sector

For the public health sector, the platforms used in the context of response to cross-border foodborne outbreaks are the following:

- The **European Surveillance portal for Infectious Diseases (EpiPulse)** is an online portal for European public health authorities and partner organisations to collect, analyse, share, and discuss infectious disease data for threat detection, monitoring, risk assessment and outbreak response. The diseases or disease groups, special health issues (e.g. antimicrobial resistance), and epidemic intelligence activities are divided into domains. Food- and waterborne disease events and outbreaks are covered under the 'FWD' domain. The EpiPulse platform portal includes **EpiPulse Cases, EpiPulse Events and EpiPulse Molecular Typing tool (MTT)** which are described below.
  - **EpiPulse Cases** is a platform for EU/EEA countries' nominated public health users to submit indicator-based surveillance data: either as annual case-based data according to the list of

EU/EEA notifiable diseases and their case definitions[2], or isolate-based WGS data with associated epidemiological and other descriptive data[3] to be reported when new data available and in relation to ongoing outbreaks without set reporting deadlines.

- Under **EpiPulse Events,** the items are classified as an 1) **Event** or a 2) **Signal**.
  - 1) **Events** are launched by countries (and some cases also by ECDC) to report unusual increases of cases in the country and asking other countries about similar increases. Event epidemiological information should be complemented with representative outbreak reference strain(s) (primarily sequence data) by the launching country (see Table 2 Step 1). Outbreak reference strains are compared with sequences in other countries and in the ECDC-EFSA One Health WGS System for possible matches (see Table 2 Step 2). This constitutes the backbone of the event-based surveillance.
  - 2) **Signals** are multi-country WGS clusters with at least one recent isolate circulating in the past year (this includes both human isolates and non-human isolates) resulting from a regular ECDC cluster analysis (see Table 2 Step 3).
- The **EpiPulse MTT** is a cluster visualisation tool and serves as the front-end application, providing public health users with an interactive interface to access, visualise, and interpret the results generated by the **ECDC WGS system** for all pathogens with submitted sequence data. It enables users in-real time to visualise human isolate-based WGS data submitted by countries and processed in the back-end infrastructure, using pre-defined bioinformatics workflows. Additionally, **EpiPulse MTT** displays clustering information for non-human isolates originating from the **EFSA WGS system**, supporting integrated surveillance across sectors.

The **ECDC WGS system** acts as the back-end infrastructure, incorporating the **U**ltrafast **B**ioinformatics calculation **E**ngine (NUBE), bioinformatic analytical components, and interoperability mechanisms with the **EFSA WGS system** to ensure data exchange and integrated analysis. It automatically interacts with EFSA by exchanging **cgMLST profiles**, as well as epidemiological and descriptive data, in accordance with the established agreement. This exchange uses **pseudonymised isolate identifiers** to maintain data privacy while enabling coordinated surveillance and outbreak investigation across agencies.

For the scope of this protocol and for the public health sector in EU/EEA countries, ECDC collaborates with experts in **the European Food- and Waterborne Diseases and Zoonoses network (FWD-Net)** consisting **of National Focal Points (NFPs)** for food- and waterborne diseases and zoonoses, and **Operational Contact Points (OCPs)** for epidemiology and microbiology of a disease and/or isolate (hereafter referred to as public health users). The National Coordinators nominate and register the network members and define their roles according to the ECDC Coordinating Competent body policy[4]. The roles of the experts are the following:

- NFPs for FWD: member and alternate;
- OCP for salmonellosis or OCP for *Salmonella* isolates (role of epidemiology or microbiology);
- OCP for listeriosis or OCP for *Listeria* isolates (role of epidemiology or microbiology);
- OCP for STEC infection or OCP for *E. coli* isolates (role of epidemiology or microbiology);
- OCP for campylobacteriosis or OCP for *Campylobacter* isolates (role of epidemiology or microbiology).

In addition, ECDC collaborates with the OCPs for bioinformatics regarding data submissions and with international public health partners who have signed an agreement with ECDC and with the European Union Reference Laboratories for public health **(EURL-PH) for FWD bacteria (EURL-PH-FWDB)**, operational since January 2026. One of the tasks of the EURL-PH-FWDB is to provide ECDC with information, guidance and scientific support in the event of a confirmed multi-country outbreak or other unusual event, upon request by ECDC

[2] Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions http://data.europa.eu/eli/dec_impl/2018/945/oj

[3] EpiPulse molecular typing working instructions

[4] https://www.ecdc.europa.eu/en/about-ecdc/who-we-are/governance/competent-bodies

- The **Early Warning and Response System (EWRS)** is a restricted web-based communication platform established to enable rapid communication and coordination among EU/EEA countries and the EC in response to serious cross-border health threats, particularly communicable diseases. It ensures timely exchange of information for risk assessment and management to protect public health. The European Commission owns the system, and ECDC operates the IT platform including hosting and development.
  - **EWRS National Contact Points/EWRS competent authorities** are designated officials or units within each EU/EEA countries responsible for managing communication and coordination through the EWRS. They act as the primary interface between national authorities and the European Commission/ECDC for notifications of serious cross-border health threats.

Food safety sector

For the food safety sector, the platforms used in the context of the present protocol are the following:

- The **EFSA WGS system** developed by EFSA in response to the EC mandate to define and set up a system for the collection of sequencing data of isolates of foodborne pathogens from food, feed, animals, and the animal and food processing environment (non-human sector), for the purpose of supporting the rapid detection of multi-country foodborne outbreaks. The scope of the system is to collect and store WGS-based typing data from the non-human sector, including genomic profiles, and corresponding metadata (i.e. experimental and epidemiological data), and to enable comparison and cluster analysis with genomic profiles obtained from human isolates.

The users of the EFSA WGS system are the following:

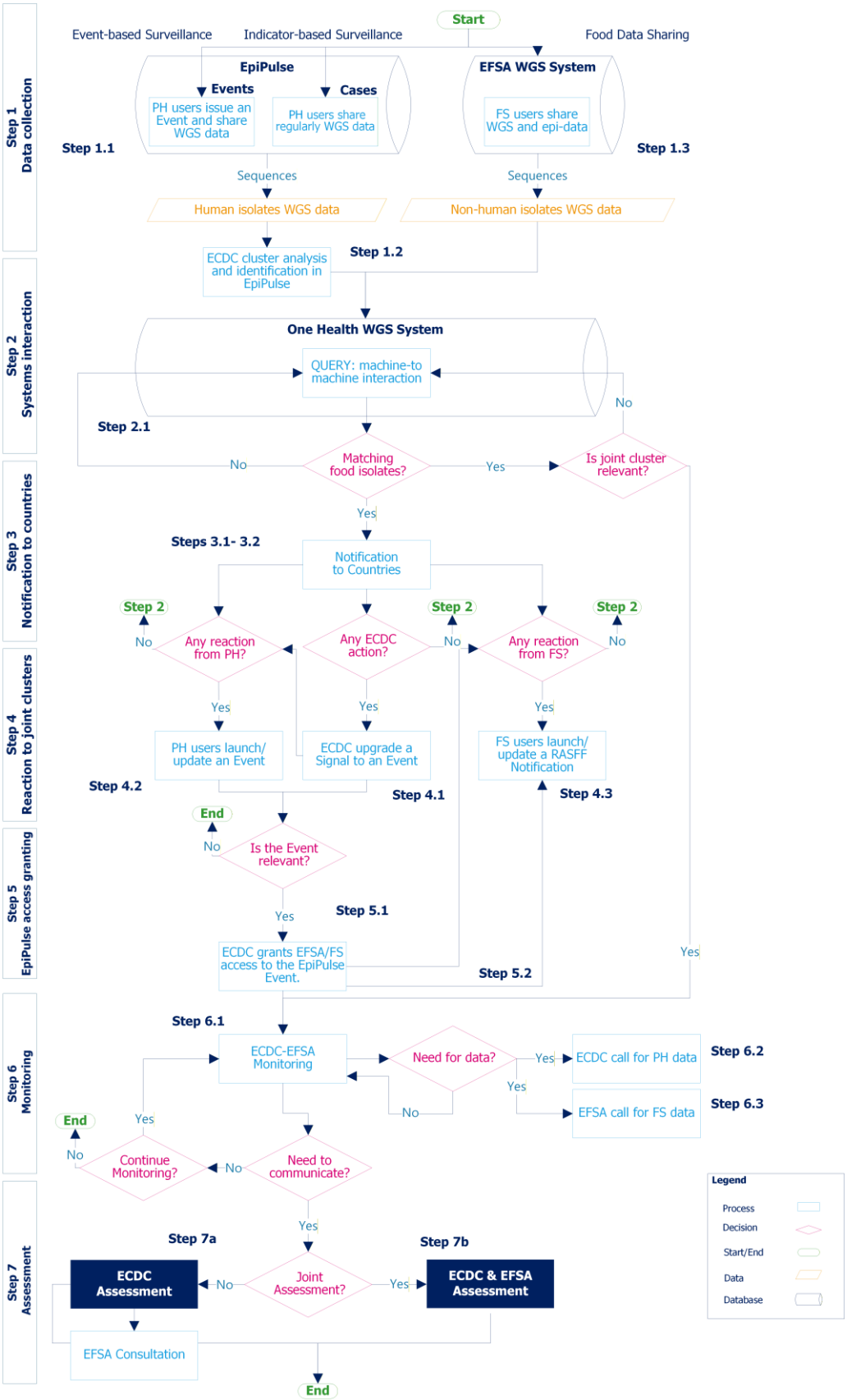
  - **Country Officers**: nominated users for the Food and Veterinary sector acting as a point of contact between EFSA, the food safety authority in their own country, and the organisations of the Data Providers in their own country.
  - **Data Providers**: nominated users for the Food and Veterinary sector in charge of the collection and submission of genomic data from their organisation.
  - **European Union Reference Laboratories (EURL):** nominated users of the food safety (FS) EURL for the specific pathogens in charge of supporting the countries in generating sequencing data from food, feed, and animal samples, and submitting them to the EFSA WGS system on behalf of the Data Provider organisation.

- The **Rapid Alert System for Food and Feed (RASFF)** is part of the Alert and Cooperation Network. RASFF is operated by the European Commission (EC) and established to ensure the exchange between countries of information (in the form of Notifications) on non-compliant food and feed traded across member countries, and supports the swift reaction by food safety authorities in case of risks to public health resulting from the food chain (https://food.ec.europa.eu/safety/rasff_en). Members of the ACN are EU/EEA countries, EFSA, Switzerland and the EC. All members have appointed dedicated single Contact Points with out-of-hours arrangements (24/7) to address any emergency related to a RASFF notification made outside office hours.

  - **RASFF Contact Points**: national food authorities nominated as contact point and acting as liaison with the national experts involved in the outbreak investigation to collect, share, and validate traceability data on non-compliant food and feed.

In addition, appointed experts from the food safety authorities of the EU/EEA countries and the EURLs for food and feed have access to EpiPulse Events as food safety users. EFSA is responsible for maintaining the list of appointed EpiPulse food safety users.

Figure 1. Steps of cross-sectoral collaboration for response to multi-country foodborne outbreak in the EU/EEA



FS=Food Safety; PH=Public Health, WGS=Whole Genome Sequencing,

Table 1. Steps of cross-sectoral collaboration for microbiological cluster and outbreak detection, and response to multi-country foodborne outbreak in the EU/EEA

STEP 1. **Data collection** **Responsible: ECDC, Member State PH and FS users**	**1.1 Event-based and Indicator-based WGS Data Submission by Public Health authorities (PH users) and cluster analysis identification** PH users launch an Event in EpiPulse Event when a national outbreak might have a potential for a cross-border dimension. PH users may consider the following aspects for launching an event: • Unexpected/unusual size/increase of cases at national level • Rare pathogen type • Match with non-human isolates • Severity of infections • Antimicrobial resistance profile • Demographics • Suspected food item. Countries should attach one or several representative outbreak sequences in the Event (FASTA files) for other countries to download and compare. Countries may also submit a representative outbreak sequence(s), or a subset of sequences linked to an Event through isolate-based reporting in EpiPulse Cases together with associated metadata. **1.2 Cluster analysis and identification** ECDC uses the WGS data of human isolates for cluster analyses and cluster identification. **1.3 Routine Food Safety authorities (FS users) Data Submission** FS users (Country Officers (COs) and Data Providers (DPs)) submit their national WGS data of foodborne pathogens and related epidemiological data (e.g. Sample ID, Isolation ID, Sampling Country, Date of Sampling, Sample Matrix) in the EFSA WGS system in the frame of the national molecular monitoring and national data sharing strategies, and in compliance with the Commission Implementing Regulation (EU) 2025/179.
STEP 2. **WGS Systems interaction** **Responsible: ECDC and EFSA**	**2.1 ECDC query and EFSA response, visualisation of the WGS cluster analyses** ECDC sends a query to the EFSA WGS system based on the identified clusters in EpiPulse. The EFSA WGS system, in case matches are identified, automatically provides as a response the cgMLST profiles, agreed minimum metadata, and WGS derived typing data. ECDC includes the received isolate profiles and related metadata into the EpiPulse MTT using the integrated MicroReact tree, for nominated users to visualise (Table 1). The EFSA WGS system displays the results of the cluster analysis generated by the joint ECDC-EFSA One Health WGS System (called 'received query') to the food safety users (COs and DPs) using a graphical (minimum spanning tree) and tabular representation according to the access rights and visibility rules (Table 1).
STEP 3. **Notification to Member States**	**3.1 ECDC notification of new or multi-country Events and Signals (multi-country WGS clusters) to countries** The public health users can subscribe to an automated email notification for information on new Events when launched in EpiPulse platform. Notifications

Responsible: ECDC, EFSA, Member States FS users	can be subscribed also when an Event becomes multi-country, and when the 'Situation awareness' is updated and available in EpiPulse Events. Users can in addition subscribe notification for multi-country WGS clusters i.e. Signals (available only for *L. monocytogenes* at the moment) resulting from a regular ECDC cluster analysis. Notifications are sent to users with matching isolates (human or non-human) in the cluster in their country. **3.2 EFSA Notification of the identified matching food isolates to countries** The EFSA WGS system automatically notifies the subscribed food safety users (COs and DPs) of the Member States on weekly basis about new non-human matches found by the ECDC query. The EFSA COs who subscribed to the service will be notified on any entries matching the ECDC queries submitted from any organisations within her or his country, while DPs who subscribed to the service will receive a notification on any entries submitted from their own organisation. FS users ensure that the minimum epidemiological data for the isolates are submitted timely to the System, if not available yet.
STEP 4. Reaction to joint clusters **Responsible:** **ECDC, Member State PH and FS users**	Following the detection of a joint cluster (matching human and non-human isolates), the responsible actors (ECDC, EFSA and public health or food safety users in Member States) can decide to perform the following steps, sequentially or in parallel. If no actions are taken, the cluster is regularly re-evaluated starting from step 2. **4.1 ECDC action** ECDC monitors daily the Events and the Signals in EpiPulse. ECDC may upgrade a Signal to an Event in EpiPulse to initiate an outbreak investigation with affected countries and to collect further epidemiological and sequence data in other countries. The following pre-defined set of criteria are considered when upgrading a Signal to an Event: • Magnitude in terms of number of cases and number of countries involved (including third countries) • Prolonged occurrence • There is a matching food isolate or potential in identifying a food source **4.2 PH users' reaction** The nominated users of the EpiPulse compare the outbreak reference strains in the Event with the strains in their national databases and inform about the outcome and additional epidemiological information as a reply in EpiPulse Event and when relevant with FS within their own country (national cross-sector interaction). **4.3 FS users' reaction** FS users may react by proceeding with the following actions: • liaise with the national RASFF Contact Point with the aim of issuing and/or sharing in RASFF the traceability information related to the matching food isolate/s. The sharing shall be done in a RASFF notification. The decision on the type of notification (News, Alert, and so on) shall follow the RASFF rules; and • provide the reference to the RASFF notification in the EFSA WGS system (i.e. notification number under the tab 'Programme Info')

	• share additional genomic data and related metadata in the EFSA WGS system • liaise with the national PH in their own country and inform about the issuing of a RASFF notification related to the matching food isolate (national cross-sector interaction). This action may lead PH users to answer or launch an EpiPulse Event (4.2.)
STEP 5. **Granting access to an EpiPulse Event** **Responsible: ECDC, and FS users**	**5.1 ECDC granting access to an EpiPulse Event** As soon as an outbreak becomes multi-country in the EpiPulse Event (cases with matching isolates in at least another EU/EEA country) OR an EpiPulse Signal is upgraded to an Event, ECDC writes a summary in the r 'Situation awareness' of Event and grants access to external stakeholders according to the access rights and visibility rules (Table 1). **5.2 FS users' reaction** FS may react in RASFF following the access granted by ECDC (5.1) performing the actions as in 4.3.
STEP 6. **ECDC and EFSA monitoring** **Responsible: ECDC and EFSA, Member State PH and FS users**	**6.1 Discussion on the prioritised Events and Signals** ECDC reviews the Events and Signals and brings prioritised clusters to ECDC-EFSA weekly meetings for discussion and monitoring. If needed or per request from a country, ECDC may organise meetings with public health experts from involved countries. EFSA contributes to the discussion via the monitoring activities that include the daily review of the Epi-Pulse Events and RASFF notifications and the search of possible alignments among data shared in the different platforms. **6.2 ECDC call for data** ECDC can encourage countries to keep EpiPulse Events updated and to submit through EpiPulse Cases human isolate sequences that are genetically close to the representative isolates. **6.3 EFSA call for data** If considered needed, EFSA can call for genomic and epidemiological data for those food isolates relevant to the foodborne event under discussion, (e.g., food isolates mentioned in RASFF whose sequence is not available from the EFSA WGS system) and the COs should: • forward the call for data to the Data Provider/s within the country • verify that the minimum epidemiological data are available, and if not, provide them at the earliest convenience.
STEP 7. **Assessment** **Responsible: ECDC and EFSA, EURL-PH-FWDB MS PH and FS users**	The agencies discuss the information (genomic, epidemiological, traceability data) provided by the PH users and by the FS users in the involved Member States and discuss the need to proceed with the production of an EU assessment. **7a. ECDC Assessment** ECDC assesses on a daily basis the need to publicly communicate cross-border events. This may result in a ECDC Assessment where EFSA is consulted on aspects related to any reference to a suspected food. **7b. ECDC and EFSA Assessment** ECDC and EFSA may agree to do a joint ECDC-EFSA assessment. An external and independent request for the production of a joint assessment (e.g. Rapid

	Outbreak Assessment) can also come from the EC (DG SANTE). The main criteria that might be considered are: • Multi-country event • Cases reported in the current and/or previous year (as visible in EpiPulse MTT) • Matching cgMLST profiles between human and non-human isolates • Epidemiological link to a suspected food source without a matching food isolate (strong evidence needed). **EURL-PH_FWDB:** Upon request by ECDC, the EURL-PH_FWDB will contribute to ECDC risk assessments or to ECDC-EFSA joint outbreak assessments by providing input on human pathogen-specific features and appropriate laboratory methodologies, including WGS-based approaches. **Countries** are expected to contribute to the joint assessment per sector as follows: **PH users Engagement:** The country nominated users of EpiPulse are expected to contribute to: • the human data collection • the validation of own country's data during consultation phase • the final check of correctness of national data during a prenotification (24 hours before publication). **FS users Engagement:** The COs and DPs of the EFSA WGS system are expected to contribute to: • the coordination of the call for genomic data, sharing of the genomic data within the country, verify that the epidemiological data of the matching isolates are as complete as possible, and if not, provide them at the earliest convenience, and indicate the reference to the RASFF notification number for the matching isolates under the tab 'Programme Info' within the EFSA WGS system • the verification and the validation of the correctness of the genomic and epidemiological data shared, including the exact correspondence between the Entry ID and the RASFF notification (matching isolates only).

Access rights and visibility rules

The users of the different sectors access the ECDC-EFSA One Health WGS System from corresponding agency's platform. Specific rules are applied to govern data visibility in both platforms for public health and food safety sector (Table 2).

EpiPulse's terms of service include rules on confidentiality and publication. Under these rules, anyone with access to EpiPulse, regardless of sector or user role, may use the information and data shared in EpiPulse only as permitted by those terms.

The use of the **EFSA WGS system** is subject to specific Terms of Use and Data Protection provisions. The access is restricted to authorised users under the ''Collaboration Agreement''. Data may include confidential or sensitive information and remains the property of the respective owners. Any reuse beyond

agreed purposes requires explicit consent by the data owner. Users must comply with confidentiality rules and are prohibited from sharing credentials or content.

Table 2. Summary of access rights and visibility rules for EpiPulse Event, EpiPulse MTT, and EFSA WGS system users

Sector	System/platform	User role	Access rights	Visibility conditions
Public Health (PH)	EpiPulse Event – Events	PH users with EpiPulse Events contributor rights	The user has access to all Events in the platform and all functionalities. User can launch an Event, write Comments, see Comments from other countries, as well as Event summary in Situation awareness, and can access to Event attachments (e.g., FASTA files).	Default for PH users in all Events: • PH users (OCPs and NFPs) in EU/EEA • EU pre-accession countries (Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia, and Serbia) • European Neighbourhood Policy partner countries (Israel). • Third countries (Australia, New Zealand, South Africa, United Kingdom, and United States). Access provided for relevant Events: • EURL-PH on FWDB • WHO Euro Countries can provide information (called Comments in the EpiPulse platform) and ECDC summarise and assess the situation in the Situation Awareness of the Event. If no cross-borne dimension observed, ECDC monitors daily but no Situation Awareness is provided.
		PH users with EpiPulse Events reader rights	Can only see summary in Situation Awareness of the Event.	DG SANTE PH when Event becomes multi-country and Situation Awareness is provided by ECDC.
	EpiPulse Event – Signals	PH users with EpiPulse Cases Wiew rights	Can see Signals of multi-country WGS clusters resulting from a regular ECDC cluster analysis in the EpiPulse Event.	If human/non-human isolates from their country in the cluster. Metadata shown for non-human isolates for PH users includes the following information: sample category, sampling/reporting country, sampling year (‘Collaboration Agreement’, Annex II).

Sector	System/platform	User role	Access rights	Visibility conditions
	EpiPulse MTT	PH users with EpiPulse Cases View rights	Can see and interpret clusters in the MTT.	PH users in the countries with human/non-human isolates from their country in the cluster. Metadata shown for non-human isolates for PH users includes the following information: sample category, sampling/reporting country, sampling year ('Collaboration Agreement', Annex II).
Food Safety (FS)	EpiPulse Event – Event	FS users with EpiPulse Events contributor rights	Can see PH Comments in the Events as well as the summary in Situation Awareness; have access to Event attachments (e.g., FASTA files) uploaded by PH users.	EFSA and FS-EURLs (for *Campylobacter*, *Salmonella*, *Listeria*, *E. coli*, including STEC) when multi-country Event and when there is a suspected or confirmed link to specific food in the Event.
		FS users with EpiPuse Events reader rights	Can only see summary in Situation Awareness of the Event.	DG SANTE FS, and FS nominated users in the EU/EEA.
	EFSA WGS system	Country Officer	View and manage their national data; Access all queries from their national users; View the outcome of ECDC queries, including the list of matching isolates in the EFSA WGS system.	When reviewing query results, users can view country label information only for their own country.
		Data Provider	View and manage own organisation's data; Access own organisation's queries; View the outcome of ECDC queries, including the list of matching isolates in the EFSA WGS system.	When reviewing query results, users can view country label information only for their own country.

Public health sector

Access to EpiPulse Events is divided into two different access rights:

1) Contributor access rights grant access to all Events and their functionalities. Contributors can launch an Event, comment under the "Comments'', read comments from other countries, and read the "Situation awareness'' summary of the country 'Comments' with assessment written by ECDC, and have access the attachments in the Events uploaded by countries (e.g. FASTA files).

- Public health users (OCPs and NFPs) in the EU/EEA countries, and the public health users in the EU pre-accession countries (i.e. Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia, and Serbia), European Neighbourhood Policy partner countries (Israel), and third

countries (Australia, New Zealand, South Africa, United Kingdom, and United States) tries have by default contributor rights for all Events.

- ECDC will provide access for EURL-PH on FWDB for relevant Events based on the EURL role, and for WHO Euro when relevant (e.g. multicounty outbreak linked countries outside the EU/EEA).

If the Event remains national based on data shared in EpiPulse Event, only the public health users have access and ECDC does not grant access to other stakeholders (EFSA, DG SANTE food safety, food safety users) nor writing a summary in the "Situation awareness''. The Events are however monitored daily by ECDC.

2) Readers access rights only grant access to the Event summary in the "Situation awareness''. Readers cannot e.g. see the individual "Comments'' from countries.

- ECDC writes a summary with assessment in the ''Situation awareness'' as soon as an event becomes multi-country (. e.g. cases with matching isolates in at least one other country) and immediately grants access to EC Directorate General (DG SANTE) for public health

Food safety users access to EpiPulse Events

The access to information on the **EpiPulse Events** is granted **to Food Safety users (different roles)** as soon as an EpiPulse Event becomes multi-country (e.g. cases with matching isolates in at least one other country) OR a Signal is upgraded to an Event in EpiPulset, AND there is a suspected or confirmed link to specific food (e.g. linked RASFF notification, results from epidemiological investigation or interviews) in the Event, AND ECDC has written the Event summary in the 'Situation Awareness' :

1) Contributor access rights are granted to EFSA and EURL for *Campylobacter, Salmonella, Listeria* or *E. coli* including STEC depending on the Event and can additionally access to PH Member State comments and attachments (which are most often FASTA files for WGS).

2) Reader access rights are granted to DG SANTE food safety, and food safety users nominated by EFSA (can only read the event summary under the 'Situation awareness').

Access to WGS clusters based on EpiPulse Cases access rights

Access to multi-country WGS clusters (**Signals** in EpiPulse Event platform) is automatically granted to the public health users with **EpiPulse Cases View right**s when their country is part of the cluster.

Access to human WGS data clusters in EpiPulse MTT

Public health users can, access, visualise, and interpret clusters in the **EpiPulse MTT** that include sequencing data from their own country when they have EpiPulse Cases View rights.

Access to non-human data WGS clusters in EpiPulse MTT

Public health users with EpiPulse Cases View rights can access clustering non-human data with a limited subset of metadata (i.e. matching isolates identified through queries performed against the EFSA database) when their country is part of the cluster. Limited metadata includes data on the sample category, sampling country, reporting country, and sampling year, if submitted by food safety users which have made this information available for public health users.

Food safety sector

The **access to data** in the EFSA WGS system depends on the user type.

- The Country Officers access their country-wide dedicated environment within the EFSA WGS system and can visualise and analyse data from all the organisations within their own country.
- The Data Providers access their organisation-wide dedicated environment within the EFSA WGS system and can visualise and analyse data from her or his own organisation.

The **access to queries** to both ECDC and EFSA databases, that both Country Officer and Data Provider can perform, depends on the user type.

- The Country Officer can access all queries performed by any user of any organisation within her or his country, and he/she can inspect the results of any query performed by ECDC.
- The Data Provider will access the queries performed by any user within her or his organisation and can inspect the results of any query performed by ECDC.

Food safety users accessing the EFSA WGS system can view the results of queries in both tabular format and graphical representations, such as minimum spanning trees. However, country-level metadata for both food and human isolates is only visible if the data corresponds to the user's own country.

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Genomic surveillance of foodborne pathogens

General surveillance objectives for food- and waterborne diseases in the EU/EEA have been published on the ECDC's web site page "European Food- and Waterborne Diseases and Zoonoses Network (FWD-Net)''[5]. Among these, a common objective for surveillance is to "Detect and monitor multinational food- and waterborne and zoonotic outbreaks with respect to source, time, population and place in order to provide a rationale for public health action''. While this is a generic objective, more specific genomic surveillance objectives will be specified for the **priority** bacteria (*Salmonella enterica*, *L. monocytogenes*, STEC, *Campylobacter* spp.) as part of defining surveillance standards. [6] Regarding *E. coli*, the specific genomic surveillance objectives in the context of this protocol specifically target STEC. The ECDC WGS system is however built to analyse all pathogenic *E. coli* and *Shigella*. A separate protocol for harmonised monitoring of AMR in human *Campylobacter* and *Salmonella* infections has been published[7].

The objective of EFSA's WGS data collection is to build a database of genomic profiles from isolates collected from food, feed, animals, and related environments. This database can be queried in the event of multi-country foodborne outbreaks to compare the profiles of non-human isolates with those from human cases, supporting the identification of the outbreak source and the affected consignments. Reporting countries are invited to voluntarily submit data on the priority bacteria. Data providers may submit data reactively, in response to EFSA's specific requests during the preparation of a Rapid Outbreak Assessment, which are issued through *ad hoc* data calls. Alternatively, countries may submit data prospectively, without a specific request. Although each Member State follows its own national strategy regarding data sharing, the WGS subgroup of the Zoonoses Network has agreed that prioritisation for prospective data sharing should be based on RASFF notifications, national outbreak investigations, and cross-sectoral national clusters[8]. In addition to voluntary submissions, under Commission Implementing Regulation (EU) 2025/179 pursuant to Article 8 of Directive 2003/99/EC, Member States are required to collect isolates of *S. enterica*, *L. monocytogenes*, *E. coli*, *C. jejuni*, and *C. coli* from food, animals, feed, and related environmental samples when these are associated with, or suspected to be associated with, a

[5] https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/fwd-net
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R2371 (*Article 13)*
[7] www.ecdc.europa.eu/sites/default/files/documents/antimicrobial-resistance-Salmonella-Campylobacter-harmonised-monitoring.pdf
[8] Minutes of the 1st specific meeting on WGS of the Zoonosis Network https://www.efsa.europa.eu/sites/default/files/2023-03/minutes-1st-wgs-subgroup-meeting_0.pdf

foodborne outbreak. These isolates must undergo WGS, and the resulting data must be transmitted to EFSA WGS system along with relevant accompanying information.

Since March 2025, EFSA imports regularly and automatically from the National Center for Biotechnology Information and the European Nucleotide Archive, publicly available genome sequencing data related to animal, food, feed, or environmental samples. This dataset aims to provide an overview of the known genetic diversity within the population of the target species, and to support the timely identification of relevant non-human isolates submitted by third countries.

Regular cluster analysis

ECDC performs automated cluster analysis for *L. monocytogenes*, pathogenic *E. coli* including STEC and *S. enterica* on a regular basis (varying for pathogen, e.g. for *L. monocytogenes* on a weekly basis) (Table 2). For all identified human clusters, a search in the EFSA WGS system is performed to identify matches with non-human isolate profiles. Queries are performed using pathogen-specific allelic distance (AD) thresholds. The AD thresholds and the frequency of the queries are jointly reviewed by ECDC and EFSA on a quarterly basis.

Ad hoc cluster analysis

Under specific circumstances, ECDC can perform single *ad hoc* queries to the EFSA WGS system, using agreed ranges of AD thresholds which can differ from those of the standard cluster definitions (analysis). These queries are typically triggered by specific EpiPulse Events. This also applies to Events where only one representative outbreak strain has been shared, and no cluster has yet been identified. The ranges of thresholds are jointly reviewed by ECDC and EFSA on a quarterly basis.

All pathogens' prioritised clusters from regular or *ad hoc* cluster analyses are discussed weekly in the ECDC-EFSA coordination meetings. These meetings serve to evaluate potential public health relevance and determine appropriate follow-up.