

Genomic surveillance in the EU/EEA, objectives, tools, examples

FWD AMR RefLabCap workshop, Copenhagen 29 October 2024



Drafted legal documents and discussions around WGS data reporting in this context

Drafted Implementing act WGS food isolates



- "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 foodborne outbreak. Member States should also be required to carry out WGS on those isolates."
- "The Member States should transmit the results from WGS on isolates of those pathogens [...] to the EFSA that developed a joint One Health system together with the ECDC."



Regulations are legal acts defined by Article <u>288</u> of the Treaty on the Functioning of the European Union (TFEU). They have general application, are binding in their entirety and are **directly applicable** in EU <u>Member States</u>.

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 (Text with EEA relevance)

Serious cross border threats to health regulation



Article 14

Digital platform for surveillance

- 7. The Commission shall adopt delegated acts in accordance with Article 31 to supplement this Regulation concerning:
 - (a) the cases where, and the conditions under which, the third countries and international organisations concerned may be granted partial access to the functionalities of the digital platform for surveillance and the practical arrangements for such access;
 - (b) the cases where, and the conditions under which, the data, information and documents referred to in Article 13 are to be transmitted using the digital platform for surveillance and the list of such data, information and documents; and
- (d) molecular pathogen data, if required for detecting or investigating serious cross-border threats to health

3.

Ongoing work for drafting Delegated act (EU legal document) regarding reporting requirements for communicable disease surveillance



- Reporting requirements in the Delegated act are to be complemented by more detailed surveillance standards that ECDC shall develop, maintain and monitor in collaboration with the networks
- These shall include for example specific surveillance objectives, surveillance methods, indicators to be monitored, mandatory key variables etc

Genomic data and surveillance standards





Whenever genomic data is relevant for the defined disease objectives, they will be included in the surveillance standards

The scope and timeliness of genomic data submission will be defined and agreed jointly with Member States



Reporting according to the standards will be mandatory



Level of reporting of genomic data will be evaluated on a yearly basis

Standards: implications for genomic surveillance for Member States





Enhanced possibilities to contextualise national WGS data

Member States need to set up systems that allows reporting of criteria described in the surveillance standards



New system for data submission (EpiPulse cases)

Standards: implications for genomic surveillance for ECDC





Maintain sufficient bioinformatics calculation capacity



Continuous work with the Member States to streamline the data submission process and eliminate any barriers for reporting



Further develop ECDC functionalities/capacities for analysing, visualising and presenting outputs from integrated data



Ensure capacity to react on signals and use integrated data for public health actions

Delegated act regarding reporting requirements for communicable disease surveillance



- Balance between what detailed level would go into a legal document which can take time to update, and the surveillance standards.
- Possibility to add that "isolates from a proportion of samples to be sequenced for xyz purposes"?

Process for a Delegated act



Commission (ECDC) prepares draft legislation



Expert/MS input and consultation (NFPs, HSC TWG)



Commission Expert Group on Public Health



Obligatory consultation of MS, but no vote and opinion is not binding. EP + Council are invited to this meeting

Interservice consultation within Commission



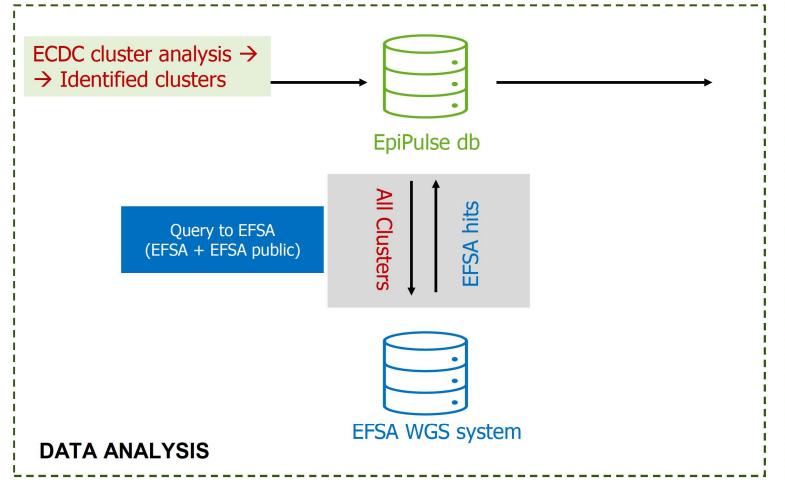
Adoption by College and publication (OJ EU)

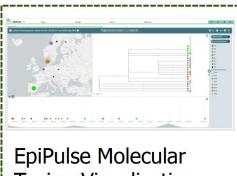


How does data sharing, comparing work in practice

ECDC EFSA One health system - overview







Typing Visualization

Human and Non-human isolates

DATA VISUALIZATION FOR PUBLIC HEALTH USER

Cluster detection



Species specific cluster criteria for automatic cluster detection

- Core cluster: Single-linkage cluster of more than two sequences within 5 allele difference (AD) threshold (only Human isolates define the core clusters)
- Extended cluster: Slightly broader cut-off, within 10 allele difference (AD,) than core cluster includes the Food isolates
- Clusters include both single country clusters as well as multi-country clusters

ECDC data visibility criteria for PH users



- RecordId can only be seen by ECDC and the submitting country
- Clusters and Signals can only be seen by involved countries
 (involved countries are currently those with human cases in the
 cluster), unless upgraded to an Event or Threat (it is however
 possible for countries to see other nearby clusters if they use the
 more exploratory features in EpiPulse)

ECDC data visibility criteria for PH users regarding non-human isolates



- For EFSA data, country of origin can only be seen by ECDC and the same country, and further restrictions on data visibility can be applied by the EFSA providers
- For EFSA Public data, no visibility restrictions on country of origin

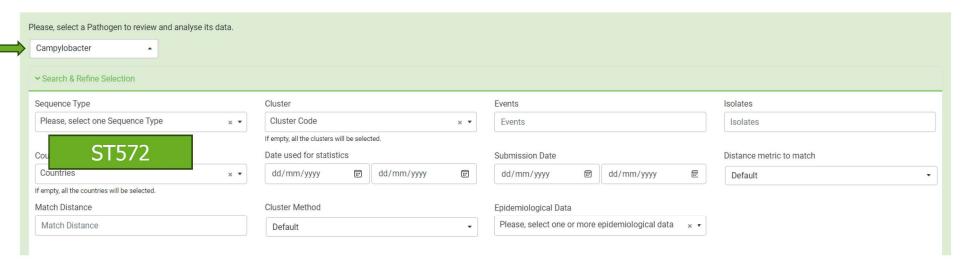
EpiPulse Molecular Typing Tool – visualisation and cluster detection of reported WGS data





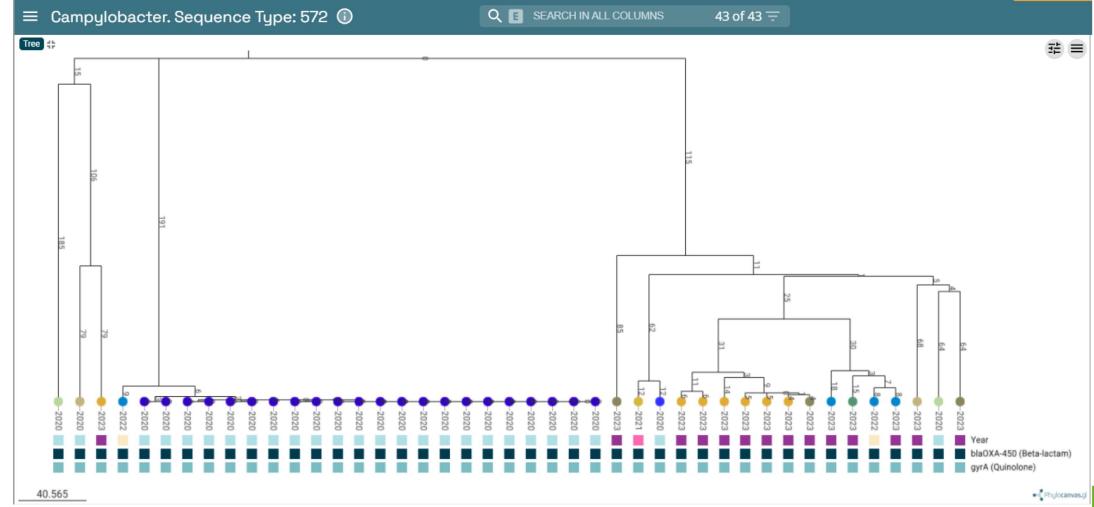
> Explore > Molecular typing tool

Please treat the data in the platform as sensitive non-classified unless specifically indicated as public.



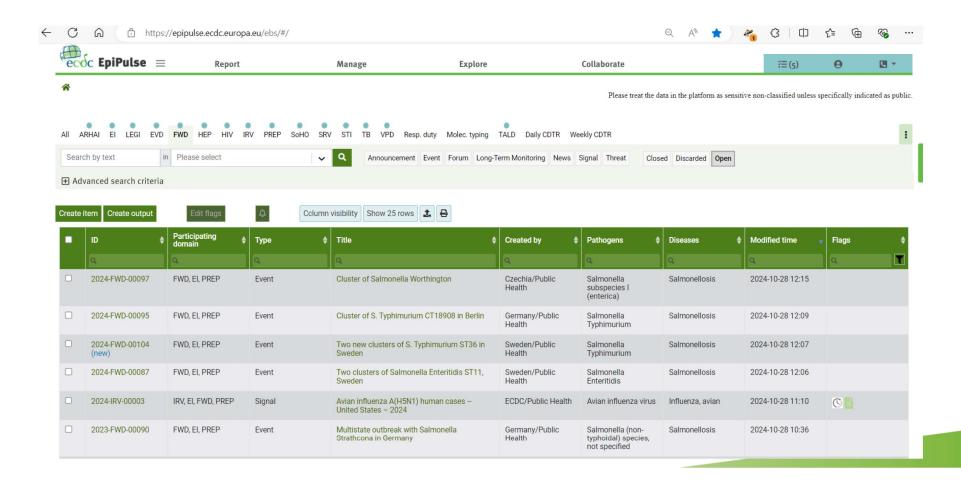
ST 572 isolates (cgMLST, Single Linkage tree)





Have you access to EpiPulse events? YES NO I DON'T KNOW





Have you access to EpiPulse Molecular Typing Tool?



YES

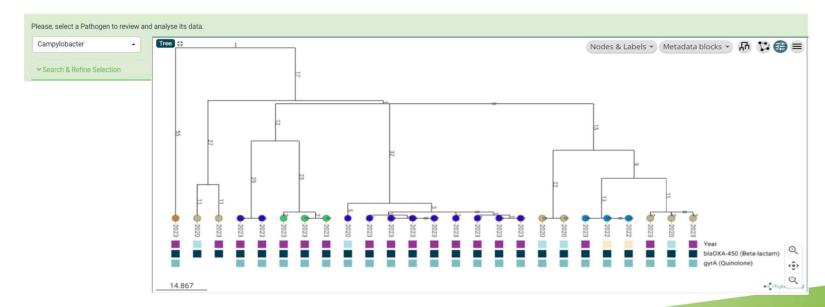
NO

I DON'T KNOW



> Explore > Molecular typing tool

Please treat the data in the platform as sensitive non-classified unless specifically indicated as public



Who can access and visualise data in the Molecular typing Tool (MTT)

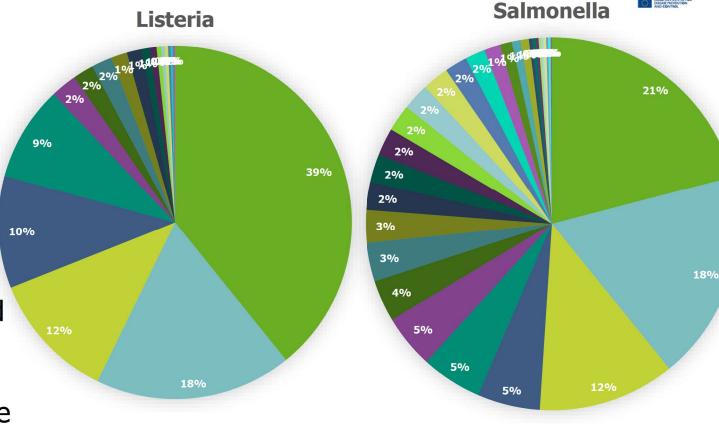


- To visualise clusters/results for the relevant diseases/pathogens for example: SALM and SALMISO (salmonellosis/ salmonella isolates i. e. Epi/Lab), TESSy download rights is needed
- To upload WGS and meta data to TESSy and visualise the results for example: SALM and SALMISO (salmonellosis/ salmonella isolates, i. e. Epi/Lab): TESSy upload, download and approve rights are needed

Can you access this link? https://epipulse.ecdc.europa.eu/typing/explore
If not, you do not have the right TESSy access rights to access EpiPulse MTT.

Country distribution of all isolates entered into the ECDC system since June 2023

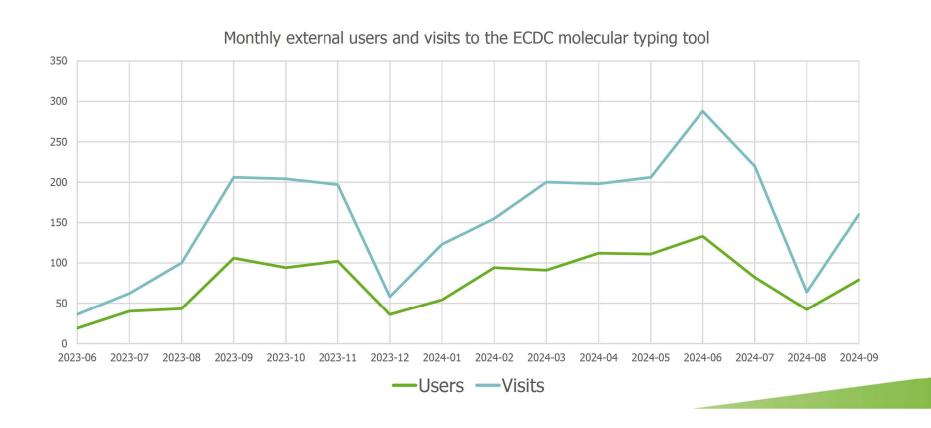
- For Listeria 5 countries represent 88% of isolates
- For Salmonella the contributions are more even
- Salmonella data are more dominated by event-based data and data for yearly AMR analysis
- This shows that the uptake of continuous prospective surveillance is still low



Use of Epipulse molecular typing webpage



The number of monthly external users is around 50-100





Show case the MTT, country user!



Questions