TESSy - The European Surveillance System

FWD Reporting Protocol 2019

Food- and waterborne diseases and zoonoses, including antimicrobial resistance in zoonotic bacteria

Surveillance data for 2018

March 2019

Contents

List of tables

Introduction

This reporting protocol is to be used for the 2019 data call for food- and waterborne diseases and zoonoses surveillance data referring to the year 2018.

ECDC's Reporting Protocols are data collection guidelines for reporting countries' data managers, and the Reporting Protocol design is intended to provide user-friendliness by:

- Introducing a uniform structure to make it easier for data managers to find data collection information across different subjects.
- Removing information not relevant to data managers.

Because reporting countries' data managers sometimes play multiple roles, it is sometimes relevant to distribute subject-specific material together with a Reporting Protocol. To maintain the uniform structure, this sort of material is now included in *Annex 2*.

How to use this document

This Reporting Protocol provides information for reporting countries' data managers in three main sections:

- *Reporting to TESSy* – contains guidelines on how to prepare data for submission to TESSy, deadlines, subject-specific information (e.g. new changes to metadata), and links to further information.
- *Annex 1* – contains:
    - A history of metadata changes for the subject(s) covered by this Reporting Protocol.
    - The metadata set for the subject(s) covered by this Reporting Protocol.
- *Annex 2* – contains subject-specific material relevant for distribution with the Reporting Protocol, for example:
    - Guidelines for data collection in the field.
    - Abbreviations.

Finding further information

Paragraphs denoted by the information icon tell where you can find further information.

Updated links to all the schedules, documentation and training materials mentioned in this Reporting Protocol are included in the *TESSy document section*, including:

- Metadata sets and history.
- Tutorials for data transformation using respectively Excel and Access.
- TESSy user documentation.
- CSV and XML transport protocols.

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Reporting to TESSy

This section provides both an overview of the TESSy reporting process and tips on where you can find useful information.

The overall process is:

1. *Familiarise yourself with the data collection deadlines*.
2. *Prepare (export and transform) your data*.
3. *Check that your data comply with the metadata*.
4. *Check that your data source profile is up-to-date*.
5. *Submit your file(s) to TESSy*.
6. *Finalise and approve your submission*.

Checking the data collection schedule

An updated link to the current data collections schedule is available in the *TESSy website*.

The data collection for the FWD and zoonoses has in 2019 three reporting intervals: the annual reporting of all FWD diseases and of antimicrobial resistance (AMR) data; the monthly reporting of *Salmonella* serotype data; and the real-time reporting of molecular typing data for *Salmonella, Listeria* and STEC/VTEC.

See also FWD reporting frequency on page 24.

Preparing data

After you have exported the data from your national database, you need to ensure that the data are in a format that TESSy can accept. This applies both to the type of file submitted to TESSy (only CSV and XML files can be submitted) and to the format of the data in certain fields.

Tutorials covering how you can transform your data to the correct TESSy format using Excel or Access are available on the TESSy documents website. Information on the file formats is available in the CSV Transport Protocol and XML Transport Protocol.

Checking metadata

The TESSy metadata define the fields and data formats that are valid as input to TESSy for a given subject.

As requirements to the data to be shared among TESSy users change, the data changes needed to support the new requirements are identified and agreed upon between the National Surveillance Contact Points, the Disease Network Coordination Groups and ECDC's Disease Experts, and then implemented as changes to the TESSy metadata.

In order to ensure that your data can be saved correctly in TESSy, you therefore need to check that your data are correctly formatted according to the most recent metadata set.

Changes to the metadata for the subject of this Reporting Protocol are described in:

- *Changes to current metadata* – changes since the last Reporting Protocol.
- *Annex 1 Metadata change history* – changes implemented in 2014, 2015, 2016, 2017 and 2018 and a summary of the changes from 2014-2019.

It is especially important to focus on:

- **Field formats**

  Many fields require that data are formatted in a specific way. For example, dates must be in the YYYY-MM-DD format; dates in the DD/MM/YYYY format will be rejected.

- **Coded values**

Some fields only permit the use of specific values (coded values). For example, **M**, **F**, **UNK**, or **Other** are the coded values for *Gender* and any other value in a *Gender* field will be rejected.

The metadata file contains all the definitions and rules you need to comply with to format your data correctly for every subject (usually a disease). The file can be downloaded as an Excel file from the TESSy documents website.

By filtering the fields in the file by subject, you can see the fields required for your subject and the rules applying to these fields.

Checking your data source profile

Before submitting your file(s), please review the profile for your data source(s) in TESSy (go to **Data Sources**), and update the information, if necessary.

Complete and up-to-date data source information for each subject is important for improving interpretation of data - each surveillance system has different features that need to be taken into account when comparing data at an international level.

If your data source information is out-of-date and you do not have access rights to update it, please request your National Focal Point for Surveillance or National Coordinator to do so.

In-depth information on the data source variables is available in the *TESSy user documentation*.

Submitting your data

Data are submitted through the TESSy web interface (go to **Upload**).

The *TESSy user documentation* provides an overview of how you submit files to TESSy and descriptions of the upload methods.

Finalising your submission

The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process.

The result of your upload – i.e. rejected or validated – is displayed immediately after the conclusion of the check in the **Validation details** webpage. Please review the result carefully:

- If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that you need to correct.
- If your file has been validated, there might be warnings and remarks relating to possible data quality issues or to potential overwriting of existing records that you should consider.

When you file has been validated and you are satisfied that all corrections have been made, please ensure prompt approval – unapproved uploads can block for the approval of other uploads.

The *TESSy user documentation* provides information on reviewing validation results and adjusting reporting periods to avoid overwriting existing records.

Changes to current FWD metadata

2019 FWD metadata changes

The changes in 2019 to the FWD metadata compared to the previous year's data call for the FWD are described in the following:

Changes for anthrax (ANTH)

- ClinicalPresentation (*New variable*)
    - New variable added for capturing the clinical presentation of the disease, as per the EU case definition.
    - Codes 'CUT' – cutaneous anthrax, 'GASTRO' – gastrointestinal anthrax, 'INHAL' – inhalational anthrax, 'MENI' – meningeal/meningoencephalitic anthrax, 'SEPTI' – anthrax septicaemia, 'UNK' – unknown

Changes for echinococcosis (ECHI)

- ClinicalPresentation (*New variable*)
    - New variable added for capturing the clinical form of the disease as they differ in terms of symptoms, severity, epidemiology, etiologic agents and transmission and also in host range.
    - Codes 'CE' – cystic echinococcosis, 'AE' – alveolar echinococcosis, 'OTHER' – other forms, 'UNK' – unknown

Changes for hepatitis A (HEPA)

- SubGenotype (*New variable*)
    - New variable added for capturing the subgentoype of the hepatitis A virus. This information will increase the understanding of HAV infection patterns in the EU and also in relation to travel outside of the EU.
    - Codes 'IA', 'IB', 'IIA', 'IIB', 'IIIA', 'IIIB', 'UNK' – unknown/not applicable

Changes for listeriosis (LIST)

- *New validation rule (Error)* for LIST if Transmission is 'MTCT' and PregnancyAssociated is 'Y'
    - The new EU case definition request reporting of only the mother in a pregnancy-associated case of listeriosis, and information on the transmission route should reflect the most likely route of infection of the mother.
    - Message: For pregnancy-associated listeriosis, please report the transmission route of the infection in the mother under Transmission.
- *New validation rule (Warning)* for LIST if PregnancyAssociated is 'Y' and 'Age' is missing
    - Information on age is important in the reporting of a pregnancy-associated listeriosis infection in order to make sure that it is the mother and not the child being reported, according to the new EU case definition.
    - Message: Please report the age of the mother in pregnancy-associated listeriosis infection under Age.
- Specimen *(Updated coded value list)*

- Listeria has been reported as a rare cause for endophthalmitis in immunocompetent persons and arthritis in immunosuppressed persons. Collating data at EU level could enhance the understanding of these localized invasive forms of listeriosis, particularly in the context of an aging EU population.
- Code 'SYNO' – synovial fluid (arthritis) and 'EYE' – eye (endophthalmitis) added

- LivingSetting *(New variable)*
  - New variable on setting added to improve the assessment of risk factors in various population groups, especially among the elderly
  - Codes 'HOME' – private household, 'NURS' - nursing home/elderly home, 'HOSP' – hospital, 'REHAB' – rehabilitation facility, 'OTHER' – other and 'UNK' – unknown
- UnderlyingCondition *(New variable)*
  - New variable added to capture underlying chronic disease conditions as these often result in more severe *Listeria* infections.
  - Codes 'BLOOD' – blood disorder, 'CANC' – cancer, 'DIAB' – diabetes, 'HEART' – chronic heart disease, 'HIV' – HIV infection/AIDS, 'KIDNEY' – kidney-related condition, 'LIVER' – liver-related condition (e.g. cirrhosis), 'NEUROCOG' – neurocognitive disorder, 'ORGAN' – organ transplant, 'RHEUMA' – rheumatological condition, 'NONE' – no known underlying condition, 'OTHER' – other, 'UNK' – unknown

Changes for isolate-based record types (CAMPISO, ECOLIISO, LISTISO, SALMISO)

- CaseId (*New variable*)
  - New variable (free text field) added to enable linking from an isolate to a case (option to link from a case to an isolate already existing in the case-based subjects). The 'CaseId' in the isolate-based record should correspond to the 'RecordId' in the case-based record and be a unique identifier for each case within the data source / surveillance system.
- ECDCCaseId (*New variable*)
  - Unique identifier within the TESSy system created at submission of a case to TESSy. This id can now be used to link from an isolate to a case. (The opposite already exist in the case-based subjects as 'ECDCIsolateId'.)
- WgsAssembler (*Updated coded value list*)
  - Many variations in pipelines can be used to perform genome assembly. A critical aspect for quality is the use of read mapping/consensus calling after the actual assembly. Codes and descriptions updated to reflect whether this was done or not.
  - Description updated: 'SPADES' – SPAdes without read mapping and consensus calling, 'VELVET' – Velvet without mapping and consensus calling
  - Codes added: 'SPADES_READMAP' – SPAdes either including (-careful option) or followed by read mapping and consensus calling. SPAdes version should be 3.11 or above, 'VELVET_READMAP' – Velvet using k-mer optimisation, and followed by read mapping and consensus calling
- WgsSraId → WgsSequenceId (*Variable renamed*)
  - Variable name changed to be applicable to any public sequence repository system (and not only the Sequence Read Archive, SRA). This variable is included in all record types that allow reporting of WGS data. For sequences stored in the European Nucleotide Archive (ENA), which is expected to be the most commonly used sequence repository for FWD, please use the variable 'WgsEnaId' instead.
  - Description: Sequence identifier, other than that from the European Nucleotide Archive, based on which sequence read or other data can be retrieved.

Changes for AMR reporting under isolate-based record types (CAMPISO$AST, ECOLIISO$AST, SALMISO$AST)

Some countries have replaced phenotypic antimicrobial susceptibility testing with whole genome sequencing. The resistance phenotype for an isolate classified as wild type/non-wild type (according to the European Committee

for Antimicrobial Susceptibility Testing, EUCAST, epidemiological cut-off values) can be fairly well predicted from the resistance genes and mutations identified in the genome. The below metadata changes would allow reporting of such data.

- TestMethod (*Updated coded value* list)
    - Code 'GEN' – sequencing or PCR, added
- SIR (*Updated coded value*)
    - Due to the structure of data in TESSy, the predicted resistance results have to be added to the existing SIR variable instead of creating a new variable
    - Codes 'PWT' – predicted wild type, and 'PNWT' – predicted non-wild type, added.

The previous metadata changes from 2014-2018 are described in *Annex 1*.

Information on changes to the metadata for other subjects is available on the *TESSy documentation website*.

Annex 1 FWD metadata

This section describes:

- *FWD diseases and record types*
- *Historical changes to the FWD metadata*

Current record type versions

Table 1 lists the FWD record types and versions covered by this reporting protocol. Case-based reporting is highly encouraged. If case-based data are not available, aggregated data may be reported.

Table 1: FWD diseases and record types

Disease	Case-based/isolate-based record type version	Aggregated record type version
Anthrax	ANTH.6	AGGR.1
Brucellosis	BRUC.5	AGGR.1
Botulism	BOTU.8	AGGR.1
Campylobacteriosis	CAMP.6	AGGR.1
Campylobacter* isolates	CAMPISO.3	—
Cholera	CHOL.5	AGGR.1
Cryptosporidiosis	CRYP.6	AGGR.1
Echinococcosis	ECHI.6	AGGR.1
Giardiasis	GIAR.5	AGGR.1
Hepatitis A	HEPA.6	AGGR.1
Leptospirosis	LEPT.6	AGGR.1
Listeriosis	LIST.9	AGGR.1
***Listeria* isolates**	LISTISO.3	—
Salmonellosis	SALM.8	AGGR.1
Salmonella* isolates	SALMISO.4	—
Shigellosis	SHIG.8	AGGR.1
STEC/VTEC infections	VTEC.7	AGGR.1
***E. coli* isolates**	ECOLIISO.3	—
Toxoplasmosis, congenital	TOXO.7	AGGR.1
Trichinellosis	TRIC.6	AGGR.1
Typhoid/paratyphoid fever	SALM.8	—
Yersiniosis	YERS.6	AGGR.1

* to be used for isolate-based AMR reporting

FWD metadata change history

Metadata changes prior to 2014 can be found on the TESSy documents website.

2018 FWD metadata changes

The changes in 2018 to the FWD metadata compared to the previous year's data call for the FWD are described in the following:

The changes for *Listeria* and *Salmonella* isolates will only come into effect once the TESSy system is fully upgraded to handle them, which is foreseen before July 2018. Member States will be notified at that point.

Changes for listeriosis (LIST)

- *New validation rule (Error)* for LIST If Gender = F and Age >=15 and Age<=55 and PregnancyAssociated is not reported
    - As the new EU case definition will request reporting of only the mother in a pregnancy-associated case of listeriosis, it is vital to capture which female cases are related to pregnancy.
    - Message: PregnancyAssociated must be reported for female cases 15-55 years
- PregnancyOutcome (*New variable*)
    - New variable added to capture the outcome of the pregnancy for reasons stated above.
    - Codes 'FATAL' – fatal outcome of fetus or newborn, 'ALIVE' – alive newborn up to first month of life, 'UNK' – unknown outcome of fetus or newborn, 'NA' – not applicable
- *New validation rule (Error)* for LIST if PregnancyAssociated = Y(Yes) and PregnancyOutcome is not reported.
    - New validation rule added to ensure that PregnancyOutcome is reported for pregnancy-associated cases of listeriosis.
    - Message: If PregnancyAssociated = Y(Yes) PregnancyOutcome must be reported.
- *Updated validation rule (Remark)* for LIST if Transmission = MTCT(mother-to-child-transmission) and PregnancyAssociated <> Y
    - Validation rule updated (now includes PregnancyAssociated <>Y) to encompass the changes in reporting of pregnancy-associated cases of listeriosis.
    - Message (No change): Please report transmission of pregnancy-associated listeriosis cases as PregnancyAssociated=Y. If person-to-person transmission is intended, please report it as Transmission="PTP".
- AgeMonth (*New variable*)
    - The age in months is needed to differentiate between pregnancy-associated cases in newborns and other types of transmission to prevent reporting of the newborn instead of the mother following the change in the new EU case definition for listeriosis
- *New validation rule (Error)* for LIST if Age<1 year and AgeMonth is not reported
    - New validation rule added to ensure that AgeMonth is reported for children <1 year to differentiate pregnancy-associated newborns from other infants below 1 year.
    - Message: AgeMonth must be reported if Age is less than one year old (Age <1).
- *New validation rule (Error)* for LIST if Age=0 year and AgeMonth=0.
    - New validation rule added to ensure that pregnancy-associated cases in newborns are reported via the mother.

- Message: This would classify as a pregnancy-associated case which should be reported via the mother.

Changes for *Listeria* isolates (LISTISO)

- PCRserogroup (*New variable*)
  - New variable added for reporting of molecular serotyping for Listeria according to *Doumith et al 2004*. Variable already available in LIST.
  - Codes 'IIa', 'IIb', 'IIc', 'Ivb', 'L', 'NA' – not applicable, 'UNK' – unknown
- WgsProtocol (*New variable*)
  - New variable, to support collection of Whole Genome Sequencing (WGS) data. Defines the protocol used for sequencing, limited to the sequencing technology used (today Illumina or IonTorrent) and the read length.
  - Codes 'HISEQ_2X100' – Illumina HiSeq 2x100, 'IONTORRENT' – IonTorrent, 'MISEQ_2X150' – Illumina MiSeq 2x150, 'MISEQ_2X250' – Illumina MiSeq 2x250, 'MISEQ_2X300' – Illumina MiSeq 2x300, 'NEXTSEQ_2X150' – Illumina NextSeq 2x150
- WgsEnaId (*New variable*)
  - New variable, to support collection of Whole Genome Sequencing (WGS) data. Defines the European Nucleotide Archive (ENA) identifier, based on which the raw read data can be accessed.
- WgsSraId (*New variable*)
  - New variable, to support collection of Whole Genome Sequencing (WGS) data. Defines Sequence Read Archive (SRA) identifier, based on which the raw read data can be accessed.
- WgsAssembler (*New variable*)
  - New variable, to support collection of Whole Genome Sequencing (WGS) data. Defines the assembler used for sequencing, optionally including parameter settings.
  - Codes 'SPADES' – SPAdes, 'VELVET' – Velvet, 'MAP_TO_LOCI1' - Mapping to individual loci, variant 1 for IonTorrent
- WgsAssembly (*New variable*)
  - New variable, to support collection of Whole Genome Sequencing (WGS) data. Defines the assembled genome, as a gzipped FASTA file. The file contents are subsequently converted into a Base64-encoded string for inclusion into either the XML or CSV data for the isolate. This is identical to how today PFGE TIFF images are sent to TESSy.
- *New validation rules added for WgsXxx variables, to make sure that specific combinations of variables are always reported together:*
  - *Error: WgsAssembler is not reported and WgsAssembly is reported*
  - *Error: WgsAssembler is reported and WgsAssembly is not reported*
  - *Warning: WgsEnaId is reported and WgsProtocol is not reported*
  - *Warning: WgsProtocol is not reported and WgsSraId is reported*
  - *Warning: WgsAssembly is reported and WgsProtocol is not reported*
  - *Warning: WgsAssembly is not reported and WgsEnaId is not reported and WgsProtocol is reported and WgsSraId is not reported*

Changes for *Salmonella* isolates (SALMISO)

- ESBL (*New variable*)
  - New variable to facilitate reporting of ESBL- and/or AmpC-production in *Salmonella*
  - Codes 'ESBL' – extended-spectrum β-lactamase producer, 'AmpC' – AmpC β-lactamase producer, 'ESBL_AmpC' – ESBL and AmpC β-lactamase producer, 'NEG' – Negative, 'UNK' – Unknown
- GenoSerotype (*New variable*)
  - New variable for reporting of *Salmonella* serotype derived from molecular methods.

- Codes same as coded value list SerotypeSalm

Changes for shigellosis

- SIR_CIP (*New variable*)
  - New variable for reporting of susceptibility to ciprofloxacin according to EUCAST clinical breakpoints for *Enterobacteriaceae*.
  - Codes 'I' – intermediate, 'R' – resistant, 'S' – susceptible, 'UNK' – unknown
- SIR_CTX (*New variable*)
  - New variable for reporting of susceptibility to cefotaxime according to EUCAST clinical breakpoints for *Enterobacteriaceae*.
  - Codes 'I' – intermediate, 'R' – resistant, 'S' – susceptible, 'UNK' – unknown
- SIR_CAZ (*New variable*)
  - New variable for reporting of susceptibility to ceftazidime according to EUCAST clinical breakpoints for *Enterobacteriaceae*.
  - Codes 'I' – intermediate, 'R' – resistant, 'S' – susceptible, 'UNK' – unknown
- SIR_AMP (*New variable*)
  - New variable for reporting of susceptibility to ampicillin according to EUCAST clinical breakpoints for *Enterobacteriaceae*.
  - Codes 'I' – intermediate, 'R' – resistant, 'S' – susceptible, 'UNK' – unknown
- SIR_SXT (*New variable*)
  - New variable for reporting of susceptibility to trimethoprim-sulfamethoxazole according to EUCAST clinical breakpoints for *Enterobacteriaceae*.
  - Codes 'I' – intermediate, 'R' – resistant, 'S' – susceptible, 'UNK' – unknown
- ECOFF_AZM (*New variable*)
  - New variable for reporting of acquired resistance to azithromycin according to epidemiological cut-off values for *Shigella*. Until EUCAST defined ECOFFs are available, it is recommended to use the ECOFF from CLSI of MIC ≥32 mg/L for *S. sonnei* and MIC ≥16 mg/L for *S. flexneri*.
  - Codes 'WT' – wild type, 'NWT' – non-wild type, 'UNK' – unknown

Changes for VTEC/STEC infections

- ClinicalManifestation *(Updated coded value list)*
  - According to the EU case definition, only symptomatic cases should be reported.
  - Code 'ASY' (Asymptomatic) removed.

Changes for yersiniosis

- Biotype *(Updated coded value list)*
  - The role of *Y. enterocolitica* biotype 1A in human disease has been controversial, but generally this biotype is considered non-pathogenic to humans. Only cases with isolation of human pathogenic *Y. enterocolitica* strains should be reported to ECDC according to the EU-case definition.
  - Code '1A' removed.

2017 FWD metadata changes

The changes in 2017 to the FWD metadata compared to the previous year's data call for the FWD are described in the following:

Changes for botulism

- NeurotoxinType (*change Required variable status*)
    - Higher completeness of this variable is desirable to know which neurotoxin types that are occurring in the EU to secure the availability of antitoxins.
    - Required status changed from False to True(error). It is still possible to report 'UNK'.

Changes for shigellosis

- *Validation rule (changed from Warning to Error)* for SHIG if Pathogen = SHISON(Shigella sonnei) & Serotype is reported
    - There are no serotypes defined for *Shigella sonnei*. The validation rule was not effective to prevent reporting of serotypes when it was a warning so changed to error.
    - Message: If Pathogen is reported as SHISON(Shigella sonnei) then Serotype should not be reported (NA is allowed).

Changes for *Salmonella* isolates

- ASTAntibioticSALM *(Updated coded value list)*
    - Some countries test imipenem for *Salmonella* instead of the meropenem (the recommended carbapenem to test). Although ECOFFs are still missing for imipenem with disk diffusion, it should be possible to report these data for later use.
    - Code 'IPM' added to allow reporting of imipenem.

Changes for toxoplasmosis, congenital

- *New validation rule (Error)* for TOXO if Age greater(or equal) than 1
    - The EU case definition only covers congenital toxoplasmosis and the data collection should clearly reflect this.
    - Message: Only congenital cases (Age < 1) should be reported for Toxoplasmosis(TOXO)
- Transmission *(Variable removed)*
    - As the reporting is now restricted to congenital toxoplasmosis, there is no need to collect information on transmission route since only mother-to-child transmission is reported.

2016 FWD metadata changes

The changes in 2016 to the FWD metadata compared to the previous year's data call for the FWD are described in the following:

Changes for cryptosporidiosis

- Pathogen (*New mandatory variable*)
    - Information on species is important for epidemiology and outbreak investigations and for understanding the clinical picture which varies by species.
    - Codes 'CRYPAR' – *Cryptosporidium parvum*, 'CRYHOM' – *Cryptosporidium hominis*,, 'CRYOTHER' – Other *Cryptosporidium* species, 'UNK' – unknown

Changes for case-based salmonellosis (SALM)

- Serotype *(Updated coded value list)*

- Serotypes described in supplements No 47 and 48 that were not listed in the White-Kauffmann-Le Minor scheme 2007 were implemented (55 serotypes).

Changes for yersiniosis

- Pathogen *(Updated coded value list)*
  - The EU case definition only encompass *Y. enterocolitica* and *Y. pseudotuberculosis*.
  - Code 'YEROTHER' (Other *Yersinia* species) removed.

Changes for *Campylobacter* isolates (CAMPISO)

- SIR *(Update 'full name' of variable)*
  - The 'full name' of the variable SIR was updated to clarify that the interpretation should be based on EUCAST clinical breakpoints according to the EU case definitions. The technical name (SIR) however remains the same.
  - New full name: Final interpretation based on EUCAST clinical breakpoints.
- *New validation rule (Warning)* for CAMPISO$AST if ResultSign = ≥ and TestMethod = MIC
  - The data validation and the EQA for AST has revealed that laboratories are not always using the ResultSign correctly. The validation rule will guide on how to report.
  - Message: Please note that in case the highest tested concentration shows growth, the results should be reported as MIC=[the highest tested concentration] and ResultSign='>'.

Changes for *Salmonella* isolates (SALMISO)

- Serotype *(Updated coded value list)*
  - Same change as for case-based salmonellosis, see above
- VNTRLocusSALM *(Updated coded value list)*
  - ECDC has finalised the validation of a protocol for MLVA typing of *S.* Enteritidis, available at *http://ecdc.europa.eu/en/publications/Publications/Salmonella-Enteritidis-Laboratory-standard-operating-procedure.pdf*. This metadata change thus reflect the introduction of MLVA typing for *S.* Enteritidis to TESSy.
  - Codes 'SETR7'– *Salmonella* Enteritidis MLVA 5-loci protocol SENTR7, 'SETR5' – *Salmonella* Enteritidis MLVA 5-loci protocol SENTR5, 'SETR6' – *Salmonella* Enteritidis MLVA 5-loci protocol SENTR6, 'SETR4' – *Salmonella* Enteritidis MLVA 5-loci protocol SENTR4, 'SETR3' – *Salmonella* Enteritidis MLVA 5-loci protocol SE-3
- VNTRProtocolSALM *(Updated coded value list)*
  - Update reflect the introduction of MLVA typing for *S.* Enteritidis.
  - Code 'SALM_Enteritidis_5-loci_protocol' – *Salmonella* Enteritidis MLVA 5-loci protocol
- ASTAntibioticSALM *(Updated coded value list)*
  - Since 1 Jan 2014, EUCAST recommend using pefloxacin instead of ciprofloxacin when screening for low-level fluoroquinolone resistance with disk diffusion.
  - Code 'PEF' added to allow reporting of pefloxacin.
- SIR *(Update 'full name' of variable)*
  - Same as for *Campylobacter* isolates above
- *New validation rule (Warning)* for SALMISO$AST if ResultSign = ≥ and TestMethod = MIC
  - Same as for *Campylobacter* isolates above

Changes for *verotoxigenic E. coli* isolates (ECOLIISO)

Although AMR data are not actively collected for VTEC infections, the same changes related to AMR as for CAMPISO and SALMISO were implemented also for ECOLIISO for the sake of consistency.

- SIR *(Update 'full name' of variable)*

- Same as for *Campylobacter* isolates above

- *New validation rule (Warning)* for ECOLIISO$AST if ResultSign = ≥ and TestMethod = MIC
  - Same as for *Campylobacter* isolates above

2015 FWD metadata changes

The changes in 2015 to the FWD metadata compared to the previous year's data call for the FWD are described in the following:

Changes for all FWD subjects

The classification of a case should follow the latest EU case definition when reporting to TESSy. Therefore, case classifications which are not applicable to the EU case definitions 2012 were removed.

- Classification *(Updated coded value list and change in severity)*
  - Code 'POSS' removed for all FWD except for VTEC, YERS
  - Code 'PROB' removed for TOXI and ECHI
  - Variable 'Classification' changed to required field for all FWD. Unknown allowed.

The variables complementing the case classification - EpiLinked, LaboratoryResults and ClinicalCriteria – have missing information for about half of the FWD cases in TESSy. Since the EU case definitions state which criteria that should be fulfilled for the classification of a case, these variables can be considered a duplication of information and an unnecessary burden to Member States. The variables were therefore removed.

- EpiLinked *(Variable removed)*
- LaboratoryResults *(Variable removed)*
- ClinicalCriteria *(Variable removed)*

To prevent incorrect reporting of mother-to-child transmission, a clarification was made to the description of this transmission route and a validation rule added.

- Transmission (*New description and validation rule when Transmission is "MTCT")*
  - New description: Transmission from mother to child during pregnancy or at birth.
  - Validation rule (true error) if Transmission=MTCT and Age>0: Message: Cases not related to congenital transmission or transmission at birth should be reported as person-to-person transmission.

The horizontal aggregate reporting formats (general and disease-specific) offers very limited possibilities in terms of data analysis and very few countries use these. The horizontal aggregate will therefore be replaced with the normal aggregate format (AGGR) to be used by countries that cannot report case-based data.

- HAGGR *(RecordType removed from Subject ANTH, BOTU, CHOL, CRYP, GIAR, HAGGR, LEPT, SHIG, TOXO, TULA)*
- BRUCAGGR *(RecordType removed from Subject BRUC)*
- CAMPAGGR *(RecordType removed from Subject CAMP)*
- ECHIAGGR *(RecordType removed from Subject ECHI)*
- LISTAGGR*(RecordType removed from Subject LIST)*
- SALMAGGR *(RecordType removed from Subject SALM)*

- YERSAGGR *(RecordType removed from Subject YERS)*
- AGGR *(RecordType added to Subject BRUC, CAMP, ECHI, LIST, SALM, TRIC, VTEC, YERS)*

Codes were missing to report foodborne transmission from wild boar meat and other game meat, e.g. bears, which are risk meats for trichinellosis. Foodborne transmission from animals not normally used as food could be captured in the code OTHERMEAT. The mixed meat would thus be moved from this code into a separate code.

- SuspectedVehicle *(Updated coded value list)*
  - Code 'WILDBOARMEAT' added to allow reporting of meat from wild boar and products thereof.
  - Code 'GAMEMEAT' added to allow reporting of meat from game and products thereof except wild boar.
  - Code 'MIXEDMEAT' added to allow reporting of mixed meat and products thereof.
  - Code 'OTHERMEAT' updated (mixed meat excluded) to allow reporting of meat from other animals and products thereof not covered by any other codes.

Changes for case-based salmonellosis

The three variables collecting the antigenic formula for the *Salmonella* serotype are set up as free text fields. This makes them difficult to analyse and they have also only been analysed at a few occasions. The variable serotype should be sufficient for the case-based reporting (Subject SALM) and it also includes the possibility to report incomplete typing at serogroup level. It will still be possible to report the full antigenic formula in the SALMISO record type for molecular surveillance.

- AntigenOText *(Variable removed from subject SALM)*
- AntigenH1 *(Variable removed from subject SALM)*
- AntigenH2 *(Variable removed from subject SALM)*

Changes for trichinellosis

A number of trichinellosis cases in the EU comes from consumption of wild boar meat and other game, e.g. bears. To account for the *Trichinella* species found in these animals, *T. britovi* was added (May 2014).

- Pathogen *(Updated coded value list)*
  - Code 'TRCBRI' added to allow reporting of *Trichinella britovi* since several countries have this species in hunted wildlife.
- See also changes in *SuspectedVehicle* relevant for trichinellosis in 'Changes for all FWD subjects' above

2014 FWD metadata changes

The changes in 2014 to the FWD metadata compared to the previous year's data call for the FWD are described in the following:

Many of the changes relate to AMR and were due to the new EU protocol for harmonised monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates.

Changes for botulism reporting

According to the current EU case definition for botulism, *C. botulinum* is mentioned as causative agent. Recent reports in the EU/EEA of cases of botulism caused by other *Clostridium* species producing rare toxin types such as botulinum neurotoxin E and F suggest the need for the inclusion of new variables in the surveillance of botulism. The new proposed variables are listed below:

- Pathogen (*New variable*)
    - Added to collect information on the characterization of pathogen, i.e. *Clostridium* species
    - Codes 'CLSBOT' - *Clostridium botulinum*, 'CLSBAR' - *Clostridium baratii*, 'CLSBUT' - *Clostridium butyricum*, 'CLSOTHER' - *Clostridium* other species, 'UNK' - unknown
- Neurotoxin (*New variable*)
    - Added to collect information on the botulinum neurotoxin type produced by the *Clostridium* strain
    - Codes 'BONTA', 'BONTB', 'BONTE', 'BONTF', 'OTHER', 'NA' – not applicable
- *New validation rules (Warning) for different combinations of variables 'LaboratoryResult', 'NeurotoxinType' and 'Pathogen'*
    - Added to make sure the reporting is compatible with the EU case definition
    - Message: According to EU case definition confirmed cases should have *Clostridium botulinum* (CLSBOT) or botulinum neurotoxin (BONTA, BONTB, BONTE, BONTF, OTHER) laboratory confirmed.

Changes for case-based campylobacteriosis

- IsolateId *(New variable)*
    - Added to prepare for isolate-based reporting of AMR data
    - *Description:* Unique identifier for each isolate within the data source / lab system related to the case.
- ECDCIsolateID *(New variable)*
    - Added to prepare for isolate-based reporting of AMR data
    - *Description:* Identifier for each isolate record that is guaranteed to (i) be unique across countries/labs/pathogens, and (ii) not contain additional encoded information.
- SIR_AMP *(Variable removed)*
    - Agreed to drop this antimicrobial from the EU monitoring.
- SIR_NAL *(Variable removed)*
    - Agreed to drop this antimicrobial from the EU monitoring.

Changes for case-based listeriosis reporting

- *New validation rule (warning) if Transmission is "MTCT" for Subject "LIST".*
    - Message: Please report transmission of pregnancy-associated listeriosis cases as PregnancyAssociated=Y. If person-to-person transmission is intended, please report it as Transmission="PTP".

Changes for case-based salmonellosis reporting

- SIR_CAZ *(New variable)*
    - New variable with codes 'S', 'I', 'R', 'UNK' added to allow reporting of antimicrobial susceptibility testing results with ceftazidime.
- SIR_MEM *(New variable)*
    - New variable with codes 'S', 'I', 'R', 'UNK' added to allow reporting of antimicrobial susceptibility testing results with meropenem.
- SIR_SMX *(New variable)*
    - New variable with codes 'S', 'I', 'R', 'UNK' added to allow reporting of antimicrobial susceptibility testing results with sulfamethoxazole (SMX).
- SIR_TMP *(New variable)*
    - New variable with codes 'S', 'I', 'R', 'UNK' added to allow reporting of antimicrobial susceptibility testing results with trimethoprim only.
- SIR_SXT *(Changed description)*

- The correct description of the antimicrobial drug code SXT is 'Susceptibility to trimethoprim-sulfamethoxazole'.

- SIR_KAN *(Variable removed)*
  - Agreed to drop this antimicrobial from the EU monitoring. Antimicrobial no longer used for treatment and epidemiological value questionable.
- SIR_SSS *(Variable removed)*
  - Antimicrobial susceptibility testing for sulphonamides should be done on sulfamethoxazole.
- SIR_STR *(Variable removed)*
  - Agreed to drop this antimicrobial from the EU monitoring. Antimicrobial no longer used for treatment and produces unreliable results in antimicrobial susceptibility testing.

Changes for case-based yersiniosis reporting

- *New validation rule (warning) if Pathogen is "YERSENT" and biotype "1A"*
  - Message: *Yersinia enterocolitica* biotype 1A is apathogenic and should not be reported according to the EU case-definition.

Summary of implemented changes to FWD metadata in 2014-2019

Table 2: Summary of the changes in record types for Food- and Water-borne Diseases (FWD) and corresponding Molecular Surveillance 2014-2019

Year	Subject	Description
2019	ANTH	**Add optional variable** ClinicalPresentation to capture the clinical forms described in the EU case definitions
	ECHI	**Add optional variable** ClinicalPresentation to separate between cystic and alveolar echinococcosis.
	HEPA	**Add optional variable** SubGenotype of HAV to increase the resolution of hepatitis A surveillance
	LIST	**Add validation rule** for Transmission and PregnancyAssociated and for Age and PregnancyAssociated
	LIST	**Update coded value list** for Specimen to capture rare localised infections
	LIST	**Add optional variable** LivingSetting to improve the assessment of risk factors in various population groups, especially among the elderly
	LIST	**Add optional variable** UnderlyingCondition to capture underlying chronic disease conditions as these often result in more severe *Listeria* infections
	LISTISO, SALMISO, ECOLIISO, CAMPISO	**Add optional variables** CaseId and ECDCCaseId to enable linking from isolate to case
		Update coded value list for WgsAssembler to separate assemblies with and without read mapping/consensus calling
		Rename variable WgsSraId -> WgsSequenceId to allow reporting of genome identifier to any public sequence repository system. ENA identifiers to be reported in separate variable.
	SALMISO$AST, ECOLIISO$AST, CAMPISO$AST	**Update coded value list** for TestMethod (ASTTestMethodSALM) and **Update coded value list** for SIR to allow reporting of predicted phenotypic resistance from whole genome sequencing or PCR
2018	LIST	**Add validation rules** for PregnancyAssociated, Gender, Age - as the new EU case definition will requested reporting of only the mother in a pregnancy-associated case of listeriosis.
	LIST	**Add optional variable** PregnancyOutcome to capture the outcome of the pregnancy now that only the mother will be reported in a case of pregnancy-associated listeriosis. **Add validation rule** for PregnancyOutcome
	LIST	**Add optional variable** AgeMonth to prevent reporting of the newborn instead of the mother. **Add validation rules** for Age and AgeMonth
	LIST	**Update validation rules** for - Gender and PregnancyAssociated - Transmission and PregnancyAssociated
	LISTISO	**Add optional variable** PCRserogroup - variable added to LIST in 2013 and should be added to LISTISO as well
	LISTISO	**Add new optional variables:** WgsProtocol, WgsEnaId, WgsSraId, WgsAssembler, WgsAssembly - to support collection of WGS data. **Add validation rules** for the new Wgs variables
	SALMISO	**Add new optional variables:** - ESBL to simplify the reporting of ESBL/AmpC - GenoSerotype to capture serotype derived from molecular typing.
	SHIG	**Add optional variables:** SIR_CIP, SIR_CTX, SIR_CAZ, SIR_AMP, SIR_SXT, ECOFF_AZM to capture resistance to the most important antimicrobials for treatment of shigellosis.
	VTEC	**Update coded value list** for ClinicalManifestation: remove ASY – Asymptomatic
	YERS	**Update coded value list** BiotypeYERS: deactivate 1A
2017	BOTU	**Change Required variable status**. The variable NeurotoxinType made a required field.
	SHIG	**Validation rule status** from warning to error to prevent reporting of serotypes for *S. sonnei*.
	SALMISO	**Update coded value list** for variable ASTAntibioticSALM with imipenem added.
	TOXO	**New validation rule** for Age to prevent reporting of other than congenital toxoplasmosis.
	TOXO	**Remove variable** Transmission as it is no longer needed

2016	LIST	**Add optional variable** AgeMonth - the new EU case definition will request reporting of only the mother in pregnancy-associated listeriosis. In order to prevent reporting of the newborn instead of the mother, the age in months is needed to differentiate between pregnancy-associated cases in newborns and other types of transmission. **Add validation rules** for Age and AgeMonth
	LIST	**Update validation rules** for - Gender and PregnancyAssociated Transmission and PregnancyAssociated
	YERS	**Update coded value list** BiotypeYERS: deactivate 1A
	SALMISO	**Update coded value lists:** ASTAntibioticSALM VNTRLocusSALM VNTRProtocolSALM
	SALMISO CAMPISO ECOLIISO	**Add validation rule** for ResultSign and Result value – to use correctly ResultSign ">="
	SALMISO CAMPISO ECOLIISO	**Update 'full name' of the variable** SIR to clarify that the interpretation should be based on EUCAST clinical breakpoints. This has no impact on data reporting since the technical variable name is not changed (SIR).
2015	all FWD subjects	**Remove default value UNK for all variables** to: - improve reporting of required variables and - to be able to separate unknown from missing values for optional variables
	all FWD subjects	**Remove variables** EpiLinked, LaboratoryResults, ClinicalCriteria. Generally missing and often misinterpreted. **Remove related validation rules**
	all FWD subjects	**Change Required variable status**. The variable "Classification" Required field status differs between the FWD. Should be synchronised
	all FWD subjects	**Update description of the variable** for Transmission = MTCT (Transmission from mother to child during pregnancy or at birth.) and add validation rule with error if age > 0
	all FWD subjects	**Remove** seldom used **recordtypes**: - HAGGR, - BRUCAGGR, - CAMPAGGR, - ECHIAGGR, - LISTAGGR, - SALMAGGR, - TRICAGGR, - VTECAGGR, - YERSAGGR. **Allow the use** of the **recordtype AGGR**.
	all FWD subjects	**Update coded value list**. Codes were missing to report foodborne transmission from wild boar meat and other game, e.g. bears, which are risk meats for trichinellosis
	all FWD subjects EXCEPT VTEC, YERS, VCJD	**Update coded value list.** Remove classification POSS from coded value list (to comply with EU 2012 case definition) **and remove related validation rules**.
	TOXO, ECHI	**Update coded value list**: remove classification PROB from coded value list (to comply with the EU 2012 case definition) **and remove related validation rules.**
	SALM	**Remove variables AntigenOText, AntigenH1, AntigenH2**: due to free text coding, the FWD coordination committee proposed to remove these variables (now covered by molecular surveillance)
	LEGI, LEGITRAVEL	**Update coded value list**. Add coded value to Pathogen: "NonSG1 - *Legionella pneumophila* non serogroup 1"
2014	BOTU	Add variables Pathogen and neurotoxin to possibly detect new species clostridium baratii and clostridium butyricum
	BOTU	Add validation rules for the reporting of the new species to be compatible with the EU case definition.
	CAMP	Add variables IsolateId and ECDCIsolate to link with a new record-type CAMPISO

	CAMP	Remove variables for monitoring anti-microbial resistance susceptibility testing, using " SIR" for Ampicilin and Nalidixic acid
	CAMPISO	Proposal for a new isolate-based record-type to monitor anti-microbial resistance patterns for *Campylobacter*
	LIST	Addition of a validation rule for the variable transmission for pregnancy-associated listeriosis
	SALM	Add variables for monitoring anti-microbial resistance susceptibility testing, using " SIR" for Ceftazidime, Meropenem, Sulphamethoxazole, Trimethoprim
	SALM	Remove variables for monitoring anti-microbial resistance susceptibility testing, using "SIR" for Sulphonamides, Streptomycin, Kanamycin
	SALM	Correct description of the variable SIR_SXT
	SALMISO	Proposal for a new isolate-based record-type to monitor anti-microbial resistance patterns for *Salmonella*
	SALMISO	Add variables imported and probable country of infection to the record-type SALMISO if not possible to link with the regular record-type SALM
	YERS	Addition of a validation rule for the pathogen and biotype to be reported to comply with EU case-definition.

Annex 2 FWD-specific material

Contact details

FWD surveillance issues: Taina Niskanen and Therese Westrell

AMR surveillance of zoonotic pathogens: Therese Westrell

Molecular typing data reporting: Saara Kotila

Email: *fwd@ecdc.europa.eu*

FWD reporting frequency

Annual reporting of FWD diseases and case-based AMR data

The FWD surveillance data and case-based data on AMR for 2018 should be provided by **31 May 2019** the latest. It cannot be assured that submissions after that date will be included in the reports. The data collected are aimed to provide the datasets for the following reports and interactive data tools:

- The ECDC web tool Surveillance Atlas of Infectious Diseases (which will be expanded to include also AMR data for FWD, possibly during 2019);
- Annual Epidemiological Report disease chapters with 2018 data (web pages on the ECDC website);
- The European Union summary report on zoonoses, zoonotic agents, and foodborne outbreaks in 2018;
- The European Union summary report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2018;

Annual reporting of isolate-based AMR data for *Salmonella* and *Campylobacter*

Isolate-based AMR data collection with reporting of measured values was officially introduced to EU surveillance in 2014, following the agreements made in the *EU protocol for harmonised monitoring of antimicrobial resistance in human Salmonella and Campylobacter isolates*. To simplify the isolate-based reporting, the antimicrobial susceptibility testing data can be submitted directly from National Public Health Reference Laboratories via BioNumerics. It is also possible to submit the data via csv files to TESSy where the isolate data is in one file and the AST results in another. The subjects to be used for the isolate-based reporting are SALMISO (record type version 3) and CAMPISO (record type version 1). Please also use the available options (variables 'IsolateId' or 'ECDCIsolateID' in subjects SALM/CAMP or 'CaseId' or 'ECDCCaseId' in subjects SALMISO/CAMPISO) to link each isolate to a case to enable further analysis of the data, e.g. on outcome and hospitalisation of cases infected with resistant bacteria.

The isolate-based data on AMR for 2018 should be provided by **31 May 2019** the latest. It cannot be assured that submissions after that date will be included in the reports. The isolate-based AMR data is gradually replacing the case-based AMR data used in the European Union summary report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food and will also be presented in the Surveillance Atlas for Infectious Diseases once adapted for FWD AMR data.

Monthly reporting of *Salmonella* serotype data

Member States are asked to report *Salmonella* serotype data in real-time or at least on a monthly basis, either through isolate-based reporting directly from National Public Health Reference Laboratories via BioNumerics or as case-based csv-files via the normal routes to TESSy. This would allow for an earlier detection of events and enable prevention of further spread.

Algorithms have been developed at ECDC to detect unusual increases of *Salmonella* serotypes in multiple countries. These events will be reported through EPIS-FWD. In addition, the data is used as background data in EPIS updates and rapid risk/outbreak assessments.

The deadline for the monthly data submission of *Salmonella* serotype data (either via SALM or SALMISO) is the 15th of every month, at which point Member States are asked to report all *Salmonella* serotype data collected since the last submission. If MLVA data for *Salmonella* serotypes *S*. Typhimurium and *S*. Enteritidis are available, Member States are also encouraged to report these together with the serotype data.

Real-time reporting of *Salmonella* and *Listeria* molecular typing data for multi-country cluster detection

Member States are asked to, on a voluntary basis but in real-time, submit isolate-based molecular typing data for *Salmonella* (MLVA for *S*. Typhimurium and *S*. Enteritidis). ECDC recommends laboratories to use the validated standard molecular typing protocols for MLVA for *S. Typhimurium* and *S. Enteritidis*, respectively. As part of the enhanced EU/EEA-level surveillance for invasive listeriosis started in March 2019, Member States are also encouraged to submit whole genome sequencing (WGS) genome assemblies and/or ENA (or other public sequence repository system) genome identifiers for *Listeria*.

The molecular typing data are submitted directly from National Public Health Reference Laboratories through XML or CSV files to TESSy. Since the reporting of this data is requested to be performed whenever new molecular typing data are available in the laboratories, there are no set reporting deadlines.