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Evaluation of regional and local laboratories capacities for detection and characterisation of *Salmonella* and *Campylobacter*

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FWD AMR · RefLabCap

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Deliverable T2.1

Evaluation of regional and local laboratories capacities for detection and characterisation of *Salmonella* and *Campylobacter*

Directorate-General for Health and Food Safety (DG SANTE) and for Public health, Cancer and Health security
EU Third Health Programme 2014-2020

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1. Background

As part of Task 2a activities in the FWD AMR-RefLabCap project, 21 public health national reference laboratories (NRLs) from 19 countries carried out a mapping and evaluation of their regional and local laboratories capacities for detection and characterisation of *Salmonella* and *Campylobacter*. The mapping exercise was executed in the period from November 2022 to March 2023.

All countries that conducted the mapping exercise produced a mapping summary report in English, which was submitted to the FWD AMR-RefLabCap project team by the 21 March. Based on these reports, the project team prepared this consolidated report containing an overview of strengths, weaknesses and needs common to all countries as well as elements which may be particular to specific countries. The conclusions of the consolidated report will form a basis for further national capacity building activities that should be supported by NRLs for reliable detection and characterisation of *Salmonella* and *Campylobacter* by the regional and local laboratories in each country.

Throughout the mapping exercise, the project team supported the NRLs and helped them to select the methodology for carrying out the mapping. We produced two guidance documents for NRLs: **Suggested outline for summary report in English**, and **Suggested questionnaire to support the mapping exercise** (see Annexes 1-2). Also, three online workshops were held: 1) to introduce NRLs to the mapping activity (3 Oct 2022); 2) to guide on the mapping strategy (26 Oct 2022); and 3) to guide with the mapping data analysis, interpretation and dissemination (31 Jan 2023). Forty-nine, 28 and 45 persons attended the three workshops, respectively. The agenda and materials from all workshops are available on the project website: https://www.fwdamr-reflabcap.eu/events/2022 and https://www.fwdamr-reflabcap.eu/events/2023. In addition, all countries were offered a financial support of up to 5000 EUR to compensate the expenses related to the mapping exercise.

This report will be shared with the NRLs and additionally the report will be discussed in a webinar organised by the project team. The project team will support the NRLs role in supporting local and regional laboratories in capacity building for *Salmonella* and *Campylobacter* detection and characterisation. The common needs will be addressed during online and physical events in relation to tasks 2b and 2c (Deliverables T2.2 and T2.3).

2. Evaluation of strengths, weaknesses, and needs

2.1. National reports and their evaluation

Overall, 21 NRLs from 19 countries submitted mapping summary reports in English, see Table 1:

i. Sixteen countries provided one report each encompassing both organisms, two countries provided two reports - one on *Salmonella* and one on *Campylobacter*, and one country provided only a report on *Salmonella*;

ii. Sixteen countries had “EU member state” status, two countries had “EU candidate” status and one country had a “potential EU candidate” status (Table 1).

Table 1: Submitted mapping summary reports in English

Country name	Organism[a]	EU Status
Belgium	S&C	Member state
Bulgaria	S&C	Member state
Croatia	S	Member state
Cyprus	S&C	Member state
Estonia	S&C	Member state
Greece	S&C	Member state
Hungary	S&C	Member state
Italy	S&C	Member state
Kosovo	S&C	Potential EU candidate
Latvia	S&C	Member state
Lithuania	S&C	Member state
Malta	S&C	Member state
Moldova	S&C	EU candidate
Poland	S&C	Member state
Portugal	S&C	Member state
Romania	S&C	Member state
Serbia	S	EU candidate
	C	
Slovakia	S	Member state
	C	
Slovenia	S&C	Member state

[a]S-*Salmonella*, C- *Campylobacter*

In total, 20 out of the 21 individual country mapping summary reports were evaluated with the aim of identifying strengths, weaknesses and needs common to all countries as well as elements which may be particular to specific countries. A report from one country was excluded from the evaluation as this country only had one diagnostic laboratory/hospital.

The summary of weaknesses, strengths and needs is based on:

- the countries' conclusions on different aspects as outlined in the suggested summary report template provided in the individual country reports;
- if the countries' conclusions were not available, we assessed the strengths, weaknesses and needs considering the recommendations in the Model protocol for national surveillance of AMR in human *Salmonella* and *Campylobacter* infections.

In the evaluation, relative terms are used to indicate the proportion of the countries where the strengths/weaknesses/needs were observed. **Most/majority** indicate a proportion of >60%, **common/frequent** indicate a proportion of 40-60%, and **some/few** indicate a proportion of <40%.

Further on, in the evaluation the following terms are used:

- **NRL**, to indicate the provider of the national report.
- **Countries**, to indicate the relative proportion of the observed strengths/weaknesses/needs.
- **Laboratories**, to indicate the local/regional laboratories that carry out detection and characterisation of *Salmonella* and/or *Campylobacter* in the countries.

2.2. Evaluation results

2.2.1. Mapping methodology

All NRLs conducting the mapping sent questionnaires to all or to a representative selection of local/regional laboratories performing *Salmonella* and *Campylobacter* diagnostics. The surveys were mostly conducted using online survey tools (e.g. EU Survey, Google survey or alternative tools) or distributed by email. In addition, a few NRLs organised phone calls, teleconferences, and visits to the laboratories with the aim to introduce the survey, to establish the contacts and/or to follow up on the responses.

2.2.2. National system for diagnostics

This section summarises the evaluation of: i) how human diagnostics of *Salmonella* and/or *Campylobacter* is done in different countries, and ii) the role of the laboratories in detection, culturing and characterisation (e.g., species identification, serotyping, other typing, AMR-testing, WGS), according to information provided by the NRLs.

Most NRLs described their diagnostics in relation to the current status of the national laboratory-based surveillance of human *Salmonella* and *Campylobacter* cases and/or AMR in the country.

In summary:

- In most countries, the national surveillance of *Salmonella* and *Campylobacter* is based on both species/serovar and AMR laboratory data provided by the local/regional laboratories and additional laboratory data provided by the NRL However, in some countries the data is only provided by either the NRL or the local/regional laboratories;
- Only a few countries have a mandatory referral of *Salmonella* and *Campylobacter* positive samples or isolates to NRL. In most countries it is either voluntary or mixed depending on the status of the laboratory (e.g., primary diagnostic, public, private, etc.) or the purpose of the referral. More than half of the NRLs did not provide information on this aspect.

Strengths:

- Local/regional laboratories performing *Salmonella* and *Campylobacter* diagnostics cover all or >50% of the geographic area in most of the countries.

- Some countries reported a well-functioning network of local/regional laboratories for *Salmonella* and *Campylobacter* disease and/or AMR surveillance.

Weaknesses:

- On the national level, most countries pointed out complex organisation and poor coordination of the surveillance of *Salmonella*, *Campylobacter* and AMR.
- Most countries indicated gaps in the national policy/legislation/national guidelines for the surveillance; poorly defined surveillance system workflows (sampling, testing, and reporting); poorly defined tasks and roles of the NRL and local/regional laboratories in the networks.
- In a few countries, only selected isolates are referred to NRL: untyped *Salmonella*, invasive strains and non-invasive strains presenting diagnostic difficulties or with special antibiotic resistance profiles. In two countries, *Campylobacter* isolates are not referred to the NRL.
- A few countries have not established a laboratory network for *Salmonella* and/or *Campylobacter*.

Needs:

- In most countries, improvements are needed to ensure a well-functioning laboratory network for *Salmonella* and/or *Campylobacter* surveillance.
- In many countries, reorganisations at the national level are necessary to optimise the surveillance of *Salmonella*, *Campylobacter* and AMR.

2.2.3. Laboratories performing primary diagnostics

This section summarises the evaluation of: i) the number of local/regional laboratories that perform detection and/or characterisation of *Salmonella* and *Campylobacter* in different countries, ii) the geographical coverage, private/government status, status regarding quality assurance, accreditation and participation in EQAs of the laboratories', and other information of relevance, according to information provided by the NRLs.

Strengths:

- In most countries, nearly all laboratories have the capacity for *Salmonella* detection, identification to the species level, and testing of AMR for clinical purposes.
- In most countries, nearly all laboratories are accredited/certified for *Salmonella* and *Campylobacter* diagnostics, though accreditation for specific tests was not indicated by most countries.
- Most of the countries indicated a good geographic coverage of local/regional laboratories performing *Salmonella* and *Campylobacter* diagnostics.

Weaknesses:

- In most countries, the laboratories are only able to serotype selected *Salmonella* serovars. Frequently, full *Salmonella* serotyping is performed only by NRLs or other expert laboratories.
- A lack of capacity for *Campylobacter* detection, species identification and especially AMR testing in a high proportion of laboratories was commonly observed.
- Commonly, a high proportion of laboratories not participate in EQAs for *Salmonella* and/or *Campylobacter*, especially for AMR testing. The common reasons are the lack of staff to perform QC procedures and/or lack of budget to pay for EQAs.
- Thirteen out of 20 NRLs provided information about the use of control materials for *Salmonella* and/or *Campylobacter* diagnostics in the laboratory network. We observed

that frequently quality control materials are not used in a high proportion of laboratories for all or some of *Salmonella* and *Campylobacter* tests.

Needs:

- National guidelines on diagnostic procedures in the laboratories that are lacking capabilities for identification and characterisation of *Salmonella* and/or *Campylobacter*.
- Inform public health or other relevant authorities about the lack of national requirements and/or funding for accreditation, quality assurance and provision of sample/isolate referral for surveillance purposes in the laboratory network.
- Provide support to the laboratories lacking accreditation and quality assurance for all laboratory activities through laboratory visits, inter-laboratory comparisons, EQAs, etc.
- Communicate to laboratories that if needed, *Salmonella* and *Campylobacter* isolates should be sent to NRL or another expert laboratory for further characterisation for surveillance purposes and provide guidance/support for sample/isolate referral.

In addition, a few NRLs provided information about the national coverage of laboratory-confirmed cases and/or AMR surveillance for *Salmonella* and *Campylobacter* (data not shown). A few other NRLs noted that the number of tests/confirmed cases by the laboratories varies, and it is difficult to estimate the coverage due to unknown true disease incidence, low isolation rates due to capacity issues for isolation (especially for *Campylobacter*), poor reporting/referral system, etc. All of the above, may lead to underdiagnosis, underreporting and low surveillance coverage.

2.2.4. Human resources, laboratory equipment and funding

This section provides the evaluation of: i) qualifications and skills of the personnel working on detection and characterisation of *Salmonella* and *Campylobacter* at local/regional laboratories (personnel in different roles: leaders, technical staff, etc) in different countries, and ii) the laboratories' capacity (e.g. availability of the needed equipment, materials, etc.) and the funding situation in relation to the detection and characterisation of *Salmonella* and *Campylobacter*, according to information provided by the NRLs.

Strengths:

- In most countries, a high proportion of the laboratories have an adequate situation regarding the qualifications/skills of laboratory staff as well as the availability of the equipment for performing *Salmonella* and *Campylobacter* diagnostics.

Weaknesses:

- In most countries, a high proportion of the laboratories have an inadequate situation regarding human and financial resources in the laboratories for performing *Salmonella* and *Campylobacter* diagnostics.
- In some countries, laboratories have an inadequate situation regarding the availability of laboratory quality management systems and efficient systems for equipment and reagent procurement.

Needs:

- Despite an overall satisfactory situation with regard to qualifications of the laboratories' staff, most laboratories continuously need training of staff and advice from the NRL. Frequently, the NRLs indicate that they need to further clarify in which areas the training is needed in different laboratories, e.g., molecular diagnostics, phenotypic and/or genotypic methods for *Salmonella* and *Campylobacter* testing and result interpretation, guidance on implementing SOPs as well as administrative procedures in laboratory management, etc.

- Some NRLs would like to evaluate current surveillance system workflow and to identify any associations between the resources and the laboratory status (e.g., primary diagnostic, public, private, etc.). Our advice is that the evaluation should include all relevant stakeholders in the area and should result in identification of areas that can be improved.

2.2.5. Diagnostic methods for detection

This section provides the evaluation of: i) the methods used for detection of *Salmonella* and *Campylobacter* in human samples in the diagnostic laboratories (include differences between these, if relevant), and ii) the storage of *Salmonella* and *Campylobacter* at the diagnostic laboratories, according to information provided by the NRLs.

Strengths:

- In most countries, laboratories perform culture-based detection of *Salmonella* and *Campylobacter* using adequate procedures and culture media.

Weaknesses:

- In most countries, there is a lack of national laboratory guidelines for *Salmonella* and *Campylobacter* detection and if guidelines exist the laboratories do not have an obligation to use them. This may have a negative effect on isolation rate and on the isolate referral to NRL.
- In some countries, laboratories use various media that are not optimal for detection of *Salmonella* and/or *Campylobacter* from stool samples.
- In some countries, culture-independent testing by rapid antigen tests or PCR-based methods is becoming more widespread without further confirmation of the positive results by culture, and thus prevents further characterisation by the local/regional laboratories or the NRL.
- In most countries, *Salmonella* and *Campylobacter*-positive samples and/or isolates are stored in the laboratories only in specific situations (e.g., suspected outbreak) or are not stored at all. The main reason for this is insufficient storage capacity.
- In some countries, the laboratories store *Salmonella* and *Campylobacter* isolates under inadequate conditions (various storage media, temperature, etc.).

Needs:

- Improve the detection of *Salmonella* and *Campylobacter* in laboratories through guidance with SOPs and training of personnel.
- Introduce more efficient/rapid cultivation and molecular detection methods to laboratory network.
- Continuous harmonisation of testing strategy, methodology, and reagents across the laboratories.
- Establish national guidelines to laboratories for long-term storage of *Salmonella* and *Campylobacter* positive samples and isolates. If laboratories cannot store *Salmonella* and *Campylobacter* positive samples/isolates, they can be advised to send them for long term storage to another laboratory with this capacity or to NRL.

2.2.6. Characterisation methods

This section provides the evaluation of the methods used for characterisation of *Salmonella* and *Campylobacter* in the laboratories for diagnostic and/or surveillance purposes, according to information provided by the NRLs.

Strengths:

- In most countries, laboratories have good methodological capabilities for identification, species determination and AST testing for patient management needs.
- In most countries, laboratories are following or performing AST that are aligned with the EUCAST guidelines .

Weaknesses:

- In most countries, many laboratories do not identify or identify only selected *Salmonella* serovars.
- In most countries, laboratories use various methods, that are not always optimal for phenotypic testing of AMR.
- In most countries, laboratories do not test the recommended panel of antimicrobials in harmonised EU protocol, but test a non-standartised panel of antimicrobials, which might be sufficient for patient handling but not for surveillance purposes.
- In most countries, laboratories do not use molecular methods for testing the presence of AMR genes or point mutations in *Salmonella* and/or *Campylobacter* isolates.

Needs:

- There is a need for continuous development of the capacities and method harmonisation for characterisation of *Salmonella* and *Campylobacter* in the laboratory network contributing to the surveillance data.
- Improvements in the isolate referral systems are necessary in cases where the laboratories do not have capacities for further *Salmonella* and *Campylobacter* characterisation or use methods that are unfit for surveillance purposes.

2.2.7. Isolate referral and linking to cases

This section summarises the evaluation of the i) referral of isolates (or positive samples) from local/regional laboratories to the NRL or other laboratory for further characterisation, including AMR-testing, ii) isolate/sample linking to case information, e.g. an identifier allowing for epidemiological investigations, and iii) the number/proportion of laboratories that refer samples/isolates to the NRL as well as the approximate number of samples/isolates referred to the NRL, according to information provided by the NRLs.

Strengths:

- In most countries, laboratories refer all or selected *Salmonella* positive isolates for confirmation and/or further characterisation to another expert laboratory or to the NRL.
- In most countries, laboratories report laboratory data on *Salmonella* and *Campylobacter* to hospitals and/or other public health authorities for infection control and/or local surveillance purposes.
- In most countries, laboratories use a Laboratory Management Information System (LIMS) for laboratory data recording.

Weaknesses:

- In most countries, a low proportion of laboratories refer *Campylobacter* isolates to another expert laboratory or to the NRL.
- In most countries, there is a poor organisation of routine sampling and sample submission practices as well as selection, frequency and ways of *Salmonella* and *Campylobacter* isolate testing and referral to NRL. There is a general lack of prioritisation of *Campylobacter*.
- In most of the countries, despite the existence of guidance for submission, laboratories often provide incomplete patient data together with the referred isolates making it difficult to link laboratory data with cases.

- Most of the countries highlight gaps in the flow of information between diagnostic laboratories, public health laboratories and national reference laboratory, often in relation to the lack of the national electronic databases/systems for data sharing.

Needs:

- Efficient communication with the laboratories to increase the awareness of referral of *Salmonella* and *Campylobacter* isolates to another expert laboratory or to NRL.
- Organise meetings with the local/regional laboratories to understand the difficulties encountered with the referral of isolates and to provide needed support and guidance for handling, storage, and transport of the isolates to the NRL (networking and feedback).
- Development and implementation of the national integrated digital system for data sharing between the local/regional laboratories, epidemiologists and the NRL is necessary.

3. Summary

Based on the overall evaluation of national local/regional capacities for *Salmonella* and *Campylobacter* detection and characterisation in 18 countries, it can be summarised that in most countries:

- there is poorly-functioning laboratory network for *Salmonella* and/or *Campylobacter* surveillance,
- there is lack of financial resources as well as lack of focus in supporting laboratory-based *Salmonella* and/or *Campylobacter* disease surveillance, and especially surveillance of AMR,
- NRLs are only part of the surveillance: they are not empowered and do not have dedicated budget to coordinate a network of local/regional laboratories that can support the national surveillance,
- *Salmonella* diagnostics and surveillance is organised better than *Campylobacter* due to the lack of prioritisation of *Campylobacter* at the national level.

In all countries, the staff of the local/regional laboratories have sufficient skills/qualifications as well as laboratory infrastructure for *Salmonella* and *Campylobacter* detection and characterisation. This forms a good basis for improvements in the laboratory-based surveillance system given that the resources can be provided. The improvements may be accommodated in various ways, and may be covered by networks that have a broader scope than just *Salmonella* and *Campylobacter*.

Annex 1. Suggested outline of summary reports

Suggested outline for summary report in English from each NRL

As part of the FWD AMR-RefLabCap project, the NRL for *Salmonella* and/or *Campylobacter* in human infections in each country are invited to map and evaluate the regional/local laboratories' capacities for detection and characterisation of *Salmonella* and/or *Campylobacter*.

The results of the mapping and evaluation should be written in national languages, and depending of the needs, may be disseminated to relevant stakeholders in own country e.g. for stakeholder engagement, to seek funding for local/regional laboratory support, etc.

In addition, a summary of the mapping results and evaluation should be made available in English for the FWD AMR-RefLabCap project team. The summary report will form a basis for planning training activities and other support activities, including individual support to each country participating in the mapping exercise depending on the needs. The deadline for the report submission is 21 March 2023.

Below is a suggested outline of the topics to be covered and included in the summary of the national mapping and evaluation exercise performed by each NRL. If your laboratory is the NRL for only *Salmonella* or *Campylobacter*, fill in the information for the relevant pathogen only.

The outline is divided in topics as specified below. Replace the text marked in yellow with your text for the topics that are relevant for your country (not all topics need to be filled in). Also, the level of details may vary depending on the topic, the results of your mapping and the availability of information. Add figures and tables when relevant.

Outline of the summary report:

1. Background
2. Diagnostics of *Salmonella* and *Campylobacter*
3. Laboratories performing diagnostics of *Salmonella* and *Campylobacter*
4. Human resources, laboratory equipment and funding at local/regional laboratories
5. *Salmonella* and *Campylobacter* detection methods used in diagnostic laboratories
6. *Salmonella* and *Campylobacter* characterisation methods used in local/regional laboratories
7. *Salmonella* and *Campylobacter* isolate referral and linking to cases
8. Other issues of relevance for your country
9. Evaluation and conclusions

Mapping and evaluation of national capacities in local and regional laboratories for the detection and characterisation of *Salmonella* and *Campylobacter* in humans

Summary report for country

Name of laboratory (NRL)
Contact person(s)
Date

1. Background

Please, briefly describe the methodology used for the mapping.
For example, the sources of information, how many laboratories were you in contact with, etc.

Write text here (insert more lines as needed)

2. Diagnostics of *Salmonella* and *Campylobacter*

Please, describe how human diagnostics of *Salmonella* and/or *Campylobacter* is done in your country and include in overall terms the role of different laboratories in detection, culturing and characterisation (e.g., species identification, serotyping, other typing, AMR-testing, WGS).

Write text here (insert more lines as needed)

Please, include your evaluation of strengths/weaknesses and gaps/further needs for the human diagnostics of *Salmonella* and *Campylobacter* in your country.

Write text here (insert more lines as needed)

3. Laboratories performing diagnostics of *Salmonella* and *Campylobacter*

Please, indicate the number of local/regional laboratories that perform detection and/or characterisation of *Salmonella* and *Campylobacter* in your country.
Include information on the geographical coverage, private/government status and other information of relevance.
Include information on the laboratories' status regarding quality assurance, accreditation and participation in EQAs.

Write text here (insert more lines as needed)

Please, include your evaluation of strengths/weaknesses and gaps/further needs for the laboratories performing diagnostics of *Salmonella* and/or *Campylobacter* in your country.
If the laboratories require further assistance from the NRL, specify the needs

Write text here (insert more lines as needed)

4. Human resources, laboratory equipment and funding at local/regional laboratories

For example, describe the qualifications and skills of the personnel working on detection and characterisation of *Salmonella* and *Campylobacter* at local/regional laboratories (personnel in different roles: leaders, technical staff, etc). Likewise, describe the laboratory capacity (e.g. availability of the needed equipment, materials, etc.) and the funding situation in relation to the detection and characterisation of *Salmonella* and *Campylobacter*

Write text here (insert more lines as needed)

Please, include your evaluation on strengths/weaknesses and gaps/further needs in relation to qualifications of the staff, laboratory equipment, funding, etc. at the local/regional laboratories.
If the local/regional laboratories require further assistance from the NRL, specify the needs.

Write text here (insert more lines as needed

5. *Salmonella* and *Campylobacter* detection methods used in diagnostic laboratories

Please, specify the methods used for detection of *Salmonella* and *Campylobacter* in human samples in the diagnostic laboratories (include differences between these, if relevant).
If culture-independent diagnostic tests are used, describe if/when isolation of the pathogen is carried out at the diagnostic laboratory or elsewhere.
Describe if/when isolates of *Salmonella* and *Campylobacter* are stored at the diagnostic laboratories.

Write text here (insert more lines as needed)

Please, include your evaluation on strengths/weaknesses and gaps/further needs for the detection of *Salmonella* and/or *Campylobacter* in the diagnostic laboratories in your country
If the laboratories require further assistance from the NRL, specify the needs

Write text here (insert more lines as needed)

6. *Salmonella* and *Campylobacter* characterisation methods used in local/regional laboratories

Please, specify the methods used for characterisation of *Salmonella* and *Campylobacter* for diagnostic and/or surveillance purposes. The characterisation could include species identification, serotyping, AMR-testing, and molecular typing methods (e.g., WGS, MLVA, PFGE).
If the laboratories provide results that are directly included in the national surveillance, describe how the communication of results is done.

Write text here (insert more lines as needed)

Please, include your evaluation on strengths/weaknesses and gaps/further needs for the characterisation of *Salmonella* and *Campylobacter* in the local/regional laboratories in your country.
If the laboratories require further assistance from the NRL, specify the needs.

Write text here (insert more lines as needed)

7. *Salmonella* and *Campylobacter* isolate referral and linking to cases

Please, describe the referral of isolates (or positive samples) from local/regional laboratories to the NRL or other laboratory for further characterisation, including AMR-testing.
Specify if the referred isolates/samples are linked to case information, e.g. an identifier allowing for epidemiological investigations.
Specify the number and proportion of laboratories that refer samples/isolates to the NRL as well as the approximate number of samples/isolates referred to the NRL.

Write text here (insert more lines as needed)

Please, include your evaluation on strengths/weaknesses and gaps/further needs for the referral of *Salmonella* and *Campylobacter* isolates in your country.
If the local/regional laboratories require further assistance from the NRL, specify the needs.

Write text here (insert more lines as needed)

8. Other issues of relevance for your country

Please, describe any other issue that is relevant for the state of play in your country with regards to local/regional laboratories capacities for detection and characterisation of *Salmonella* and *Campylobacter*

Write text here (insert more lines as needed)

Please, include your evaluation on strengths/weaknesses and gaps/further needs in relation to these issues.
If the local/regional laboratories require further assistance from the NRL, specify the needs.

Write text here (insert more lines as needed)

9. Evaluation and conclusions

Please, provide your overall evaluation of strengths/weaknesses and gaps/further needs in relation to the regional/local laboratories' capacities in your country for detection and characterisation, including AMR determination, of *Salmonella* and *Campylobacter*.
Prioritise the needs for capacity building in the local/regional laboratories.
Overall conclusion.

Write text here (insert more lines as needed)

Annex 2. Suggested questionnaire to support the mapping exercise

Mapping of the local/regional laboratories capacities for the detection and characterisation of *Salmonella* and *Campylobacter*

You are hereby invited to participate in a survey of clinical microbiology laboratory capacity for the detection and characterisation of Salmonella and Campylobacter. The survey is organised by the NRL within the framework of of the Food and Waterborne Diseases and Antimicrobial resistance – Reference Laboratory Capacity (FWD AMR-RefLabCap) project.

FWD AMR-RefLabCap is a four-year project on "Provision of EU networking and support for public health reference laboratory functions for antimicrobial resistance in *Salmonella* species and *Campylobacter* species in human samples". The project is managed by the European Health and Digital Executive Agency (HaDEA), on behalf of the Directorate General for Health and Food Safety (DG SANTE of the European Commission) and in executed in close cooperation with the European Centre of Disease Prevention and Control (ECDC). The contractors for the project are the Technical University of Denmark (DTU Food, Denmark) and Statens Serum Institut (SSI, Denmark).

Well-functioning microbiology reference laboratory services are essential to support the implementation of effective actions to combat AMR as set out in the European One-Health Action Plan against Antimicrobial Resistance COM (2017) 339 and Decision (EU) 1082/2013 on serious cross-border health threats. The purpose of the FWD AMR-RefLabCap project is to strengthen coordination, support and capacity building in national reference laboratory functions for testing and surveillance of AMR in *Salmonella* and *Campylobacter* in human samples. The overall aim of the project is to improve the proficiency of the local/regional laboratories at the local, regional and national levels in all countries participating in the EU Health Programme. These activities complement the ongoing activities of the ECDC for AMR surveillance in human *Salmonella* and *Campylobacter* infections.

The national reference laboratory/national expert laboratory (NRL or NEL) is already participating in a range of activities organised in the FWD AMR - RefLabCap project: e.g. capacity building activities, including training, external quality assessment (EQA) schemes and networking activities to improve their capacities for detection, phenotypic and genotypic characterisation of *Salmonella* and *Campylobacter*.

At this point, as part of FWD AMR – RefLabCap activities, the NRL/NEL have been asked to conduct a mapping survey on the capacity for detection and characterisation of *Salmonella* and *Campylobacter* within their national network of clinical microbiology laboratories or if it is not present by engaging with national clinical laboratories.

Your laboratory has been selected by the NRL/NEL to participate in this mapping exercise. We kindly ask you to complete the questionnaire to assist us in our mapping and evaluation of the capacity of the local clinical microbiology laboratory for *Salmonella* and

Campylobacter. The questionnaire was developed in collaboration with the the FWD AMR-RefLabCap project, and contains 13 general questions and a maximum of 29 specific questions. The survey aims at identifying strengths and weaknesses to inform targeted capacity building activities in your laboratory. A report with the main findings and conclusion of the national survey will be elaborated (in national languages and a summary in English) by the NRL/NEL in your country by March 2023. The English summary will be sent to the RefLabCap project, and the national report will be circulated to the local participants.

How to complete the questionnaire

Please use Microsoft Edge, Mozilla Firefox or Google Chrome to complete the questionnaire. If you use other browsers this might cause compatibility issues. You can complete parts of the survey and save a draft of your answers. After clicking on 'save as draft', you will be automatically redirected to a page with a link to where you can retrieve your draft to edit and submit your answers. Be sure to save this link! When you have entered all your answers, please press "submit" at the bottom of the page.

For FAQs: https://ec.europa.eu/eusurvey/home/helpparticipants

General part

Diagnostics of *Salmonella* and *Campylobacter*

(section 3 in mapping summary report)

1. Please complete the table on details of your laboratory

	Information about the laboratory
Name of the laboratory	
Name and surname of the contact person	
Email address of the contact person	
Address and institution of the laboratory	
Region/Area covered by the laboratory	
Estimated patient population size covered (approximate number of people in the geographical area the laboratory covers)	
Organisation of the laboratory (e.g. hospital, university, public health, private company etc.)*	

**please use classification relevant to your country*

2. Does your laboratory carries out diagnostic testing of *Salmonella* and/or *Campylobacter* (select both answers, if relevant):
Includes both, culture- and PCR-based detection

a) Salmonella
b) Campylobacter
c) None of the above

3. How many samples and/or isolates are annually tested at your laboratory for the following pathogens?
Includes all testing methods

a) *Salmonella* (please specify)_____
b) *Campylobacter* (please specify)_____

4. Does your laboratory perform species identification of *Campylobacter*? (please select all relevant answers)
Includes both, phenotypic and genotypic testing

a) Yes, C. jejuni
b) Yes, C. coli
c) Yes, other species (please indicate species)_____
d) None of the above

5. Does your laboratory perform species/serovar identification of *Salmonella*? (please select all relevant answers)
Includes both, phenotypic and genotypic testing

a) Yes, species
b) Yes, all serovars
c) Yes, selected serovars (please indicate serovars)_____
d) None of the above

6. Does your laboratory perform antimicrobial susceptibility testing for *Salmonella* and/or *Campylobacter? (*select all relevant answers)
Includes both, phenotypic and genotypic testing

a) Yes, on all *Salmonella* isolates
b) Yes, on selected *Salmonella* isolates (please indicate the selection criteria)_____
c) Yes, on all *Campylobacter* isolates
d) Yes, on selected *Campylobacter* isolates (please indicate the selection criteria)_____
e) None of the above

7. Does your laboratory hold accreditation or certification for some or all laboratory services provided?
This could have been obtained for one or more methods under national or international standards for laboratory Services

a) Yes (please provide the details)_____
b) No

8. Does your laboratory use control material (specimens, DNA etc.) from a reliable source for quality control testing of the following methods? (please select all relevant answers)
Includes both, phenotypic and genotypic testing

a) Salmonella
   a. Detection
   b. Species identification
   c. Serovar identification
   d. Antimicrobial susceptibility testing
   e. No, the laboratory does not have access to controls from reliable sources

b) Campylobacter
   a. Detection
   b. Species identification
   c. Antimicrobial susceptibility testing
   d. No, the laboratory does not have access to controls from a reliable source

9. Has your laboratory participated in any external quality assurance (EQA) schemes for the following methods within the last 3 years? (please select all relevant answers)
Includes both, phenotypic and genotypic testing

c) Salmonella
   a. Detection
   b. Species identification
   c. Serovar identification
   d. Antimicrobial susceptibility testing
   e. No, laboratory did not participate in any EQAs

d) Campylobacter
   f. Detection
   g. Species identification
   h. Antimicrobial susceptibility testing
   i. No, laboratory did not participate in any EQAs

10. Does your laboratory provide testing services to other laboratories? (please select all relevant answers)
Include any type of tests for detection and characterisation of *Salmonella* and *Campylobacter*

a) Yes, for *Salmonella*
b) Yes, for *Campylobacter*
c) No

11. Is your laboratory a member of any of the following types of network? (please select all relevant answers)

a) National network of clinical laboratories
b) Regional network of clinical laboratories
c) National group of laboratories involved in capacity building activities in diagnostics and/or research
d) International group of laboratories involved in capacity building activities in diagnostics and/or research
e) No, none of the above

12. Does your laboratory participate in any type of national surveillance for *Salmonella* and/or *Campylobacter*? (please select all relevant answers)
a) Voluntary continuous surveillance
b) Mandatory continuous surveillance
c) Sentinel surveillance (for example by submitting data in shorter periods a number of times per year)
d) No, none of the above

13. What kind of support would you like to receive from the national reference laboratory (NRL) and/or national network?
a) Provision of control materials (isolates, DNA etc.)
b) Shipment of samples/isolates
c) External quality assessment (EQA) exercises for phenotypic antimicrobial susceptibility testing
d) Support for outbreak detection and management (including guidance)
e) Training/workshops for laboratory staff
f) NRL support visit to your laboratory
g) Long-term storage of isolates
h) Participation in laboratory network
i) Accreditation practices
j) Other areas of support
k) We are not interested in or able to join a national network and receive support from the network including the NRL

Specific part

Human resources, laboratory equipment and funding at local/regional laboratories

(section 4 in mapping summary report)

14. On a scale from 1 to 5, how would you rate staffing situation in relation to the workload resulting from the testing of *Salmonella* and/or *Campylobacter* in your laboratory (with 1 being not adequate at all and 5 being fully adequate)?
(e.g. diagnostic testing, quality assurance, participating in EQA, paperwork, training and continuous education of staff etc.)

15. On a scale from 1-5, how would you rate the situation in relation to qualifications and skills of technical staff for all types of *Salmonella* and /or *Campylobacter* testing in your laboratory (with 1 being not adequate at all and 5 being fully adequate)?
Please provide details for specific type of testing, if needed

16. On a scale from 1-5, how would you rate the situation in relation to availability of financial resources to perform *Salmonella* and/or *Campylobacter* testing in your laboratory (with 1 being not adequate at all and 5 being fully adequate)? (e.g. equipment and materials for diagnostic testing, quality assurance, participating in EQA, training and continuous education of staff etc.)

17. On a scale from 1-5, how would you rate the situation in relation to availability of documentation for all methods used in your laboratory (protocols, guidance for interpretation of results) for *Salmonella* and/or *Campylobacter* testing in your laboratory (with 1 being not adequate at all and 5 being fully adequate)?
Please provide details for specific methods, if needed

18. On a scale from 1-5, how would you rate the situation in relation to availability of documentation (SOPs, IQC, QA and biosafety procedures) for all types of *Salmonella* and/or *Campylobacter* testing in your laboratory (with 1 being not adequate at all and 5 being fully adequate)?
Please provide details for specific type of testing, if needed

19. On a scale from 1-5, how would you rate the situation in relation to availability of procedures for the procurement, inventory, use and storage of laboratory equipment, consumables and reagents for all types of *Salmonella* and/or *Campylobacter* testing in your laboratory (with 1 being not adequate at all and 5 being fully adequate)?
Please provide details for specific type of testing, if need

Salmonella and *Campylobacter* detection methods used in diagnostic laboratories
(section 5 in mapping summary report)

20. Which media does your laboratory use for culture-based detection of the following pathogens? (please select all relevant answers)
- *a) Salmonella*
  - a. Direct plating, please indicate media in use_____
  - b. Selective enrichment and selective plating, please indicate media in use_____
- *b) Campylobacter*
  - a. Direct plating, please indicate media in use_____
  - b. Selective enrichment and selective plating, please indicate media in use_____

21. What are the following procedures in your laboratory if *Salmonella* and/or *Campylobacter* is detected using culture-independent methods (please select all relevant answers)
- a) In all cases, the laboratory performs culture-based detection
- b) In selected cases, the laboratory performs culture-based detection
- c) All positive samples are sent to another laboratory for culture-based detection
- d) None of the above
- e) Other procedure, please specify_____

22. Does your laboratory store *Salmonella* and/or *Campylobacter*-**positive samples**? (please select all relevant answers)
- a) Yes, we freeze-store all samples (please specify the temperature and the length of the storage)_____
- b) We freeze-store only selected samples (please specify the temperature and the length of the storage)_____
- c) We store samples differently (please specify the temperature and length of the storage)_____
- d) We don't store positive samples

23. Does your laboratory store *Salmonella* and/or *Campylobacter* **isolates**? (please select all relevant answers)
- a) Yes, we freeze-store all isolates (please specify the temperature and the length of the storage)_____
- b) We freeze-store only selected isolates (please specify the temperature and the length of the storage)_____
- c) We store isolates in a different way (please specify the temperature and length of the storage)_____
- d) We don't store isolates

Salmonella and *Campylobacter* characterisation methods used in local/regional laboratories
(section 6 in mapping summary report)

24. Which of the following methods does your laboratory use for identification of *Salmonella* and/or *Campylobacter*? (please select all relevant answers)
- *a) Salmonella*
  - a. MALDI TOF

b. Biochemical tests
c. Antisera
d. Molecular methods
e. None of the above, please specify_____

b) Campylobacter

a. MALDI TOF
b. Biochemical tests
c. Molecular methods
d. None of the above, please specify_____

25. Does your laboratory perform antimicrobial resistance testing for the following antimicrobials? (please select all relevant answers)

Includes both, phenotypic and genotypic testing

a) Salmonella

a. Ampicillin (AMP)
b. Chloramphenicol (CHL)
c. Meropenem (MEM)
d. Cefotaxime (CTX)
e. Ceftazidime (CAZ)
f. Ciprofloxacin (CIP)/pefloxacin (PEF)
g. Gentamicin (GEN)
h. Colistin (COL)
i. Tetracycline (TCY)
j. Trimethoprim (TMP)
k. Azithromycin (AZM)
l. Sulfamethoxazole (SMX)
m. Tigecycline (TGC)
n. None of the above
o. Other antimicrobials, please specify_____

b) Campylobacter

a. Gentamicin (GEN)
b. Erythromycin (ERY)
c. Ciprofloxacin (CIP)
d. Tetracycline (TCY)
e. None of the above
f. Other antimicrobials, please specify_____

26. Does your laboratory perform phenotypic and/or genotypic AMR testing of bacterial isolates in compliance with the 'EU protocol for harmonised monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates'?

a) Yes
b) No (please specify the reason and which set of guidelines you follow instead)_____

27. Which phenotypic antimicrobial susceptibility testing guidance (for methodology and breakpoints) do you use in your laboratory? (please select all relevant answers)

a) EUCAST
b) CLSI
c) Other guidance, please specify_____

28. Which methods does your laboratory use for phenotypic testing of AMR in *Salmonella* and/or *Campylobacter*? (please select all relevant answers)

a) Automated system (e.g. Vitek)
b) Commercial broth microdilution (e.g. Sensititre/Trek)
c) In-house micro broth dilution
d) Agar dilution
e) Gradient strips (e.g. Etest)
f) Disk diffusion
g) Other methods, please specify_____

29. Which genotypic testing method does your laboratory use for testing the presence of antimicrobial resistance genes or point mutations in *Salmonella* and/or *Campylobacter* isolates? (please select all relevant answers)

a) Conventional PCR

b) Single-gene sequencing
c) Real time PCR
d) DNA array
e) Whole genome sequencing (WGS)
f) Other methods, please specify_____

30. Please indicate the purpose of antimicrobial resistance testing in your laboratory (please select all relevant answers)
a) To inform the clinicians on possibilities for antibiotic treatment
b) To inform infection prevention and control measures
c) Other purposes, please specify_____

31. Does your laboratory provide individual reports on testing results for *Salmonella* and/or *Campylobacter*? (please select all relevant answers)
Includes all types of tests
a) Yes, to hospitals/other healthcare facilities
b) Yes, to relevant public health authority
c) Other, please specify_____

Salmonella and *Campylobacter* isolate referral and linking to cases
(section 7 in mapping summary report)

32. Does your laboratory (or other authorities) issue guidance on sampling practices of patients suspected to be infected with *Salmonella* and/or *Campylobacter*? (please select all relevant answers)
Guidance can be issued by the laboratory, the hospital and/or local, regional or national health authorities and may contain instructions about populations to be sampled, use of antimicrobial therapy, possible exposure, etc..
a) Yes, *Salmonella*
b) Yes, *Campylobacter*
c) No, none of the above

33. Does your laboratory (or other authorities) issue guidance on submission of clinical samples (including types and quality of samples, shipment conditions and documentation required) to their users? (please select all relevant answers)
Guidance can be issued by the laboratory, the hospital and/or local, regional or national health authorities and may contain instructions about sample type, container and transport medium, transport method etc.
a) Yes, instructions on submissions of clinical samples are provided in a laboratory user manual/handbook /standard operating procedure document or information is provided on a website
b) Yes, instructions on submission of clinical samples are provided on request e.g. via phone calls from users
c) No, instructions on submission of clinical samples are not provided

34. Does your laboratory refer (send) newly detected isolates or positive samples to the national reference (or expert laboratory) laboratory for further testing? (please select all relevant answers)
a) Yes, *Salmonella*
b) Yes, *Campylobacter*
c) No, none of the above

35. Does your laboratory (or other department) routinely communicate pre-defined data sets on species/serovar ID and/or antimicrobial test results from your laboratory for any of the following purposes? (please select all relevant answers)
a) Infection prevention and control purposes
b) Local surveillance purposes (e.g. surveillance within the specific area, etc.)
c) Early warning purposes (e.g. accumulation of cases, new variants of concern)
e) No, none of the above

36. Does your laboratory (or other authorities) issue guidance on positive sample/isolate referral (includes handling, storage, transportation and frequency) from your laboratory to the national reference (or expert) laboratory? (please select all relevant answers)
Please answer 'yes' if guidance is followed by your laboratory staff
a) Yes
b) No
c) Other, please specify_____

37. Does your laboratory (or other authorities) issue test requisition form (e.g. may include background information about laboratory methods used in your laboratory, results, patient data) for positive sample/isolate referral from your laboratory to the national reference (or expert) laboratory? (please select all relevant answers)
Please answer 'yes' if guidance is followed by your laboratory staff
a) Yes
b) No
c) Other, please specify_____

38. How does your laboratory record information about samples/isolates tested in your laboratory (includes collection, tracking, storage and diagnostic test results)?

a) We use a pre-defined physical paper form
b) We use electronic laboratory information management system (LIMS) or software application (e.g.WHONET)
c) Other, please specify_____

39. How does your laboratory send laboratory data to the national reference (or expert) laboratory or to relevant public health authorities? (select all relevant answers)

a) We send a pre-defined physical paper form
b) We send a pre-defined form by email
c) We use a pre-defined web-based form
d) We have access to electronic laboratory information management system (LIMS) or software application (e.g.WHONET)
e) Other, please specify_____

40. Does your laboratory have access to case data for samples sent to your laboratory for *Salmonella* and/or *Campylobacter* testing? (please select all relevant answers)

a) Patient age
b) Patient gender
c) Travel information
d) Hospitalisation status
e) Underlying diseases
f) Antimicrobial treatment
g) None of the above
h) Other, please specify_____

41. Does your laboratory have procedures for laboratory test result recording, review and notification of laboratory results?

a) Yes
b) No
c) Other, please specify_____

42. Does your laboratory have procedures for patient and/or laboratory data protection and data loss?

a) Yes
b) No
c) Other, please specify_____

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