D3.3

Guidelines for the submission and selection of project proposals (Joint Research and Joint Integrative Projects)

WP3 Joint Research Projects

Responsible Partner: Sciensano

Contributing partners: ANSES, BfR, RIVM, SVA, UCM, University of Surrey, WBVR

GENERAL INFORMATION

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DOCUMENT MANAGEMENT

Deliverable	D3.3 Guidelines for the submission and selection of project proposals (Joint Research and Joint Integrative Projects)
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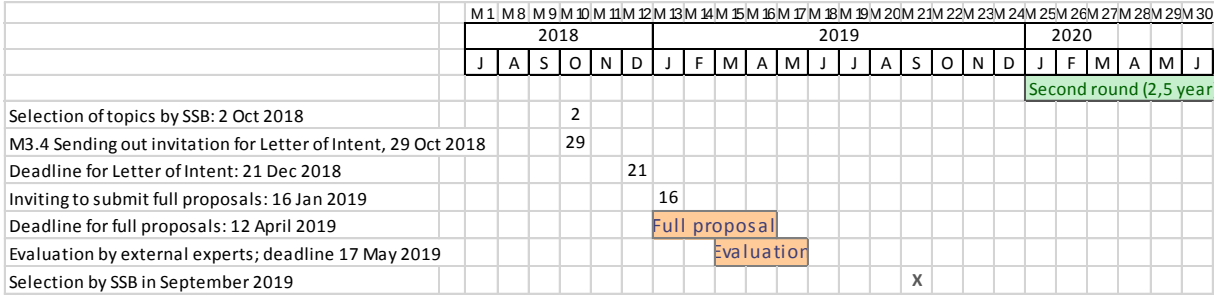
Guidelines
Second internal call for proposals for Joint Research Projects and Joint Integrative Projects

PROPOSAL SUBMISSION DEADLINES:

Invitation to submit a Letter of Intent:	October29, 2018
Deadline for receipt of Letter of Intent:	December 21, 2018 (8 weeks)
Invitation to submit full proposals:	January 16, 2019
Deadline for full proposals:	April 12, 2019 (12 weeks)
Deadline for external evaluation:	May 17, 2019 (5 weeks)
SSB meeting to select projects	September 2019
Expected communication on outcome:	October 2019



1. Call Background

The H2020 project OneHealth EJP involves a network of 38 partner organisations plus the Med-Vet-Net Association, most of which host reference laboratories in the fields of life sciences, medicine, public health, veterinary medicine, animal sciences and environmental sciences across 19 European countries.

OneHealth EJP **aims to create a network of research institutes** that focuses on foodborne zoonoses, antimicrobial resistance and emerging zoonotic threats. The context of the OneHealth EJP fits in the holistic and trans-disciplinary "One Health" approach, i.e. involving human health, animal health, food safety and the environment. A number of research and integrative activities are planned, such as information dissemination, education and training programmes, signal sharing and risk assessment structures, surveillance approaches, access to strain collections, bio-banks, databases, harmonization and standardization of diagnostic tests.

The **scope of the OneHealth EJP** is foodborne zoonoses, antimicrobial resistance and emerging threats in humans, animals and the environment, however, vectorborne zoonoses are excluded. As for

emerging threats, the focus is primarily on threats emerging from 2017, with a suspected zoonotic potential.

The **objectives** of the OneHealth EJP are:

- To build a sustainable framework for an integrated community of national public entities with research activities, most of them encompassing reference laboratories and existing zoonoses networks of institutes in the domains of life sciences, medicine, veterinary medicine, animal sciences, food sciences and environmental sciences;
- To integrate the complementary expertise of partners across Europe to identify, characterize and assess the risks related to transmission of emerging or re-emerging zoonotic pathogens, antimicrobial resistance and microbiological toxins in the interface of animals, food and humans; and
- To provide further tools to risk managers for the implementation of efficient prevention and control measures by using a One Health approach.

The operational **approach** of the OneHealth EJP is to enhance collaboration among beneficiaries through setting up common classic scientific projects (i.e. Joint Research Projects), projects where integrative activities among partners are dominant (i.e. Joint Integrative Projects) and activities such as PhD grants, summer school etc. (i.e. Education & Training).

- A **Joint Research Project** (JRP) typically is a classic, scientific study aiming at specific results fulfilling a research plan.
- A **Joint Integrative Project** (JIP) focuses on developing common approaches, databases, models, methodologies or protocols that support collaborative processes within the scope of the OneHealth EJP, such as platforms for uploading, sharing and analysing sequence data, experimental facilities or risk assessment structures. The deliverables of a JIP should become integrated into the work processes of project partners during the course of the project and allow for additional consortium partners to join after completion of the JIP.

Taking into account the multiple requests from the stakeholders ECDC and EFSA and from the Research Executive Agency, **special care should be taken to avoid duplication with recent or on-going EU** (or even national) **research projects** (see information requested in both the letter of intent and the full proposal).

See www. OneHealthEJP.eu for more information on the OneHealth EJP.

Following the organisation of the first internal call in 2016, resulting in the selection of 13 projects that commenced on 1 January 2018, the second call will lead to the launch of additional research and integrative projects in January 2020. Research consortia exclusively formed of beneficiaries of the OneHealth EJP and Linked Third Parties are invited to submit proposals related to defined priority topics (see section 2).

Please note that this is an internal call. Project consortia including organizations that are not beneficiaries nor Third Parties of the OneHealth EJP (see Annex 1) are not eligible for EU co-funding.

2. Topics for Joint Research Projects and Joint Integrative Projects

Research groups among the beneficiaries of the OneHealth EJP consortium are invited to submit proposals related to the priority topics listed in Annex 2 (Joint Research Projects) and Annex 3 (Joint Integrative Projects).

Proposals for a particular topic are expected to address most of the mentioned objectives.

3. Timeline

This internal call for project activities (Joint Research Projects and Joint Integrative Projects) involves a two-step submission procedure (see further). For details on the schedule for the submission of proposals, see above.

The **project period will be 2,5 years for both joint research and joint integrative projects**. There will be no opportunity to extend the selected projects of the second call.

The EC Horizon2020 requirements for European Joint Programmes include the submission of an annual summary progress report, a yearly intermediate report and an annual work plan. Project leaders will be asked to provide input into these OneHealth EJP reports. Furthermore, project leaders must comply with H2020 rules concerning, among others, ethics issues, dissemination and publication rules and the submission of a project specific data management plan. Both the OneHealth EJP WP3 and WP4 teams and the Support Team will guide project leaders through these mandatory tasks.

4. Budget

The OneHealth EJP is a five-year project that runs from January 2018 to December 2022. The OneHealth EJP falls into the concept of a co-fund action: it is 50% funded by the EC for 45 M€ and 50% funded by the organizations forming its consortium for another 45 M€. Therefore, the costs for implementing the OneHealth EJP reach a total of 90 M€.

There are two types of activities within the OneHealth EJP:

1. The **overarching activities** such as project governance, management, communication and sustainability, which are dedicated to the interest of the whole OneHealth EJP community. For this reason, these overarching activities are 100% financed by the EC funds. 10% of the total costs of the OneHealth EJP projects (9 M€) are set aside for these overarching activities.
2. The **scientific and integrative activities** such as JRPs and JIPs, as well as the training and education activities, which are carried out by the OneHealth EJP partners. These activities are therefore co-financed for 56% by the project partners and for 44% by the EU funds. In conclusion, 90% of the total costs of the OneHealth EJP (81 M€) will be dedicated to finance the scientific and integrative activities.

The following **budget allocation** can be given **for the second call of projects**:

- Joint Research Projects: a total of 23.0 M€;
- Joint Integrative Projects: total budget of 17.5 M€.

The Scientific Steering Board, in its meeting of October 2nd 2018, validated the allocation of 40.5 M€ to research and integrative projects for the second call for proposals.

The detailed breakdown of the budget per selected topics is as follows:

Activity	Domain	Topic	Maximum total budget (M€)
JRP	FBZ	5 topics (see below)	13.5
	AMR	2 topics (see below)	5.0
	ET	2 topics (see below)	4.5
JIP		4 topics (see below)	17.5
	GRAND TOTAL		***40.5***

5. Background facility

On the private part of the **One Health EJP website** (see the public group "Second call for research and integrative projects") a **forum** is available that can be used to look for suitable consortium partners, to present your expertise and capacities or simply to propose new ideas. Also **background documentation and templates** necessary to complete proposals are available on this page.

It is therefore essential that Project Leaders connect to the private part of the One Health Website:

- One Health EJP URL: https://onehealthejp.eu/;
- To access the private part you must first register (register button is in the upper right part of the home page);
- Once registered and accepted, you need to request access to the "Second Internal Call for Research and Integrative Projects" group (groups page link is in the upper right part of the home page);
- Once your access request is accepted, you have full access to all facility and documentation necessary to successfully submit your proposal.

Remind that proposals are expected to be submitted by e-mail (see below).

6. Identification of project leaders and selection of proposals

The project leader

The project leader has the following tasks:

- be the single contact point on behalf of the consortium partners in that project;
- submit the full-proposal on behalf of the consortium partners by means of the specific template;
- manage the research project or integrative project and be responsible for its progress;
- compile and submit reports/deliverables to the Support Team on behalf of the research consortium;
- ensure that the project adheres to H2020 rules regarding e.g. ethics issues, dissemination and publication rules as well as drafting and implementing a plan for data management.

The project leader must inform the OneHealth EJP WP3 Leader or WP4 Leader of any event that might affect the implementation of the project.

The procedure for submission of project proposals

Project proposals must be sent by e-mail to the Support Team as listed below (see contact details below)

This procedure encompasses two steps:

1. Submission of a short preliminary description of the proposal. Candidate project leaders demonstrate their interest to the OneHealth EJP Coordinator by submitting a **Letter of intent**. At this step, there will not be any selection, but proposals will be checked for eligibility. Furthermore, recommendations on changes in scope or on combining similar project ideas may be given.
2. Submission of a **full proposal** that will be evaluated by independent external scientists. A selection of these proposals will be proposed for funding based on defined criteria.

A Submission of Letter of Intent: Identification of the project leaders

Partners of the OneHealth EJP should first demonstrate their interest in setting up a Joint Research Project or Joint Integrative Project that is anticipated to start on January 1st, 2020. To do so, the candidate project leader has to fill in a template (maximum 5 pages; Annex 4) that collects the following data:

- Title of the proposal, type (JRP or JIP) and priority topic to which the proposal refers;
- Identification of the candidate project leader (name, affiliation);
- Identification of partners:
    - Name of organisation, scientific contact person for each organisation
    - Spread over the EU regions (N, E, S, W)
    - Expertise: animal or public health, feed, food and environment
    - Strategy to form the consortium (expertise that has been looked for) and efforts done to involve partners, in particular those that have not led to inclusion in the proposed project consortium.

  Remarks:

    - **At the time of the submission of the letter of intent, not all partners need to be identified**;
    - To facilitate the search for partners, the forum on the "Second Internal Call for Research and Integrative Projects" group on the private space of the OHEJP Website (www. OneHealthEJP.eu) should be used (matching the best capacity and competences with expertise needed).
- Clarification of which of the objectives of the priority topic will be met and how;
- A broad description of the proposal (about 1 page);
- A general work plan description (about 1 page);
- Detailed reference (hyperlink, doi etc.) to an EU level opinion document, strategic research agenda, expressed key EU Stakeholders needs or similar that shows that the project proposed falls within the EU priorities. The applicant should also show awareness of earlier and ongoing work (e.g. recent or actual EU funded projects; for instance see Annex 5: List of related on-going EU projects), activities of ECDC, EFSA and European Commission, and explain in what way this work is complementary (i.e. to avoid redundancy and duplication of work) (abstract, about 1 page);
- Contribution of the project to the overarching objectives of the OneHealth EJP, i.e. alignment and integration of EU capacity, and impact of the expected results on the overall preparedness and response of the partners;
- The expertise of the project partners in this field (incl. most relevant publications) or evidence of leading developments in the relevant field (for integrative projects);
- Estimation of the total budget needed for the project (i.e. total budget; costs will be co-funded for 44% by the EU and for 56% by the partner organisations forming the project consortium).

To prevent possible conflicts of interest, the following will be checked:

- One Health EJP Scientific Steering Board members must not be a candidate project leader or deputy leader of the proposal, nor should they represent their institute in any work package of the proposal (task leader), and
- The members of the OneHealth EJP Project Management Team must not be a candidate project leader or deputy leader of the proposal.

The submission of the letter of intent implies that all Scientific Directors or equivalent of the respective OneHealth EJP beneficiaries agree with its content (see paragraph: Formal commitment of the partner organisations).

The duly filled-in letter of intent has to be sent to the Support Team (see contact details below). Every letter of intent will be considered (eligibility check by WP3 and WP4) according to:

- the consortium composition: a minimum of 5 organisations from 5 different countries, at least one public health (Med) and one animal health (Vet) organisation; for JIP proposals it is anticipated that the countries represented in the consortium participate with at least one Med and one Vet partner (with an exception for countries where only one of the two are represented in the consortium), and that at least 7 different countries are covered;
- the geographical spread: at least one country from three of the four European regions North (DK, EE, NO, SE), East (BG, CZ, HU, PL, RO), South (ES, IT, PT) and West (AT, BE, DE, FR, IE, NL, UK); special effort should be undertaken to include those OneHealth partners that are not participating in the on-going projects from the first, 2016 call (see "Second Internal Call for Research and Integrative Projects" group on the private space of the OHEJP Website (www.OneHealthEJP.eu) for details);
- compliance with the objectives described in the priority topic description;
- at least one detailed relevant reference to a EU level opinion document, strategic research agenda, EU stakeholder need or similar;
- the efforts taken to avoid duplication of work, amongst others, with recent or ongoing EU projects/initiatives (see Annex 5: List of on-going EU projects);
- the proposed funding amount as described under Annex 2 (Joint Research Projects) and Annex 3 (Joint Integrative Projects).

The OneHealth EJP Coordinator, in consultation with the Work Package leaders and deputy leaders (i.e. the Project Management Team) may:

- reject the proposal if the above-mentioned criteria are not entirely met; in that case, the candidate project leader will not be invited to submit a full proposal,
- recommend the candidate project leader to readjust the proposal to better suit the objectives of the related topic description,
- propose candidate project leaders to combine their proposals if these are related to the same priority topic.

This decision should be clearly articulated when providing feedback to the candidate project leaders. During the evaluation phase of the full proposals, the PMT will assess whether the recommendations for readjustment or merging have been followed.

The appointed project leaders will submit their full proposal to the OneHealth EJP Support Team (see below).

Contact details of the OneHealth EJP WP3 & WP4 teams and Support Team

OneHealth EJP WP3 Team (Joint Research Projects): Hein Imberechts, Fanny Baudoin and Hendrik-Jan Roest

Phone H. Imberechts: +32 474 989 843 Email: ohejp@sciensano.be

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Phone H-J. Roest: +31 320 238 026OneHealth EJP WP4 Team (Joint Integrative Projects): Ann Lindberg and Manuela Caniça

Phone A. Lindberg: +46 707 783 322 Email: ohejp-jip@sva.se

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OneHealth EJP Support Team: Arnaud Callegari and Camille Pestre

Phone A. Callegari: +33 149 773 868 Email: ohejpcoord@anses.fr

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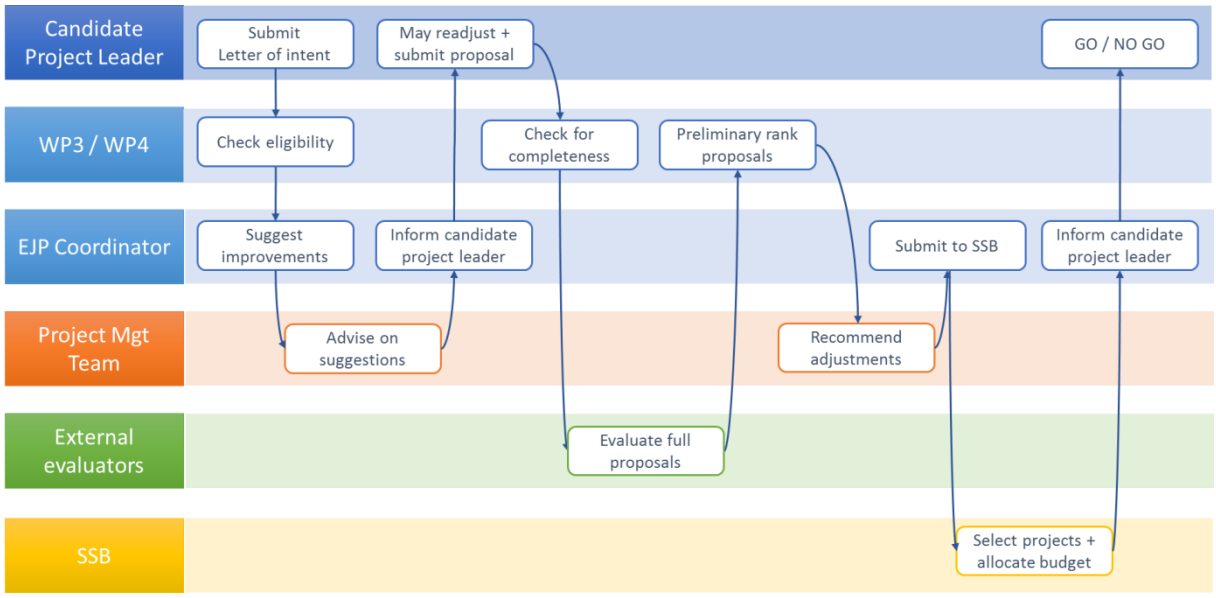
B Submission and Selection of Full Proposals



Flow of the proposal and interaction with the various partners in the evaluation process

Full proposals have to be submitted to the OneHealth EJP Support Team. Their evaluation will be administered by the WP3 and WP4 teams for the Joint Research Projects and Joint Integrative Projects, respectively. Their role is:

- To check for completeness of the dossier and to maintain an overview (e.g. priorities, budget, timing, …) of the project proposals;
- To contact external experts in order to evaluate the project proposals, to collect the scientific evaluations and to make a preliminary rank of the proposals;
- To transfer the evaluated proposals and accompanying documents (e.g. evaluation sheets) to the OneHealth EJP Coordinator.

Invitation to submit the full-proposal

The following information in the application is mandatory (**please describe concisely**; estimation for a consortium with 15 partners: about 25 pages, corresponding to more or less 12.500 words; see specifications per item):

Title and acronym of the proposal

Type (JRP or JIP) and priority topic to which the full proposal refers

Name of the project leader and of all applicants, with full affiliations

Short CV of each participating key scientist (at least one per participating organization) (max 10 lines each person)

This part summarise the major activities and competencies of the person over the last 5 years.

- Name of organisation, scientific contact person for each organisation
- Spread over the EU regions (N, E, S, W)
- Expertise: animal or public health, feed, food and environment
- Information that indicates the coordinator's skill to manage international projects

Objectives description

Clearly indicate the objective(s) in the priority topic description that will be dealt with in your project and how (maximum half a page).

Project abstract

Brief summary of proposed research or development programme (maximum half a page).

Background

Detailed background on the project and state of the art in the field should be given, as well as a description of the impact the project may have. (maximum one page).

Progress beyond state of the art

Explain what progress or novelty will be made beyond the current state of the art (maximum half a page).

Project aims

Describe achievements of proposed research or developments (maximum one page).

Work plan

The overall work plan shall include:

- The name of each Work Package and how they are linked together
- A Gantt and a Pert chart
- Explain the role and involvement of each participating organization

Maximum 5 pages.

Annual Work package description (please complete one Annex 7 per WP per year of implementation: total 3 annexes, one for 2020, one for 2021 and another one for 2022)

- Organise the work package into tasks and sub-tasks when necessary.
- Appoint a Work Package leader for each Work package, and Task and sub-tasks leaders when appropriate (leaders shall be clearly identifiable. Their role is to coordinate the work. They also endorse the responsibility that the work is carried out as described).
- Include milestones (intermediate steps that focus on major progress points) and deliverables (outputs or products at a given moment during the project).

Maximum 1.5 pages per WP.

Alignment and integration

Describe how this international cooperation will strengthen the partner organizations in terms of a common technology, method, approach etc. and how it will lead to the harmonization of technological and scientific knowledge. Describe the search for added value that cannot be reached by the individual partners, the aim to improve the organizations' performances, how the international cooperation will lead to a better integration of OneHealth partners in the objectives of the OneHealth EJP (maximum half a page).

For JRPs, describe any integrative activities that your project will encompass, for example:

Capacity building / training
Experimental facilities
Detection / typing methods / protocols / GLP

Strain collection / reference materials / bio-banks
Digital infrastructure / databases / data sharing protocols / data access / bioinformatics
Surveillance strategies / reporting / signalling
Legal / policy aspects

Relation to ongoing national and international projects/activities relevant to the present proposal

Description of the efforts done to scan related ongoing or recently terminated projects and activities of key EU stakeholders. Please clearly indicate how selected projects contribute to (and do not overlap with) other existing activities funded at EU or even MS level.

Resources requested

Description of human resources, equipment, subcontracting, travel and other additional costs of planned project (maximum half a page).

Budget (please complete Annex 8)

Indicate all planned costs in the different proposed cost items.

Training opportunities

Description of training and/or exchange activities foreseen in the project, if applicable (maximum half a page).

Ethics (please complete Annex 9)

Please fill in the self-assessment (Annex 9). This document will be evaluated by two Ethics Advisors familiar with the OneHealth EJP. If the proposal is accepted for funding, the Ethics Advisors will draft recommendations that project leaders will have to adhere to.

Literature references

Maximum 10 literature references can be listed related to the project by providing the author, title, journal, year, volume, pages; etc. These literature references shall refer to the proposal.

Keywords

Provide up to 5 keywords to describe the scientific scope or integrative nature of your application; the keywords will inter alia be used to identify and assign external experts to your project.

Duration of the project

The maximum duration is fixed at 2,5 years, mandatorily from 1st January 2020 up to 30th June 2022.

The OneHealth EJP's WP3 and WP4 will check the proposals for completeness (eligibility check) and send the documents to the external evaluators for assessment.

Certificate of co-financing (please complete one Annex 10 for each participating organisation)

This certificate aims at ensuring that each participating institute accepts to engage the necessary co-financing in order to implement the project.

Scientific evaluation by external experts

The evaluators must not belong to the OneHealth EJP partner organisations. To promote the comparison of the outcome, all related proposals (i.e. submitted within a specific priority topic or a domain, or the JIP proposals) will, if feasible, be assessed by the same evaluators. Each proposal will preferably be evaluated by three experts.

A specific procedure for the evaluation process will be provided to the evaluators.

The following criteria will be taken into account by the external evaluators:

- Ability to align with call text objectives: How well does the proposal adhere to the objectives listed in the topic description?
- Scientific excellence and/or innovative approach: Does the project propose a sound and scientifically qualified concept that promises progress beyond the state-of-the-art? Are the

objectives realistic, are the scientific and technological methodologies and the work plan convincing? Is a multi-disciplinary approach stimulated?

- Quality and efficiency of the implementation: Projects should be assessed for the coherence and effectiveness of their work plan, including appropriateness of the allocation of tasks and resources; complementarity of the participants within the consortium; appropriateness of the management structures and procedures, including risk and innovation management. Also the effectiveness of the proposed measures to exploit and disseminate the project results, to communicate the project, and to manage research data where relevant should be evaluated.
- Integration
    - For JRP: Does the project contain relevant integrative activities (i.e. capacity building, development of protocols, strains and biobank collections, databases, surveillance strategies, legal aspects) that will allow partner organisations to improve harmonization or alignment in order to better support their prevent-detect-response tasks within the scope of the project topic?
    - For JIP: Will the project aim at the cooperation and collaboration of a larger group of organizations and member states to attain the general objective of the OneHealth EJP, i.e. to improve preparedness and prevent-detect-response? Will additional organizations be able to join at a later stage?
- Sustainability and impact. Will the outcome of the project have consequences over a long period of time or rather provide punctual response? Is the project outcome likely to have a positive long term impact on the economy (free travel over borders, trade of animals and food, recall of contaminated food stuffs etc.), the environment (impact of preventive and mitigating measures, reduce transportation, etc) and is there a potential for providing evidence for EU policies in the relevant domain (foodborne zoonoses, antimicrobial resistance)?

The evaluations will be collated by the WP3 and WP4 teams for the Joint Research Projects and Joint Integrative Projects, respectively. All projects will be ranked according their scores, per priority topic. One or more post-assessment meetings with the evaluators are envisaged in order to come to a consensus about the ranking.

The Project Management Team will discuss the ranking and may recommend adjustments (e.g. to allow responding to an actual epidemiological situation, in order to broaden the variety of topics, if concluded that the full proposal did not sufficiently take into account the recommendations expressed when assessing the letter of intent, etc.), and should thoroughly justify its advice.

Subsequently, the OneHealth EJP Coordinator will submit the project proposals and their ranking to the Scientific Steering Board.

Final assessment of the research proposals by the Scientific Steering Board

The ranked JRP and JIP proposals, including the evaluation forms and other relevant documents, will be submitted to the Scientific Steering Board for their assessment and the final selection of projects to be funded.

An SSB meeting is planned for September 2019. The SSB will make its decision based on the external assessment of the proposals, the eligibility criteria, the available budget and advice of the PMT. Preferably the decision will be made based on consensus and should be explained.

Subsequently, the WP3 and WP4 teams will contact the project leaders to inform them on the outcome. Projects are due to start January 2020.

7. Formal commitment of the partner organisations

As selected projects are 44% EU funded, each participating partner organisation of each selected project must fill in annex 10 certificate of co-financing, in order to certify that expected amounts to be co-funded will be made available in course of implementation of the project.

Without this formal commitment of each partner organisation of a selected project, a project cannot start in January 2020.

8. Ethics

All project proposals will include an ethics self-assessment (Annex 9), properly filled in by the candidate project leader. Under the condition of its selection by the Scientific Steering Board in September 2019, the project proposal and the self-assessment will be evaluated by the Ethics Advisors who are acquainted with the OneHealth EJP. The advisors will determine possible ethics issues according to the H2020 rules and will recommend relevant actions, which project leaders will have to adhere to after the start of their JRP or JIP.

9. Legal aspects

The selected JRPs and JIPs will be included in the OneHealth EJP's Annual Work Plans of year 3, 4 and 5. As such, the selected JRPs and JIPs will follow the rules of H2020 and the OneHealth EJP Consortium Agreement with respect to scientific and financial management, data management and reporting, and legal aspects such as access rights and Intellectual property rights.

10. Annexes

All documents will be available on the OneHealth EJP website.

Annex 1. OneHealth EJP beneficiaries

Please see www.OneHealthEJP.eu for the composition of the OneHealth EJP consortium.

Annex 2. Priority topics for Joint Research Projects

Foodborne domain list

FBZ 2.1: Source attribution of bacterial foodborne zoonoses and antimicrobial resistance considering also the environment and non-livestock reservoirs (e.g. pets and wildlife) as sources

Context

Several bacterial foodborne pathogens of zoonotic origin and their antimicrobial resistance patterns have a complex and multifaceted epidemiology. Current source attribution studies for these pathogens mainly focus on food-producing animal reservoirs and transmission routes other than those mediated by the environment. Improved knowledge on the epidemiology of these pathogens requires expanding the range of potential sources and transmission routes to include also the environment and non-livestock reservoirs, such as pets and wildlife.

Objectives

- To fill knowledge gaps regarding potential sources of foodborne zoonoses.
- To critically assess and improve existing models (including risk assessment models) for source attribution of zoonotic bacterial pathogens and antimicrobial resistance, explicitly including the natural environment, wildlife and companion animals as potential sources.
- To quantify the contributions of the main domestic/wild animal, food (including the retail level) and environmental sources and transmission routes to the burden of zoonotic bacterial pathogens and antimicrobial resistance, typically transmitted through contaminated food or water, with consideration of geographical differences throughout Europe and consortium partners.
- To use both conventional and novel (NGS-based) typing techniques for pathogen and antimicrobial resistance characterization, as well as epidemiological data, for the purposes of source attribution.
- To develop new or improve existing models for source attribution that account for multi-directionality of transmission: from sources to humans and vice versa, as well as transmission among sources and within the human population itself.

Expected results

- Updated knowledge on sources of foodborne zoonoses and antimicrobial resistance.
- Quantitative estimates for the sources and transmission routes of bacterial pathogens and antimicrobial resistance that also account for the environment, non-livestock reservoirs, and geographical differences.
- Development of novel or improved source attribution models and baseline knowledge resources to trace the origins and transmission routes of bacterial foodborne pathogens and antimicrobial resistance.

Requirements

Not defined

Estimated total cost for this topic

3 M€ (i.e. 44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium).

FBZ 2.2: Benchmarking biosecurity practices for pig farming across Europe using national surveillance data and management standards for identifying best practice to prevent biological hazards, particularly Salmonella and hepatitis E virus, from entering the food supply chain

Context

Farm biosecurity is the combination of all preventive measures and practices implemented to keep infectious diseases and pests away from the animals as to optimize animal health, productivity and safety of food products of animal origin. Preventing the introduction and spread of zoonotic pathogens, as well as of pathogens requiring antimicrobial treatment, in the farm environment is of primary importance. This topic focuses specifically on pig farm biosecurity. Due to differences in pig production systems across countries and taking into account the ever-evolving nature of husbandry practices, environmental (climate) conditions and epidemiological patterns of certain biological hazards, the optimal solution in one area might not be optimal in another. It is therefore important to identify best practice in different countries. There are many microorganisms and problems that need to be tackled in pig farming, so it is necessary to keep a broad perspective on the topic, but particular attention is given to Salmonella and hepatitis E virus (HEV), as they are a specific public health concern in this sector across Europe.

Objectives

The overall aim of the research projects within this topic is to enable authorities, the industry, and veterinarians to implement best practice for pig farming in order to prevent entry and spread of zoonotic pathogens and antimicrobial resistance in the food supply chain.

- To benchmark biosecurity systems for pig farming across Europe in order to identify best practice for efficient and cost-effective biosecurity in pig farms, considering also possible effects at post-production (e.g. retail) level if possible/relevant, with emphasis on Salmonella and HEV. Interventions to be considered include surveillance/control programs, vaccination, cleaning and disinfection practices, farm management practices and feeding practices, including the impact of microbiotas (competitive exclusion).
- To develop tools to evaluate the effectiveness of biosecurity interventions and tools to evaluate the cost-effectiveness of such interventions.
- To develop education and communication tools for farmers, veterinarians and the food industry.
- To use a farm-to-fork approach to the greatest adequate extent in terms of bringing together research actors from different 'silos' (e.g. farm biosecurity and processing controls).
- To ensure that projects build on efforts of ongoing EU wide activities, such as HEV-net.

Expected results

- Easily available best practice guidelines and scoring/evaluation systems for biosecurity measures for pig production systems and the relevant stakeholders to be used as a decision support system.
- Methods for evaluating the effectiveness of implemented biosecurity measures in pig farms.

– An inventory of possible biosecurity measures and their cost-effectiveness for zoonotic pathogens of public health significance, including but not limited to Salmonella and HEV, in different pig farming situations.

Requirements

It must be ensured that **projects build on efforts of ongoing EU wide activities**, such as HEV-net. Proposals should also build on existing results provided from the FP7 EU funded project EFFORT and demonstrate how duplication is avoided. The consortium should explain how they engaged with the EFFORT team to ensure complementarity and how they would, if possible, share existing data and infrastructures.

Estimated total cost for this topic

3 M€ (i.e. 44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

FBZ 2.3: Source attribution and transmission routes of foodborne pathogens other than bacteria, with emphasis on Toxoplasma gondii

Context

Source attribution studies have mainly focused on bacterial foodborne pathogens and less on parasitic and viral pathogens of zoonotic origin. This topic aims to fill this gap by encouraging research projects aiming at tracing the sources and transmission routes of non-bacterial foodborne pathogens, with particular emphasis on *Toxoplasma gondii*, one of the most common parasites in developed countries.

Objectives

– To develop novel or improve existing models (including risk assessment models) for source attribution of non-bacterial zoonotic pathogens, including all relevant domestic/wild animal, food (including the 'retail level') and environmental sources. Both bottom-up and top-down source attribution modelling approaches may be used.

– To quantify the contributions of the main animal, food and environmental sources and transmission routes to the burden of non-bacterial zoonotic pathogens, with emphasis on *T. gondii* among others. Geographical differences in epidemiology should be addressed.

– To use both conventional and novel (NGS-based) techniques for pathogen typing, as well as epidemiological and risk assessment frameworks, for the purposes of source attribution.

– Regarding *T. gondii* in particular, proposals should consider research that has been done on this pathogen and to explicitly address whether and how the project results would contribute to the development of innovative and effective interventions.

Expected results

– Quantitative estimates and risk assessments for the sources, transmission routes, and geographical differences of foodborne pathogens other than bacteria, particularly *T. gondii*.

– Development of novel or improved source attribution models and baseline knowledge resources to trace the sources and transmission routes of non-bacterial foodborne pathogens.

– Outcomes providing a basis for the development of innovative and effective interventions.

Requirements

Not defined

Estimated total cost for this topic

3 M€ (i.e. 44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

FBZ 2.4: Determinants of the reversal of the decreasing trend in Salmonella incidence in humans and poultry in the EU

Context

The significantly decreasing EU-wide trend in lab-confirmed human salmonellosis cases has levelled off during 2012-2016, and the proportion of human *Salmonella* Enteritidis infections has increased. At primary production, the EU prevalence of *S*. Enteritidis in laying hens has also stopped decreasing and has even increased in recent years. The reasons for the reversal of such decreasing trends in the EU in humans and poultry are largely unknown. Speculations have been made about a possible premature relaxation of Salmonella control measures in poultry, including vaccination programmes and hygiene controls, as well as possible deficiencies in the enforcement of existing rules by certain authorities and sensitivity of statutory sampling programmes in commercial laying hen flocks with low within-flock prevalence, which could challenge the identification of positive flocks. Other explanations could be improvements in reporting and ascertainment of cases in national surveillance programs, emerge and spread of more virulent strains, and/or increased exposure to potential (and possibly hitherto under-recognized) sources of infection.

Objectives

- To identify determinants of the increase in Salmonella incidence in humans and poultry in several European countries, trying to explain why the reversal of the decreasing trend in some countries was more pronounced than in others.
- To perform cross-sectorial investigations on the performance of surveillance systems for human salmonellosis and Salmonella control programmes in animals, making sure to avoid duplication with ORION activities.
- To perform studies on the possible changing (molecular) epidemiology of Salmonella in humans and animals, taking into account possible changes in exposure patterns.

Expected results

- Identification of the causes and co-causes leading to the reversal of the decreasing trend in Salmonella incidence in humans and poultry in the EU.
- Identification of new opportunities for better control measures and monitoring of Salmonella at farm level as to re-establish a decreasing trend in Salmonella incidence in humans and poultry.
- Identification and characterization of potential “high-risk” Salmonella clones involved in the recent upsurge, including their development, as well as molecular and epidemiological signatures.

Requirements

To explicitly consider an EFSA opinion on this matter expected to be released in January 2019 to the greatest adequate extent when submitting the full project proposal.

Estimated total cost for this topic

3 M€ (i.e. 44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

FBZ 2.5: Better tools for detection and investigation of foodborne outbreaks, including antimicrobial resistant pathogens, as well as economic assessments of potentially increased cluster detection through whole genome sequencing

Context

There is a need to reengineer national and supranational event-based surveillance and response systems for infectious diseases to improve detection and investigation of foodborne outbreaks, including outbreaks of antimicrobial resistant pathogens. Public health, food safety and animal health experts all need to have access to such surveillance and response systems to ensure a One Health approach.

Objectives

- To develop combined epidemiological and bioinformatics tools for improved foodborne outbreak detection and investigation (e.g. algorithms for real-time data analysis and visualisation), including outbreaks of antimicrobial resistant pathogens, based on the most advanced and complete typing (e.g. WGS) and epidemiological (e.g. person, space and time) information.
- To develop bioinformatics tools allowing for direct data comparability and interoperability (e.g. in silico reconstruction of different typing schemes).
- To facilitate the interacting use of such tools by public health, food safety and animal health experts at local, national and international levels.
- To assess the potential direct and indirect economic impact of such improved surveillance and response systems at the national and EU level.
- To ensure that the development of tools for WGS will be compatible with the work and mandate of EU wide systems and organizations in these areas.

Expected results

- An integrated surveillance dashboard in which molecular and epidemiological data for foodborne pathogens and their antimicrobial resistance profiles can be interactively analysed, visualized and interpreted by different stakeholders, making sure to avoid overlap with ORION activities.
- Bioinformatics tools for in silico conversion of high-throughput genome sequencing data to different typing schemes, including functional genomic screens.
- Economic assessments of potentially increased cluster detection through improved WGS surveillance for foodborne pathogens.

Requirements

Microbiologists, bioinformaticians, molecular biologists, epidemiologists from at least four partner organizations in at least four countries as key partners with experience in molecular epidemiology, NGS and bioinformatics, plus at least eight associated partners with access to NGS (from at least eight countries).

Proposals should build on existing results provided from the H2020 EU funded project COMPARE, and demonstrate how duplication is avoided. The consortium should explain how they engaged with the COMPARE team to ensure complementarity and how they would, if possible, share existing data and infrastructures.

Estimated total cost for this topic

2.8 M€ (i.e. 44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

IMPORTANT REMARK FOR THIS TOPIC

Proposals for this topic should consist of two parts:

- Part 1 should address the topic without 'economic assessments of potentially increased cluster detection through whole genome sequencing'. For this part of this topic **1.5 M€** has been allocated;
- Part 2 of the proposal should address the 'economic assessments of potentially increased cluster detection through whole genome sequencing'. To this part of this topic **1.3 M€** will be allocated only under the condition that this amount of budget becomes available at the project selection step through underspending of the total budget for research projects.

Antimicrobial Resistance domain list

AMR 2.1: Development of new tools for early (real-time) detection of resistant pathogens in humans and animals, as well as new diagnostic tools, in particular on-site tests for humans and animals

Context

The EU action plan on AMR calls for several actions, focusing on the areas with the largest benefits for MSs, e.g. promoting the prudent use of antimicrobials, enhancing cross-sectorial work, improving infection prevention, and consolidating surveillance of AMR and antimicrobial use. Improved knowledge on detection, effective infection control and surveillance, as well as development of novel diagnostics are key objectives of the "Boosting research, development and innovation on AMR" pillar of the action plan.

Objectives

- To develop new tools for early (real-time) detection of resistant pathogens in humans and animals.
- To develop new diagnostic tools for AMR in humans and animals, in particular on-site tests.
- To support the use of IT solutions in developing tools for diagnosing resistant infections in human and animal populations.
- To ensure that the development of new tools will be compatible with the work and mandate of EU wide systems and organizations in these areas.

Expected results

- New tools that can be easily used by different stakeholders for early warning of emerging resistant pathogens in different human and animal populations.
- New on-site diagnostic tests and IT solutions for AMR in humans and animals that will encourage/facilitate the uptake of AMR diagnostics in medical and veterinary practice.

Requirements

Not defined

Estimated total cost for this topic

2 M€ (i.e. 44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

AMR 2.2: Dynamics of AMR selection, clonal spread and horizontal gene transfer in humans, animals and the environment, including epidemiology of resistant microorganisms and antimicrobials in the environment and their (environment-mediated) spread

Context

There are several gaps and inconsistencies in our understanding of the epidemiology of AMR. This concerns mainly the dynamics of AMR selection, clonal spread and horizontal gene transfer in human and animal populations, as well as the epidemiology of resistant microorganisms and antimicrobials in the environment and their environment-mediated transmission pathways.

Objectives

- To study the origins and transmission dynamics of resistant bacteria (e.g. import vs. local selection, zoonotic vs. anthropogenic vs. environmental transmission).
- To study clonal spread of resistant bacteria vs. horizontal gene transfer in the dissemination of resistance within the One Health approach.
- To investigate geographical differences and trends in AMR and antimicrobials in the natural environment, including the influence of animal husbandry on the occurrence and spread of AMR and antimicrobials in the environment and in people living in proximity to farms.
- Special attention should be focused on multidrug and emerging resistances, in addition to resistance to critically important antimicrobials for human and animal treatment.
- Multidisciplinary approach including microbiology, genomics (i.e. WGS) and epidemiology should be used.

Expected results

- Identification and characterization of mechanisms and underlying drivers of AMR development, selection, transmission, clonal spread and horizontal gene transfer in humans, animals and the environment relevant for the European setting.
- Evidence for geographical differences and trends in AMR and antimicrobials in the environment, as well as the ecological consequences of antimicrobial usage in animal husbandry.
- Models explaining the links between antimicrobial usage in animals, AMR in the environment, and the risks for public health.

Requirements

Proposals should build on existing results provided from the FP7 EU funded project EFFORT, and demonstrate how duplication is avoided. The consortium should explain how they engaged with the EFFORT team to ensure complementarity and how they would, if possible, share existing data and infrastructures

Estimated total cost for this topic

3 M€ (i.e. 44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

Emerging Threats domain list

Scope of **new emerging threats** in the context of the OneHealth EJP: the focus is primarily on threats emerging from 2017, with a suspected zoonotic potential. Research should support elucidating the aetiology, epidemiology or pathogenesis of the causative agent or should support the improvement of early warning, preparedness or response. Vectorborne zoonoses are excluded.

ET 2.1: Development of a toolkit to characterize emerging threats by combining genomic and phenotypic information

Context

Microbiological threats are often unpredictable, irrespective of the efforts aiming at mitigating the effects of antimicrobial usage, as well as their minimisation or prevention. In spite of implementation of networks for signalling of microbiological threats across Europe (i.e. EWRS, EMERGE, ENIV, RASFF), including imported pathogens, food-transmitted or zoonotic, and exchanging information on emerging pathogens, there is still potential for improvement of preparedness and response to such threats. There is a need to develop rapid tools to characterize emerging threats by combining genomic and phenotypic information, as well as epidemiological data, as to allow for early detection, identification and control of emerging threats, and ultimately, for fast and appropriate decision making and response.

Objectives

- To develop new or adapt existing methods and tools to characterize emerging threats by combining genomic and phenotypic information along with new sources of epidemiological data (i.e. digital epidemiology) in cooperation with established networks like EMERGE, ENIVD, EWRS, IHR.
- To allow for early detection, identification, and characterization of emerging threats, including novel tools for analysis and sharing of epidemiologically relevant data -on zoonotic bacterial, viral and parasitic food- and waterborne threats, as well as on emerging antimicrobial resistance or virulence patterns.
- To ensure that the development of these new tools and methods will be compatible with the work and mandate of EU wide systems and organizations in these areas.

Expected results

- A toolkit for characterization of emerging threats by combining genomic and phenotypic information (along with epidemiological data) to be used for rapid, early detection, identification and characterization of emerging threats transmitted via animals, feeds, foods, water or natural environment.

Requirements

Not defined

Estimated total cost for this topic

2 M€ (i.e. 44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

ET 2.2: Development and harmonization of NGS and non-NGS methods for the detection of foodborne parasites

Context

Foodborne parasites are a public health problem of increasing importance due to, e.g., global movement of people and goods. There is no comprehensive legal framework for parasites in food except for *Trichinella*. *Echinococcus* is included in the annex IA of the Zoonoses Directive among the first priority organisms to be monitored in food. There are currently no suitable methods for routine monitoring of parasites along the food chain. Indeed, the methods used to characterize foodborne parasites are often cumbersome and do not cover the entire spectrum of threats. The lack of rapid and comprehensive analytical approaches for some of these pathogens negatively affects

management of human infections, trade, food chain sustainability and food security. Technology increasingly allows for developing or re-directing analytical methodologies for the detection of pathogens, which are more rapid and reliable than the standard approaches based on cultural strategies and potentially can cover pathogens that are currently not identifiable or misdiagnosed. Such technologies have the potential to deliver rapid assays on platforms applicable to field use such as bed/farm/pen-side tests, as well as in the food production chain.

Objectives

- To develop sampling strategies for the detection of foodborne parasites in food samples.
- To develop and validate specific and sensitive NGS and non-NGS (e.g. pheno-genotypic and histochemical) methods for rapid and reliable detection of foodborne parasites in the whole food production chain, covering all the process from sampling to sample preparation and analysis of results.
- To assess the newly developed methods against the existing ones.

Expected results

- Specific and sensitive, validated NGS- and non-NGS-based methods for rapid and reliable pheno/genotypic detection of foodborne parasites in the whole food production chain.
- Production of data on the presence of certain parasites in the food chain to support risk assessment models and intervention strategies for the control of foodborne parasites.
- Proficiency testing schemes for the assessment of the performance parameters of the optimised/developed methods.

Requirements

Parasitologists, bioinformaticians, molecular biologists from at least three partner organizations in at least three countries as key partners with experience in detection methods for parasites, and bioinformatics, plus at least eight associated partners with access to NGS including metagenomics (from at least eight countries).

Estimated total costs for this topic

2.5 M€ (44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

Annex 3. Priority topics for Joint Integrative Projects

Background to integration - the One Health socio-political landscape

EJP integrative activities aim to strengthen preparedness and generate collaborative change. To understand the drivers for collaborative change in the public health and animal health sectors, it can be of interest to reflect on the current socio-political landscape in which One Health activities are prioritised and executed in Europe.

In general, health priorities are largely determined within sectors, naturally influenced by the political system. In Europe, prioritised zoonotic infections are dominated by foodborne hazards, which is reflected through the comprehensive feed and food safety legislation. Still, for public health, the management of zoonotic infections, including those that are food-borne, have to compete with other important public health issues including not only other infectious diseases but also lifestyle health problems such as e.g. diabetes, cancer and cardio-vascular diseases. Supra-national and national needs for preparedness for serious infectious diseases are driven by requirements to adhere to the International Health Regulations Decision 1082/2013/EU on serious cross-border threats to health.

For animal health, public management of zoonotic infectious diseases is highly influenced by economic decisions related to trade. Animal, food and feed issues that influence public health is of high regulatory importance, but the needs for preparedness for infectious diseases are also related to trade and to the regulatory framework on transboundary diseases of high priority (epizootic diseases).

In the food sector, the responsibility for producing safe food is on the food business operator. Public management of food hazards focus mainly on ensuring that the legislation is adhered to (through official controls). Thus, priorities in the food sector are linked to public health and, as indicated above, highly guided by EU level processes and legislation.

The ability to make trade-offs between EU level and national priorities also differ between the sectors. Where there is a high degree of independence between public health systems in different MS, animal health systems are under a great degree of EU level legislation and -coordination. Consequently, the mechanisms for prioritisation of investments in animal health and food surveillance are largely executed at EU level, which is in contrast to public health where priorities tend to be defined at the national level.

Simplistically put, one can say that the animal health-food sector puts major effort in preventing public health hazards, but the socio-political system always balances actions and restrictions against the consequences for free trade. In contrast, the public health sector deals with the consequences of breaches in feed-animal-food system. The focus is mainly on preventing further human illness and there is no obligation to consider trade and other economic consequences in the agri-food sector. These different perspectives, which are sometimes in conflict, also influence the landscape in which Med-Vet institutions are to collaborate.

It can be noted that in terms of responsibility for the EU Commission to coordinate crisis management, there is a link between Decision 1082/2013/EU on serious cross-border threats to health, implementing the International Health Regulations, and EU level food and feed crisis management as guided by Article 55-57 of Regulation 178/2002, laying down the general principles and requirements of food law, establishing the EFSA and laying down procedures in matters of food safety. The above-mentioned differences in perspective come into play also at this level.

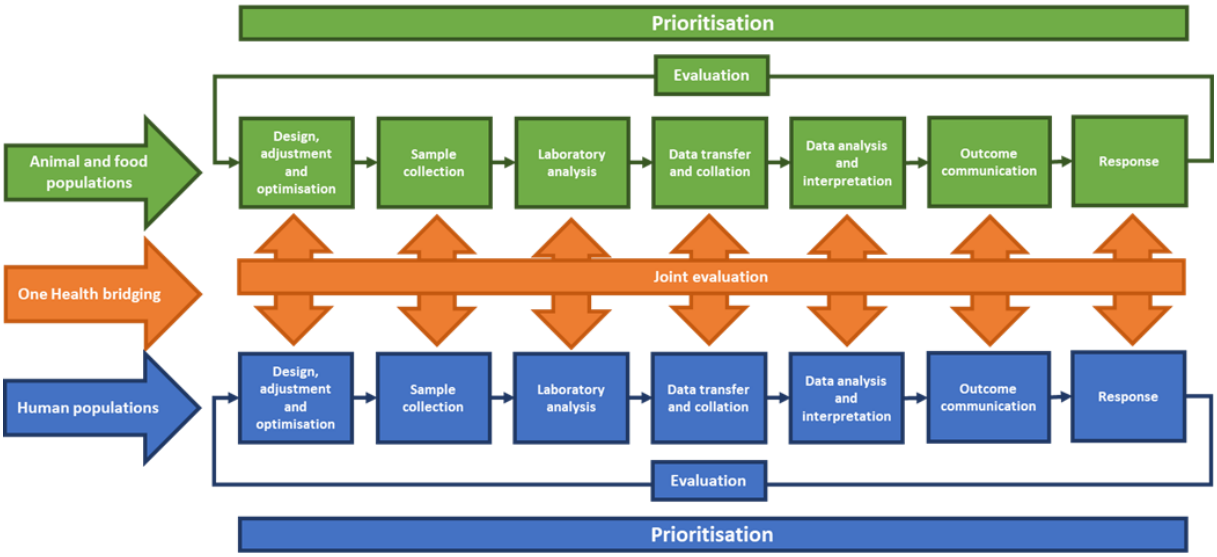
Approach to development of integrated preparedness

The purpose of integrative activities and projects within the OHEJP is to strengthen the joint preparedness of partners to prevent, detect and respond to hazards within their joint remit, both nationally and in collaboration within other EU institutes and -agencies. Due to the legislated landscape in which OHEJP partners operate, and due to the close relationship and collaboration with EFSA and ECDC, there are already many strategies, initiatives, activities and systems in place to develop the capacity to respond to joint hazards within the field of foodborne zoonoses, antimicrobial resistance and emerging threats. The objective of Joint Integrative Projects (JIP) is not to replicate, but to strengthen existing, well-functioning systems. The guidance and insight of EFSA and ECDC is of major importance to help such alignment. The objective of JIPs is also to bridge the gap between the sectors by successively focusing on the inter-sectoral mechanisms along the chain from preparedness to response, and to investigate and improve how the work processes of microbiologists, epidemiologists and information specialists function across the Med-Vet interface at the national level (Figure 1). Strengthening of inter-sectoral mechanisms at the national level will subsequently benefit the supra-national level.

A generic means to work systematically towards an overall higher institutional performance is to benchmark, identify best practice and to leverage the capacity through peer-to-peer twinning activities, through skills training and by development of supportive infrastructure. This is the approach of the integrative activities of the OHEJP, and the JIPs are one means to achieve that.

Two JIPs have been launched to date. COHESIVE focuses on the ability to pick up, share and communicate signals as well as the ability to conduct joint risk assessments. ORION focuses on the semantic and technical interoperability between the sectors, with focus on surveillance information.

For the second call of the OHEJP, call topics have been developed for steps in the prevent-detect-respond chain that were not covered in the first call. IA-1 is focusing on capacity to jointly design, adjust and optimise surveillance activities across the sectors. IA-2 and IA-3 targets ways to improve the joint laboratory capacity and IA-6 focuses on best intervention practice and outbreak response.



Schematic illustration of the preparedness and response systems within which OHEJP partners act, and the steps at which One Health integrative activities take place. Adapted from Iversen *et al*. (2018).

Integrative topics list

IA 2.1: Joint databases of reference materials and data, incl. metadata

Context

- Access to well-defined reference materials is important both for method validation and for proficiency testing (PT). Procedures for quality control of reference materials are subject to a great degree of standardisation, but the preconditions differ between the public health, food and animal health sectors. Although general PT standards exist, they do not capture challenges associated with designing cross-sectoral PT's, i.e. trials able to test the ability to jointly solve diagnostic problems that involve the same pathogen but sector-specific matrices, case-matrix specific pathogen quantities and -viability. Such guidance for cross-sectoral PT could complement existing sectoral standards by specifically focusing on the needs that evolve when proficiency is to be tested at the One Health interface.
- The EU Joint Research Center's (JRC) Institute for Reference Materials and Measurements (IRMM) is a well-established provider and standard setter e.g. in the field of biomarkers and biochemical analyses. In the field of microbiological analyses, the picture is more diverse, although e.g. EURL's have a similar responsibility and/or can provide lists of reference materials within their specific remit. Information about characterised materials, their source and where they are stored is also available at the global level (e.g. via PubMLST, PulseNet). However, for zoonotic pathogens where EU level reference functions are not established, such standards are few or do not exist.
- The OHEJP partners represent countries with diverse epidemiological conditions, and most have access to national collections of strains and biological samples that can be used for research as

well as for routine diagnostic needs. However, the usefulness of such collections for research and for identification of new reference materials is a function of their accessibility and the metadata available. There is an opportunity within the OHEJP to leverage the use of such national collections, and to share experience and knowledge of systems available for recording and querying information about them, by applying principles and tools from open data and open research.

- Data on animal populations, food and feed consumption are regularly needed for risk assessments both at national and EU level. However, the availability and quality of such data differs between EU member states and their availability to OHEJP partners may be constrained by organisational, legal or technical aspects. They may also be openly available in the public domain. The OHEJP provides an opportunity to better understand and improve the availability of such data, and also drive the development of national processes for generating them or increasing their usefulness in support of EU level risk management.

Objectives

- To develop guidance for cross-sectoral proficiency testing, aimed at trialling the collaborative systems' ability to solve food-borne outbreaks and other trans-sectoral challenges,
- To make an inventory of current use and existence of reference materials across OHEJP partner institutes, for selected, prioritised pathogens,
- To conduct a gap analysis with respect to accessibility, quality and usefulness of existing reference materials from a One Health perspective,
- To identify existing systems (software, databases) in place to record and query collections of biological materials held by OHEJP partners, for routine diagnostic needs and for research, and develop an approach for making such collections more widely accessible, within defined limits,
- To investigate and benchmark the availability and quality of demographic data commonly used for risk assessments among OHEJP partners, and describe any constraints for making them more easily accessible,
- To promote national participation in initiatives from EU authorities that serve to make high quality demographic data more readily available for risk assessments,
- For the two bullet points above, to have an early and close coordination with existing data collection initiatives such as EFSA's SIGMA project.

Expected results

- Guidance aimed at improving the design of cross-sectoral proficiency tests, for a better understanding of the collaborative systems' performance,
- Knowledge of state of the art regarding availability and access to well-defined microbiological reference materials that are useful for One Health proficiency testing,
- Centrally available knowledge of relevant collections of biological materials among OHEJP partners, and of systems in place for stock keeping,
- The collections of biological materials held by OHEJP partners are more widely accessible, within defined limits,
- Knowledge of the status with regards to availability of relevant national data for risk and outbreak assessments, and a road map for how to make them more readily available, taking into account existing initiatives from EU authorities, such as EFSA's SIGMA project.

Requirements

- At least 14 partners from 7 countries with key expertise relevant to the topic area, such as e.g. microbiology, epidemiology and information science.
- Should involve pairs of Med-Vet partners from same countries to contribute to national integration.
- With respect to tasks related to reference materials, a close collaboration with the relevant EURL's should be considered to ensure sustainability.
- The involvement all OHEJP partners in some of the activities (surveys, training) should be planned for.

Estimated total costs for this topic

4.5 M€ (44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

IA 2.2: Harmonised protocols and common best practice

Context

- A key component in the interoperability between animal and public health surveillance systems is the comparability of laboratory diagnostic output across the sectors. There are strategies in place that aim to successively develop the EU One Health capacity to identify and interpret cases and sources across geographic regions and over time, but there is still a substantial variation in national capacity. Much of the focus today is on the interoperability with regards to advanced molecular typing methods to detect and solve outbreaks. But the understanding of One Health priorities, and of effects on public health of interventions in the animal/food sectors, is also affected by the capacity of first line/primary diagnostics. This includes the capacity of public health microbiological laboratories, of laboratories carrying out analyses of food samples in official and own controls as well as of veterinary laboratories involved in passive and active animal health surveillance. For example, test performance, as expressed by diagnostic sensitivity and specificity, is rarely known, although it is commonly needed e.g. for risk assessments and for design and evaluation of surveillance programmes. OHEJP partners serve a role as National Reference Laboratories and EU Reference Laboratories and have mandates to support national primary diagnostic capacity.
- ECDC has been mapping national microbiology capabilities in EULabCap surveys since 2013, which has provided evidence to monitor the development towards identified strategic goals in the field of public health microbiology. For the other sectors, EU Reference Laboratories are in place for a range of foodborne pathogens, supporting NRL's in their responsibility for quality assurance of national laboratory capacity. The global strategic overview of laboratory capacity in the animal-food field, as provided by EULabCap for public health microbiology, is missing. Also, there is no joint basis for strategic capacity building in the field of laboratory interoperability across the animal health – food – public health interface.
- The capacity of national laboratory services can be influenced by dependencies on laboratories in other MS, and on cross-border transportation services. This potential vulnerability can also be a strength in situations where laboratories can provide back-up functions and redundancy for one another. To leverage general preparedness, laboratory dependencies have to be understood, and suitable service agreements have to be in place.
- The use of laboratory services within healthcare and official controls is subject to public procurement procedures under EU law. The suitability of such services with respect to One Health needs is rarely considered in procurements, and there is a variation in national guidance

to local and regional competent authorities, which injects differences in the quality of laboratory services and official controls in the food chain. Cross-border coordination of guidance regarding relevant requirements for procurement of laboratory services is desirable.

Objectives

- To benchmark One Health laboratory interoperability, capacity and performance across all OHEJP partner countries.
- To identify prioritised methodological fields in need of harmonisation across the Med-Vet interface, taking into account developments in other OHEJP joint research projects as well as initiatives taken by EFSA, ECDC and other relevant standard setting bodies.
- Based on a gap- and needs analysis, taking into account existing initiatives and projects: to develop and implement harmonised and interoperable protocols for detection and typing of foodborne pathogens and AMR determinants across the animal health – food – public health interface.
- To raise general EU capacity with respect to laboratory interoperability and capacity across the animal health – food – public health interface, through a partner training and support system,
- To improve cross-border interoperability and crisis preparedness by mapping laboratory dependencies and by establishment of agreements regarding prioritised laboratory services, as needed.
- To implement harmonised protocols for detection and typing of foodborne pathogens and AMR determinants, and map constraints to implementation.
- To produce guidance to competent authorities in charge of procuring microbiological laboratory services for primary diagnostic testing in the public health, food and animal health sectors.

Expected results

- A One Health version of the EULabCap instrument, developed with an aim to be repeatable.
- Knowledge of the status of One Health laboratory interoperability and capacity across all OHEJP partner countries,
- A roadmap for systematic methodological improvement with respect to One Health laboratory interoperability, including identification of constraints to such improvement and suggestions on how they can be mitigated. The roadmap should be developed in dialogue with EFSA and ECDC and be of value to strategic guidance at EU level.
- Where prioritised needs exist; development and implementation of new harmonised and interoperable protocols for detection and typing of foodborne pathogens and AMR determinants across the animal health – food – public health interface,
- Procurement guidance is available so that the laboratories within healthcare and official controls are capable to contribute to solving inter-sectoral problems involving humans, food, animals and the environment,
- An increase in general EU capacity to deal with foodborne zoonoses, antimicrobial resistance and emerging threats across the animal health – food – public health interface by partner-to-partner delivery of training based on the outcome of EULabCap and similar benchmarking tools, as well as training related to the above-mentioned developments.

Requirements

- Key expertise relevant to the topic area, such as e.g. epidemiology, microbiology and economics.

- The consortium should include a balanced number of Med-Vet partners from at least 7 countries that scored both high, as well as low/intermediate in the EULabCap survey 2016.
- The involvement all OHEJP partners in some of the activities (surveys, training) should be planned for.

Estimated total costs for this topic

4.5 M€ (44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

IA 2.3: Common frameworks for designing and implementing surveillance and control activities

Context

- The chain from prevention and detection to response involve several institutional capacities including laboratory services and epidemiological planning of surveillance and analyses and communication of surveillance data. Similar to how the EULabCap assessment provides national benchmarking and guidance on microbiological laboratory development needs, an assessment of the cross-sectoral epidemiological functionality could generate useful information for future strategic initiatives and targeted support.
- Surveillance activities vary in nature between Med-Vet sectors, where the former is usually passive in nature whereas the former often involves active surveillance activities. In the food sector, investigations are highly guided by EU regulation 2017/625 on official controls and other official activities. There is no joint framework for integrated design of cost-efficient surveillance along the food chain and across the Med-Vet interface. Such a framework would provide valuable guidance and ensure that surveillance, incl. official controls, is transparent, comparable and meets societal needs.
- There is an opportunity to better support multi-country foodborne outbreak investigations by improving methods and formats for systematic data collection at national level, thereby leveraging the national capacity to contribute. Such development should take place in dialogue with EFSA and ECDC, and build on existing procedures and systems.
- Certain surveillance objectives such as case finding and early detection show many similarities with the objectives of official controls in the food chain, i.e. strategies for detection of non-compliance in food business operations use risk-based approaches which is also used in surveillance aimed at detecting cases of endemic disease or new introductions. In fact, the use of risk-based approaches is implicit in the food legislation, and is also encouraged in the animal health field. Animal health surveillance legislation has successively developed towards the use of output-based standards, i.e. standards focusing on the quality of evidence provided by the system (e.g. confidence in freedom at a certain design prevalence), rather than defining inputs (e.g. the number samples required). This is in stark contrast to official controls, where input-based standards still prevail. There seems to be an opportunity to improve the output from official controls by applying methodological principles from risk-based animal health surveillance.

Objectives

- To develop or adapt existing operational frameworks for design and implementation of sectoral surveillance to fit the needs of the One Health intersect.
- To benchmark the ability to design, implement and evaluate fit-for purpose One Health surveillance for prioritised hazards, including both laboratory-based surveillance and surveillance based on analysis of epidemiological indicators.

- To identify best practice approaches to effectively contribute to EU level surveillance of foodborne hazards, antimicrobial resistance and emerging threats, and share experiences within the OHEJP, for example through peer-to-peer twinning activities and skills training.
- To investigate the possibility to define output-based standards for official controls of food and feed, and to consider methods to design, implement and evaluate official controls using such standards, considering other initiatives with similar objectives such as the EFSA-funded project STOC-FREE.
- To interact with EFSA and ECDC to produce a roadmap for future national development of surveillance capacity, taking into account the need to establish sustainable governance of the One Health surveillance system nationally and at EU level. The role of existing EU level initiatives, such as SIGMA, should be considered.

Expected results

- An operational framework that provides guidance to OHEJP institutions regarding design and implementation of surveillance of inter-sectoral hazards,
- An "EUEpiCap" instrument, a survey tool designed to assess epidemiological interoperability and capacity across member states and developed with an aim to be repeatable.
- Knowledge of the status of One Health epidemiological interoperability and capacity across all OHEJP partner countries,
- Best practice approaches for designing, implementing and evaluating surveillance of foodborne hazards, antimicrobial resistance and emerging threats are disseminated and adopted by OHEJP partners,
- Output-based standards are defined for relevant areas covered by official controls of food, including veterinary medical products and residues.
- There is a roadmap to guide future development of One Health surveillance nationally among OHEJP partners, which is in line with EFSA and ECDC priorities, and a sustainability plan to follow up developments,

Requirements

- At least 14 partners from 7 countries with key expertise relevant to the topic area, such as e.g. microbiology, epidemiology and information science.
- Should involve pairs of Med-Vet partners from same countries to contribute to national integration.
- The involvement all OHEJP partners in some of the activities (surveys, training) should be planned for.

Estimated total costs for this topic

4.5 M€ (44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

IA 2.4: Sharing best intervention practice – twinning and simulation exercises

Context

- Approaches to intervene and control endemic hazards such as foodborne zoonoses and antimicrobial resistance differ depending on biological, epidemiological, technical, cultural and socio-economic preconditions. National policies, organisational structures and financial priorities may also influence the palette of feasible options. The hazard situation varies across EU member

states, and so does the national experiences with control of different pathogens at different stages along the food chain.

- OHEJP partners have mandates to contribute to EU level awareness and preparedness, advise risk managers regarding possible interventions, and have broad experience with control in various socio-cultural contexts. Consequently, the OHEJP constitutes an opportunity to share best-practice approaches regarding interventions, incl. communication, along the entire chain from stable to table, and thereby increase the joint capacity to control foodborne zoonoses, antimicrobial resistance and emerging threats. A best-intervention-practice twinning system between countries would complement the strategic priorities of EU authorities that also serve to support national capacity building.
- One of the main objectives of the OHEJP is to increase the societal preparedness to respond to joint challenges such as foodborne zoonotic outbreaks, increase in antimicrobial resistance or other emerging threats. Today, the animal health, food and public health sectors are part of different response systems, and the ability to deal with One Health challenges is dependent on the existence of functional connectivity between these sectors, at national and EU level, and both in crisis and in peace-time. A first step is to have a functioning cross-sectoral signalling system, which is the focus for the JIP COHESIVE. Simulation exercises are commonly used as a tool to train and evaluate the capacity of a response system, and cross-sectorial exercises have previously been arranged at the EU level, for example for pandemic influenza. There is an opportunity for the OHEJP to align with training initiatives from ECDC, EFSA and/or the Commission and arrange one or more simulation exercises tailored to prioritised threats and testing specific capacities within the scope of the OHEJP. The evaluation of a simulation exercise provides a means to identify vulnerabilities in the response system by targeting mitigating measures to share best practice where they are most needed.

Objectives

- To identify best-practice approaches to the control of relevant foodborne zoonoses and antimicrobial resistance in various socio-cultural contexts,
- To develop a best-intervention-practice twinning system across, to innovatively benefit from the experience of all OHEJP partners,
- To design, implement and evaluate one or more simulation exercises targeted towards hazards of high relevance to EU risk managers, and testing key capacities in the joint OHEJP response.

Expected results

- Knowledge of the range of approaches used in OHEJP partner countries to intervene with and control foodborne zoonoses and antimicrobial resistance,
- Identification of best intervention practices in different socio-cultural contexts,
- Definition of one or more scenarios, of high relevance to EU risk managers, and key capacities to test and monitor,
- A simulation exercise that tests the joint capacity of OHEJP partners to respond to highly relevant hazards,
- An evaluation that provides an understanding of how the capacity can be further strengthened, which can form the basis for future developments

Requirements

- At least 14 partners from 7 countries with key expertise relevant to the topic area, such as e.g. microbiology, epidemiology and information science.

- Expertise in contingency planning and in the planning and execution of simulation exercises
- Should involve pairs of Med-Vet partners from same countries to contribute to national integration.
- The involvement all OHEJP partners in some of the activities (surveys, training, exercises) should be planned for.

Estimated total costs for this topic

4.0 M€ (44% funded by EC funds and 56% funded by OneHealth EJP beneficiaries forming the consortium)

Annex 4. Template for Letter of Intent

Letter of Intent template for submission by December 21st, 2018 (max 5 pages)

Please, see the "Second Internal Call for Research and Integrative Projects" group on the private space of the OHEJP Website (www. OneHealthEJP.eu) to retrieve the template in Word format. **Please submit Annex 4 as a Word document, NOT as a PDF.**

Title of the proposal, type (JRP or JIP) and priority topic to which the proposal refers
Identification of the candidate project leader (name, affiliation)
Identification of partners – Name of organisation, scientific contact person for each organisation – Spread over the EU regions (N, E, S, W); special effort should be undertaken to include those OneHealth partners that are not participating in the on-going projects (see "Second Internal Call for Research and Integrative Projects" group on the private space of the OHEJP Website (www.Onehealthejp.eu) for details); – Expertise: animal or public health, feed, food and environment – Strategy to form the consortium (expertise that you looked for) and efforts done to involve partners, in particular those that have not led to inclusion in the proposed project consortium
Clarification of which of the objectives of the priority topic will be met and how
A broad description of the proposal

A general work plan description (about 1-2 pages)
Detailed reference (hyperlink, doi etc.) to a EU level opinion document, strategic research agenda, expressed key EU Stakeholders needs or similar that shows that the project proposed falls within the European priorities. The applicant should also show awareness of earlier and ongoing work (e.g. recent or actual EU funded projects) activities of ECDC, EFSA and European Commission, and explain in what way this work is complementary (i.e. to avoid redundancy and duplication of work) (abstract, about 1 page)
Contribution of the project to the overarching objectives of the OneHealth EJP, i.e. alignment and integration of EU capacity, and impact of the expected results on the overall preparedness and response of the partners
The expertise of the partners in this field (incl. most relevant publications) or evidence of leading developments in the relevant field (for integrative projects)
Estimation of the total budget needed for the project (i.e. total budget; costs will be co-funded for 44% by the EU and for 56% by the partner organisations)
This letter of intent has been prepared with the agreement of the scientific directors (or similar) of the respective institutes partners.

Annex 5. List of on-going EU and OneHealth EJP projects

This document was drafted by the OneHealth EJP WP2 team and summarizes some of the relevant recent and on-going EU projects that may be referred to in the actual proposals. It is available on the "Second Internal Call for Research and Integrative Projects" group on the private space of the OHEJP Website (www. OneHealthEJP.eu), accessible after registration.

For completeness, the list of on-going (first call) OneHealth EJP projects is also available on the website.

Please note that proposals should not only consider these EU projects, but also any national project, EU level opinion document, strategic research agenda, expressed key EU Stakeholders needs or similar initiative that shows that the project proposed falls within the European priorities.

Annex 6. Template for Full Proposal

Full Proposal template for submission by April 16th, 2019

Please, see "Second Internal Call for Research and Integrative Projects" group on the private space of the OHEJP Website (www. OneHealthEJP.eu) to retrieve the template in Word format. **Please submit Annex 6 as a Word document, NOT as a PDF.**

Please describe concisely; estimation for a consortium with 15 partners: about 25 pages, corresponding to more or less 12.500 words; see specifications per item.

Title and acronym of the proposal
Type (JRP or JIP) and priority topic to which the full proposal refers
Name of the project leader and of all applicants, with full affiliations
Short CV of each participating key scientist (at least one per participating organization) *(max 10 lines each person)* This part summarise the major activities and competencies of the person over the last 5 years. – Name of organisation, scientific contact person for each organisation – Spread over the EU regions (N, E, S, W) – Expertise: animal or public health, feed, food and environment – Information that indicates the coordinator's skill to manage international projects
Objectives description *(maximum half a page)* Clearly indicate the objective(s) in the priority topic description that will be dealt with in your project and how.
Project abstract *(maximum half a page)* Brief summary of proposed research or development programme
Background *(maximum one page)* Detailed background on the project and state of the art in the field should be given, as well as a description of the impact the project may have.
Progress beyond state of the art *(maximum half a page)* Explain what progress or novelty will be made beyond the current state of the art.
Project aims *(maximum one page)* Describe achievements of proposed research or developments.
Work plan *(maximum 5 pages)* The overall work plan shall include: – The name of each Work Package and how they are linked together – A Gantt and a Pert chart – Explain the role and involvement of each participating organization

Annual work package description (please complete one Annex 7 per WP) *(maximum 1.5 pages per WP)*: – Organise the work package into tasks and sub-tasks when necessary. – Appoint a Work Package leader for each Work package, and Task and sub-tasks leaders when appropriate (leaders shall be clearly identifiable. Their role is to coordinate the work. They also endorse the responsibility that the work is carried out as described). – Include milestones (intermediate steps that focus on major progress points) and deliverables (outputs or products at a given moment during the project).
Alignment and integration *(maximum half a page)* Describe how this international cooperation will strengthen the partner organizations in terms of a common technology, method, approach etc. and how it will lead to the harmonization of technological and scientific knowledge. Describe the search for added value that cannot be reached by the individual partners, the aim to improve the organizations' performances, how the international cooperation will lead to a better integration of OneHealth partners in the objectives of the OneHealth EJP. For JRP, describe any integrative activities that your project will encompass: – Capacity building / training – Experimental facilities – Detection / typing methods / protocols / GLP – Strain collection / reference materials / bio-banks – Digital infrastructure / databases / data sharing protocols / data access / bioinformatics – Surveillance strategies / reporting / signalling – Legal / policy aspects
Relation to ongoing national and international projects/activities relevant to the present proposal *(maximum one page)* Description of the efforts done to scan related ongoing or recently terminated projects and activities of key EU stakeholders. Please clearly indicate how selected projects contribute to (and do not overlap with) other existing activities funded at EU or even MS level.
Resources requested *(maximum half a page)* Description of human resources, equipment, subcontracting, travel and other additional costs of planned project.
Budget (please complete Annex 8) Indicate all planned costs in the different proposed cost items, describe them and refer to which project WP and task they apply.
Training opportunities *(maximum half a page)* Description of training and/or exchange activities foreseen in the project, if applicable.
Ethics Please fill in the self-assessment (Annex 9). This document will be evaluated by two Ethics Advisors familiar with the OneHealth EJP. If the proposal is accepted for funding, the Ethics Advisors will draft recommendations that project leaders will have to adhere to.
Literature references Maximum 10 literature references can be listed related to the project by providing the author, title, journal, year, volume, pages; etc. These literature references shall refer to the proposal.
Keywords Provide up to 5 keywords to describe the scientific scope or integrative nature of your application; the keywords will inter alia be used to identify and assign external experts to your project.

Duration of the project The maximum duration is fixed at 2,5 years, mandatorily from 1st January 2020 up to 30th June 2022.
Certificate of co-financing (please complete one Annex 10 for each participating partner institute This certificate aims at ensuring that each participating institute accepts to engage the necessary co-financing in order to implement the project.

Annex 7. Template for Full Proposal: Work package description form

Please, see the "Second Internal Call for Research and Integrative Projects" group on the private space of the OHEJP Website (www. OneHealthEJP.eu) to retrieve the Work Plan in Word format. **Please submit Annex 7 as a Word document, NOT as a PDF.**

Important preamble: How to complete the "Description of work section" of the Project Description Form

The EC reporting dynamics requires that work plans and reports are submitted and validated by the EC on an annual basis. The annual reporting period of the OHEJP will be from 1st January to 31st December. Joint Research Projects and Joint Integrative Projects of the second round should strictly keep to that timing and therefore start from 1st January 2020.

In order to comply with these dynamics, please prepare as many work plans as the number of annual periods your project takes place over (i.e. for a 2,5 years project starting on 1st January 2020, you should prepare 3 separate yearly work plans, one for 2020, one for 2021 and another one for the last 6 months of your project in 2022).

You are strongly encouraged to organise entire work packages (WP) and related tasks (T) and subtasks (sT) within separate annual reporting periods. However, it is possible that the implementation of the work (WPs, T and sT) may have to be planned over two or more annual reporting periods.

Example:

In a project of 2,5 years (requiring 3 distinct work plans):

Possible Gantt chart of the project:

	FIRST ANNUAL PERIOD First work plan						SECOND ANNUAL PERIOD Second work plan						THIRD ANNUAL PERIOD Third work plan		
	M1-2	M3-4	M5-6	M7-8	M9-10	M11-12	M13-14	M15-16	M17-18	M19-20	M21-22	M23-24	M25-26	M27-28	M29-30
WP1															
T1.1															
T1.2															
T1.3															

In the "description of work" section (see form below) of the work plan **for the first year of the project**, you can for example indicate:

- "WP1 takes place over the first, the second and the third year of the project"
- T1.1 takes place over the first year of the project
- T1.2 takes place over the first and the second year of the project

In the "description of work" section (see form below) of the work plan **for the second year of the project**, you can for example indicate:

- "WP1 takes place over the first, the second and the third year of the project"
- T1.2 takes place over the first and the second year of the project
- T1.3 takes place over the second and the third year of the project

In the "description of work" section (see form below) of the work plan **for the third year of the project**, you can for example indicate:

- “WP1 takes place over the first, the second and the third year of the project”
- T1.3 takes place over the second and the third year of the project

WORK PLAN

Template

Priority Topic reference[i]										
Project title										
Project acronym										
Coordinator institute (number and acronym)[ii]			Deputy Leader institute (number and acronym)							
Project Coordinator person name			Project Deputy Leader person name							
Indicate for which annual period of the OHEJP the project description applies[iii]:										
Project Start month		M25			Project End month[iv]					
Participant	1	2	4	6	7	8	9	10	11	12
	Anses	Ages	Sciensano	NDRVMI	SZU	VRI	BfR	FLI	RKI	DTU
P.M										
Participant	13	14	15	16	17	18	19	20	21	22
	SSI	UT	VFL	INIA	UCM	MVNA	INRA	IP	APHA	PHE
P.M										
Participant	23	24	25	26	27	28	29	30	31	32
	UoS	OKI	NUIG	TEAGASC	ISS	IZSAM	IZSLER	RIVM	WbvR	FHI
P.M										
Participant	33	34	35	36	37	38	39	40	41	
	NVI	PIWET	INIAV	INSA	IISPV	IC	SLV	FOHM	SVA	
P.M										

Objectives

-
-

Description of work[v]

WP[vi]:
WP start month
WP end month
WP Leader
Deputy WP Leader
WP participants
Description of the WP[vii]:

Task[viii]:
Task start month
Task end month
Task Leader:
Deputy Task Leader[ix]:
Task Participants:
Description of the task[x]:

Sub-Task[xi]
Sub-Task start month
Sub-Task end month

Sub-Task Leader: Deputy Sub-Task Leader[xii]: Sub-Task Participants:		
Deliverables[xiii]		
Ref[xiv]	Title	Due month[xv]
Milestones[xvi]		
Ref[xvii]	Title	Due month[xviii]

GUIDANCE NOTES:

[i] Indicate here the reference of the call topic your projects responds to, e.g. FBZ-1, IA-SH-2, AMR-3, ET-1

[ii] Use the same institute number and acronym as indicated in this form.

[iii] Annual periods of the OHEJP differ from annual periods of your project proposal. Year 1 of your project proposal corresponds to Year 3 of the OHEJP. The three annual work plans that you wil submit will be encoded Y3, Y4 and Y5

[iv] The OHEJP lasts from 1st January 2018 to 31st December 2022 (5 years – 60 months). The 60 months duration will be coded from M1 to M60. A 2.5 years project will last from M25 to M54.

[v] The work is organised into work packages (WP) in which tasks (T) and possibly sub-tasks (sT) are implemented. Add as many WPs, tasks and sub-tasks as necessary. The organisation of the work to be carried out as described in this annual work plan must also be reflected in the Gantt chart.

[vi] Number the WP as WP1, WP2, WP3, etc… and entitle them

[vii] Explain the objectives of the WP and how it fits into the overall project and how it is linked with the other WPs. Indicate the role of each WP participant.

[viii] Number tasks as follows: JRP#-WP#-T# e.g. task number 2 of WP3 will be indicated as JRP#-WP3-T2. Similarly sub-tasks should be numbered as follows: JRP#-WP#-T#-ST# e.g. subtask 4 of task 2 of WP5 will be indicated as JRP#-WP5-T2-ST4

[ix] Ideally in order to ensure a good follow-up and management of implementation of the tasks, Deputy Task Leaders may be appointed but this is not compulsory.

[x] Explain the objectives of the task and how it fits into the overall WP and is linked with the other tasks. Explain how the task will be implemented and indicate the role of each task participant.

[xi] If any. It may be useful to describe several subtasks if the task they refer to must be divided into several ones

[xii] Ideally in order to ensure a good follow-up and management of implementation of the subtasks, Deputy subtask Leaders may be appointed, but this is not compulsory.

[xiii] A deliverable is the concrete result of all or part of the work implemented. Deliverables will be submitted to the EC as a proof of the work achieved and will be a basis to evaluate the OHEJP progress and efficiency. Add as many deliverables as appropriate.

[xiv] Please number the deliverables as follows: D-JRP#-WP#.D#, e.g. the second deliverable of WP3 will be numbered D-JRP#-WP3.2

[xv] The same month numbering applies as for the Project start/end months (see endnote iii). Indicating M35 means that the deliverable should be submitted to the OHEJP WP3/WP4 Leaders before the end of M35.

[xvi] A milestone is a stage of achievement of the project. It can be reached at the same time as when a deliverable is available (a concrete result that constitutes a stage of achievement), but it can also reflect a crucial time point in the project without leading to the release of a deliverable (e.g. samples are ready and assays can start).

[xvii] Please number the milestones as follows: M-JRP#-M# e.g. the sixth milestone of a project will be numbered M-JRP#-06. Milestones are numbered CHRONOLOGICALLY.

[xviii] As for the deliverables the same month numbering applies as for the Project start/end months (see endnote iii). Indicating M35 means that the corresponding stage of achievement of the project must be verifiable by the OHEJP WP3/WP4 Leaders at the end of M35.

Annex 8. Template for Full Proposal: Budget

Please, See "Second Internal Call for Research and Integrative Projects" group on the private space of the OHEJP Website (www. OneHealthEJP.eu) to retrieve the budget sheet template in Excel format. **Please submit Annexes 8 as an Excel document, NOT as a PDF**.

Important notices regarding Annex 8

- The template file is composed of several spreadsheets, one summary budget spreadsheet and as many other spreadsheets as cost items.
- Where necessary complete the yellow cells in each relevant spreadsheet
- For each cost budgeted you must describe it and refer to the corresponding task(s) of the project
- Complete one file per participating institute per year (3 files per participating institute)
- Name each file as:
    - Project acronym
    - Institute name
    - Project year (Y)
    - E.g.: safefood_anses_Y1
- Contact the support team for any further clarification needed (ohejpcoord@anses.fr)

Annex 9. Ethics Self-Assessment

Please see the “Second Internal Call for Research and Integrative Projects” group on the private space of the OHEJP Website (www. OneHealthEJP.eu), to retrieve the excel sheet for Ethics Self-Assesment.

OneHealth EJP Ethics Self-assessment table v3

Link to guidance (v 6.0, July 2018)

Instructions:

- Each candidate JRP or JIP leader must complete this questionnaire
- For guidance, please use the guidance document
- Send the completed form to ohejp@sciensano.be **together with your full proposal**

1. HUMAN EMBRYOS/FOETUSES			
Does your research involve Human Embryonic Stem Cells (hESCs)?		Yes	No
Will they be directly derived from embryos within this project?		Yes	No
Are they previously established cells lines?		Yes	No
Does your research involve the use of human embryos?		Yes	No
Can you confirm that your research will not destroy those embryos?		Yes	No
Does your research involve the use of human foetal tissues / cells?		Yes	No
2. HUMANS			
Does your research involve human participants?		Yes	No
Are they providing sensitive or personal information?		Yes	No
Are they volunteers for social or human sciences research?		Yes	No
Are they persons unable to give informed consent?		Yes	No
Are they vulnerable individuals or groups?		Yes	No
Are they children/minors?		Yes	No
Are they patients?		Yes	No
Are they healthy volunteers for medical studies?		Yes	No
Are they residents in a non-EU country?		Yes	No
Does your research involve physical interventions on the study participants?		Yes	No
Does it involve invasive techniques?		Yes	No
Does it involve collection of biological samples?		Yes	No
If your research involves processing of genetic information or collecting personal data, see also section 4.			
3. HUMAN CELLS / TISSUES			
Does your research involve human cells or tissues (other than from Human Embryos/Foetuses, i.e. section 1)?		Yes	No
Are they available commercially?		Yes	No
Are they obtained within this project?		Yes	No
Are they obtained from another project, laboratory or institution?		Yes	No
Are they obtained from biobank?		Yes	No
4. PERSONAL DATA			
Does your research involve personal data collection and/or processing?		Yes	No
Does it involve the collection and/or processing of sensitive personal data (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical		Yes	No
Does it involve processing of genetic information?		Yes	No
Does it involve tracking or observation of participants?		Yes	No
Does your research involve further processing of previously collected personal data (secondary use)?		Yes	No
5. ANIMALS			
Does your research involve animals?		Yes	No
Are they legally protected animals?		Yes	No
Are they vertebrates?		Yes	No
Are they non-human primates?		Yes	No
Are they genetically modified?		Yes	No
Are they cloned farm animals?		Yes	No
Are they endangered?		Yes	No
Please indicate the species involved (Maximum number of characters allowed: 1000)			

6. THIRD COUNTRIES				
	In case non-EU countries are involved, do the research related activities undertaken in these countries		Yes	No
		Specify the countries involved:(Maximum number of characters allowed: 1000)		
		Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	Yes	No
		Do you plan to import any material - including personal data - from non-EU countries into the EU?	Yes	No
		Specify material, countries and legal permissions involved: (Maximum number of characters allowed: 1000)		
		Do you plan to export any material - including personal data - from the EU to non-EU countries?	Yes	No
		Specify material, countries and legal permissions involved: (Maximum number of characters allowed: 1000)		
		If your research involves low and/or lower middle income countries, are benefits-sharing actions planned?	Yes	No
		Do you plan to use biological resources that are subject to Access and Benefit Sharing (Nagoya Protocol) Regulations (Regulation (EU) No. 511/2014; Implementing Regulation (EU) 2015/1866)	Yes	No
		Specify material and countries: (Maximum number of characters allowed: 1000)		
		Could the situation in the country put the individuals taking part in the research at risk?	Yes	No
7. ENVIRONMENT & HEALTH and SAFETY				
		Does your research involve the use of elements that may cause harm to the environment, to animals or plants?	Yes	No
		Does your research deal with endangered fauna and/or flora and/or protected areas?	Yes	No
		Does your research involve the use of elements that may cause harm to humans, including research staff?	Yes	No
8. DUAL USE				
		Does your research involve dual-use items in the sense of Regulations 428/2009, or other items for which an authorisation is required?	Yes	No
9. EXCLUSIVE FOCUS ON CIVIL APPLICATIONS				
		Could your research raise concerns regarding the exclusive focus on civil applications?	Yes	No
10. MISUSE				
		Does your research have the potential for misuse of research results?	Yes	No
11. OTHER ETHICS ISSUES				
		Are there any other ethics issues that should be taken into consideration? Please specify	Yes	No
		Please specify: (Maximum number of characters allowed: 1000)		
I confirm that I have taken into account all ethics issues described above and that I will comply with the regulation as set out in the Grant Agreement (i.e. Art. 34) before the start of any activity in which ethics issues apply.			*I confirm: yes or no*	
Document completed by			**Acronym of JRP or JIP**	
Date:				
Signature:				

Annex 10. Certificate of co-financing

Please see the “Second Internal Call for Research and Integrative Projects” group on the private space of the OHEJP Website (www.OneHealthEJP.eu), to retrieve Annex 10 and submit them signed as a PDF (One signed certificate per participating institute).

CERTIFICATE OF CO-FINANCING

I, the undersigned [insert name], [insert position], authorised person of [insert name of organisation], certify that the organisation I represent accepts to co-finance the One Health EJP project [insert name of the JRP/JIP] during its entire duration for a total expected amount of € [insert the sum of the three annual EU funding amounts budgeted in the JRP/JIP budget files (cells Q10 of spreadsheet “summary budget”)]

[Date]

[signature and stamp]