Call for proposals

ECDC BIORISK EXPERT GROUP - TO IMPROVE KNOWLEDGE, INFORMATION, COORDINATION AND SCIENTIFIC ADVICE IN THE AREA OF BIORISKS

Framework Partnership Agreement

GRANT/2009/008

1. OVERVIEW

1.1. Title

ECDC BIORISK EXPERT GROUP - TO IMPROVE KNOWLEDGE, INFORMATION, COORDINATION AND SCIENTIFIC ADVICE IN THE AREA OF BIORISKS

1.2. Background information

ECDC general

The European Centre for Disease Prevention and Control (ECDC) was established by the European Parliament and Council Regulation 851/2004 of 21 April 2004 to identify, assess and communicate current and emerging threats to human health from communicable diseases[1]. In the ECDC founding regulation it is clearly stated that the centre shall provide technical assistance, including training, and act as a coordinator of European networks in the field of public health, including initiatives supported by the European Commission. As part of this process, the ECDC now initiate a call for proposal that aims to improve knowledge, information, coordination and scientific advice in the important area of biorisk.

ECDC and cooperation with microbiology laboratories

ECDC does not have and will not, in the foreseeable future, have any laboratories of its own. Therefore, the centre relies on the MS expertise and laboratory capacities to support ECDCs specific public health core functions and disease specific work within its mandate and reflected in the annual and multi-annual workplans[2]. Details of ECDC's mandate and functions are set out in the above referenced Regulation, accessible through the ECDC web site, but notable here is ECDC's role stated in Article 5 related to networking activities in terms of:

a. supporting networking activities of the competent bodies recognized by the MS
b. encouraging cooperation between expert and reference laboratories
c. fostering development of sufficient capacity within the Community for diagnosis, detection, identification, and characterization of infectious agents which may threaten public health
d. cooperation with member states in the area of scientific and technical assistance, collection of data and identification of emerging health threats.

[1] http://www.ecdc.europa.eu/en/About_us/Key_documents/Documents/ecdc_regulations.pdf

[2] http://www.ecdc.europa.eu/en/About_us/Key_documents/

ECDC is continuing its work on implementing strategies for cooperations with microbiology laboratories and research institutes, aiming for added value by coordination and strengthening of European public health microbiology and by defining the role of the Member States, the European Commission, ECDC, WHO partners and other key stakeholders. The biorisk dimension is a cornerstone in all above mentioned activities and it is important for the centre to have a clear idea of what capacity and expertise currently exists in this field in the EU and also identify areas that need strengthening.

Definition of Biorisks and key stakeholders

What is "**biorisk**"? In recent years, the term biorisk has expanded to include hazard identification, risk assessment and risk control in not only the field of biosafety, which describes practices that are implemented to prevent the unintentional or accidental exposure to biological agents in laboratories, but also biosecurity. The latter term refers to the measures that secure biological material and information that could cause harm to health or economic loss as a result of malicious release, intentional loss, theft or misappropriation.

Several European Commission funded projects have been undertaken to coordinate the European biosafey and biosecurity efforts. These include: "Biosafety Europe,"[3] which aimed to harmonize biosafety and biosecurity practices, "BIOSAFE,"[4] targeting preparation and response to deliberate release of biological agents, and "EuroNetP4,"[5] a network of P4 laboratories with the focus to increase preparedness to health threats to European population resulting from natural infection or deliberate release of class 4 biological agents.

Some of these projects are concluded, but the outcomes and the continuing dialogue about these important issues are further refined and communicated in different forums. One important forum for such networking and information exchange is the European Biosafety Association (EBSA)[6]. EBSA was founded 1996 and contains members representing most European Union member states as well as both civil and private sector. The association strives to establish and communicate best practices, and to encourage discussions in developing the fields of biosafety and biosecurity. EBSA is also one of the 21 pan European learned societies in the field of public health that works together with ECDC as part of a networking forum, the ECDC Scientific Consultation Group.

As part of its scientific advice function, the ECDC needs a biorisk expert core group to keep abreast of the developments in this multidisciplinary and cross-sectorial field and to network with the larger community of biorisk professionals. Such a group would support ECDC to distill and disseminate the good results developed in current and past Commission funded projects and related initiatives that have a public health dimension and to identify areas requiring further development or studies. Moreover, this group, will be requested by ECDC to address scientific questions or to implement scientific reviews and provide guidance on biorisk topics of interest to the Commission bodies and the

[3] http://www.biosafety-europe.eu/

[4] http://www.nvi-vaccin.nl/nvi_projectsites/index.php?id=2

[5] [4]http://www.euronetp4.eu/

[6] www.ebsaweb.org

Member States. This will be especially important in situations of public health emergency, when rapid and up-to date recommendations, risk assessments, and follow-up analysis may be needed (e.g. outbreaks due to lab accidents). With respect to ECDC's current and future work with laboratories in the Member States in the field of public health, a robust "biosafety programme", which includes information and training resources, would be important to ensure the quality of work with ECDC partner laboratories and the work be performed in a safe environment.

2. IMPLEMENTATION OBJECT OF THE CALL FOR PROPOSALS

2.1. General objective

Building on ECDC liaison work with EU-funded projects and key stakeholders, including the Commission, European Biosafety Association (EBSA), MS and WHO, in the area of Biorisks, the aim of this **project** is to establish and coordinate an ECDC core group of biorisk experts. This core group of experts will engage with the biorisk community at large and provide specific requested expert technical advice and strategic input to support ECDC in the tasks of scientific advice and training on biorisk issues in an EU context.

2.2. Specific objectives

The specific objectives of the entire four-year project are:

1. To set-up and coordinate an expert group in the field of biorisks and engage the wider community of biorisk professionals and key stakeholders to exchange information, knowledge, and for implementation of project workplans.

2. To provide scientific advice on selected biorisk topics and information resources for the ECDC Microbiology web site.

3. To provide rapid scientific advice to ECDC by means of *ad hoc* input to scientific questions and for rapid risk assessments related to public health events where there is concern of biorisks (i.e. lab accidents or similar (un)intentional release incidents).

4. To provide overview of existing training initiatives and to develop a comprehensive plan to communicate this information and to implement training in needed areas for biorisk professionals.

2.3. Main actors of the management and communication

Definitions for the following actors of the management and communication aspects of the project are described below:

Coordinating partner – is the host institute, organisation, and/or private company that will have overall responsibility for the project. The coordinating partner should organise the following roles/functions to ensure project implementation: a **Project Leader**, who will act as the lead for the coordination and a **Project Administrator** who will have the overall responsibility for day-to-day project coordination and management. Both the **Project Leader** and **Project Administrator** are the key contact persons for liaising with ECDC and with Associate Partners. The Project Leader and Project Administrator should both be employed by the Coordinator as one individual or as separate roles.

Partners - are the consortium members. They are responsible for coordinating and conducting work at a regional or national level, are expected to contribute technical expertise, and play a key role in obtaining relevant data for the project as appropriate (e.g. in the test phase).

Management team – consists of 3-5 people including the Project Leader and selected representatives from Partners. The Management Team is expected to meet (face-to-face or with teleconference) with the Steering Committee regularly throughout the project duration and not less than once every 6 months.

Steering Committee – will be established to oversee project activities and to ensure the quality and relevance for the European added value of the project. The Steering Committee will be selected by ECDC and will include representatives from ECDC, and other experts in the field (e.g. considering e.g. the WHO, European Commission).

2.4. Deliverables of the call for proposals

The work to be carried out under the agreement to be awarded is organised in the following four main Work Packages (WPs) (Table 1 summary) and the related deliverables (**D**) listed below for the entire planned duration of the project of 48 months (4 years). We use the notation of "m" to indicate "month" from project start (**m0**) to project end (**m48**).

Table 1. Overview of Work Packages and main deliverables (D)

Work Package	Title and list of Deliverables (D)
WP1	**COORDINATION - – THE ECDC BIORISK EXPERT GROUP IS ESTABLISHED AND ITS COORDINATION ENSURED**
	D1.1 – the ECDC Biorisk Expert Group with agreed members and functional roles is established and a kick off meeting held at ECDC, Stockholm (**m1-3**) followed by bi-annual meetings (**m3-48**). D1.2 - a Steering Committee is identified and established and a regular communication plan developed (**m3**) including at least 1 face-to-face meeting or teleconference per year organised (**m6-48**) D1.3 – core group and external liaison meetings as needed and with identified key stakeholders, agreed with ECDC, are organised (**m6-48**) D1.4 - an annual report for project implementation and monitoring, comprising all the Work Packages (WP1-4), is provided (reporting periods to be agreed upon) including regular summary and sharing of meeting notes from D1.1-1.3 (**m1-48**)
WP2	**SCIENTIFIC ADVICE – SCIENTIFIC ADVICE ON SELECTED TOPICS, AND/OR ON A RAPID *AD HOC* BASIS, IS PROVIDED.**
	D2.1– Topics for scientific advice studies, including situational analysis and strategic planning, in field of biorisks are identified and the projects implemented and published as agreed with ECDC (**m1-48**) D2.2– procedure established for provision of (rapid) scientific advice from ECDC Biorisk expert group according to ECDC templates and internal

	procedures is established (**m1-3**) D2.3 – provision of *ad hoc* (rapid) scientific advice or comments in field of biorisks in response to scientific questions posed to ECDC, key scientific publications in the field, and/or in response to health threats (**m3-48**)
WP3	**COMMUNICATION - BIORISK INFORMATION RESOURCES ARE DEVELOPED AND DISSEMINATED TO THE PUBLIC AND/OR TO A RESTRICTED GROUP**
	D3.1– Content for the ECDCs web portal section "Electronic Laboratory Information System for Europe (ELISE)" in the area of biorisks is agreed on, developed, and content updates are regularly provided (**m1-48**) D3.2 – Sign-up as ECDC expert promoted and implemented to expert networks and associations in biorisks (**m3-48**) D3.3 – Scientific papers, other scientific advice and risk assessments produced in WP2 prepared for joint publication with ECDC to a restricted and/or public forum (**m1-48**)
WP4	**TRAINING AN OVERVIEW OF EXISITING TRAINING PROGRAMMES, RESOURCES, AND OPPORTUNITIES IN THE EU IS PROVIDED AND A ROLE FOR ECDC IDENTIFIED FOR FUTURE IMPLEMENTATION**
	D4.1– An overview of existing training opportunities, initiatives, and sources of training materials is provided and a road map for future training initiatives presented indicating the role of ECDC (link to WP2; D2.1) (**m1-48**) D4.2 – The plans in training in biorisks from D4.1 are implemented (**m3-48**)

2.5. Work Packages and activities

The successful applicant is requested to coordinate their work in agreement with and under the supervision of ECDC. In the coordination of the project (**WP1**), the applicant carries out biorisk group meetings and engages with the larger community of biorisk specialists and international initiatives in the field. The biorisk scientific advice, information, and other resources gathered from all WPs (**WP2-4**) of the project (i.e. guidelines, documents, meeting and training announcements, etc…) will be directly integrated into the ECDC knowledge management systems (acronym KIS = knowledge information systems) and other central ECDC directories for contacts. For training initiatives in the field of biorisks the applicantgroup brings together and actively disseminates the existing information to relevant groups. The group works closely with ECDC to identify the role of ECDC in such training and to identify areas of cooperation.

WORK PACKAGE 1 (WP1) - COORDINATION – THE ECDC BIORISK EXPERT GROUP IS ESTABLISHED AND ITS COORDINATION ENSURED

Work package 1 (WP1) is focused on establishing an expert (core) group of multidisciplinary experts in the field of biorisks who can be a reliable source of technical expertise and input for the scientific advice and preparedness and response core functions

at ECDC. Moreover, the group should have a broad knowledge in the biorisks area and appropriate links to EU and global initiatives to give some strategic directions to the activities performed in the workpackages, particularly for development of years 2-4 of the project.

ECDC Biorisk Expert Group size and composition

There is no predetermined size to the bidding applicant/consortium, the expert group, and/or any enlargement of the group or liaisons with the broader community/network of experts. ECDC foresees that a realistic size would be between 9-13 persons. Assignment of alternates could be processed after contract signing. It is a key factor that the final ECDC Biorisk core group is of a size and expert representation that allows effective work, communication, and liaison with the wider body of experts that this ECDC Biorisk core expert group will need to engage with and pool knowledge from, to implement the project objectives.

The applicant should, therefore justify the size of the core group proposed and describe the representation from the different public and/or private sectors and any division of tasks therein in the proposal. For all experts, especially in the private sector, appropriate conflict of interest declarations will be made during the work of the project.

It would be necessary to have high representation in the core group from those experts who are biosafety professionals (with lab background) that work in areas relevant to public health, risk of infectious diseases, and with human focus. But it is advantageous to have representatives that also can cover the animal health area, particularly those that fall into the category of zoonotic pathogens.

Coordination and liaison meetings

An important part of the first years work will be for the expert group to meet together to discuss their project plans and scientific work. In addition liaison meetings with ECDC, the Steering Committee, and with key stakeholders should be planned for. One of the meeting points should include the annual EBSA meeting. Other meetings of the group should be proposed and those which are to involve ECDC should take place in Stockholm to nurture engagement of the wider body of ECDC experts and activities. The applicant should plan for and entirely coordinate at least 4 meetings of the core expert group, 2 of these meetings should involve ECDC, and a separate meeting/workshop should be devoted to liaison with key stakeholders such as Commission bodies (e.g. key directorates such as DG SANCO, DG RTD, DG JLS, DG Enterprise and agencies including EFSA, OSHA), related pan-European initiatives (i.e. past-and-present projects in the biorisks area), EBSA, WHO, and other international key stakeholders relevant to execution of project deliverables. Scientific programme and participants should be agreed upon with ECDC in advance. The project should cover for the travel, accommodation, and relevant subsistence expenses for all the participants to the meetings.

ECDC staff however will be covered by ECDC according to its internal procedures. Expenses by the consortium and relevant meeting participants should be included in the budget estimation.

Summary of Work Package 1: COORDINATION – THE ECDC BIORISK EXPERT GROUP IS ESTABLISHED AND ITS COORDINATION ENSURED	
Activities year 1	- Establish expert group (ca. 9-13 persons) in biorisks that represents the field and is able to perform the work of the WP2-4 in terms of provision and communication of scientific advice and training initiatives - Set up appropriate steering committee and links to key partners in the field - Coordinate meetings and/or needed workshops of the expert group with ECDC (2 meetings – m1 and 11 proposed), with the core expert group itself (2 additional meetings between m1-12), and with key stakeholders in the area (1 separate meeting – possible to time it as satellite meeting at EBSA annual meeting or separate venue). One meeting should involve the Steering Committee (m11 proposed) - Provide regular reporting of coordination aspects of group
Key Milestones/Deliverables year 1	- expert group established and coordination, management, and steering ensured (D1.1-1.4)
Project Duration	48 months
Estimated Budget year 1	50,000 Euros

WORK PACKAGE 2 (WP2) - SCIENTIFIC ADVICE– SCIENTIFIC ADVICE ON SELECTED TOPICS, AND/OR ON A RAPID AD HOC BASIS, IS PROVIDED.

ECDC is developing co-operations with laboratories in the Member States in the European Union to fulfil its mandate in surveillance, planning and response, and scientific advice for infectious diseases. It is therefore important to ECDC to promote good practices in the laboratory partners it works with and in the EU as a whole. Part of this involves good advice and access to resources in the area of biorisks. Therefore, WP2 is focussed on having the ECDC Biorisk Expert Group to work on specific biorisk topics in the field to develop guidance and resources in the EU context. ECDC suggests implementing these in the following areas of studies for the expert group but is open for further suggestions or instrumental topic modifications refined in the joint meetings of the Biorisk Expert Group and the Steering Committee:

Year 1 = situational analysis of biorisks and biorisk initiatives in the EU – mapping past and ongoing initiatives and development of a road map indicating synergistic role for ECDC with other bodies and international programmes.

Year 1-4 = examples of topics to be agreed upon include: - situational analyses in the area of laboratory accidents, cost-benefit analysis of biosafety/security measures, definition and mapping laboratory capacity P3/P4 laboratories, mobile laboratories, transport of infectious disease materials.

In addition to the above scientific studies, following ECDC templates and general procedures, the Biorisk Expert group is expected to provide *ad hoc* advice throughout the duration of the framework agreement. The advice will feed into ECDC risk assessments and other guidance, such as provision of answers to scientific questions, and in some cases it may need to be provided rapidly. Therefore the group will have to develop agreed procedures to do so and to account for the contributions, in situations where ECDC should provide assistance for use by the MS and other interested bodies. Examples include comment on breaking scientific papers or initiatives in the biorisk field, (confidential) input into analysis of laboratory accidents data, and other technical guidance for good biorisk management practices in the laboratory and or response to contamination or decontamination recommendations. However, it is clear that a defined amount of time for ad hoc requests should be budgeted and the scope defined in the start up of the expert group (refer to WP1).

Summary of Work Package 2: SCIENTIFIC ADVICE– SCIENTIFIC ADVICE ON SELECTED TOPICS, OR ON A RAPID *AD HOC* BASIS, IS PROVIDED.	
Activities	- perform scientific studies in areas of biorisks where there is EU added value and agreed priority
Key Milestones/Deliverables year 1	- Agree topic for year 1 scientific study and publication in appropriate peer-reviewed journal or other forum (D2.1) - Develop list of topics for further scientific study and plan for implementation, including priority list and feasibility analysis (D2.1) - Established procedure for provision of (rapid) scientific advice and scope of requests (D2.2) - Provision of *ad hoc* scientific advice in the form of risk assessments, answering scientific questions, and other request for specific information resources in the field (links to WP3 Communication) (D2.3)
Project Duration	48 months
Estimated Budget year 1	20,000 Euros

WORK PACKAGE (WP3) COMMUNICATION - BIORISK INFORMATION RESOURCES ARE DEVELOPED AND DISSEMINATED TO THE PUBLIC AND/OR TO A RESTRICTED GROUP

As part of its mandate ECDC should be a source of up-to-date scientific advice and resources in infectious diseases in a public health context. This requires the compilation of the best and most useful resources in the fields that ECDC works in. In the area of biorisks, ECDC has been requested through its special forum of Member State health authority-appointed technical experts in the Microbiology field (National Microbiology Focal Points) and other cooperating partners to develop laboratory information resources. This is specifically true for the area of biorisks (e.g. MS biosafety guidelines, biorisk regulations, ISO standard documents, links to societies and associations, shipping and transport guidelines and the like material and documents). It is true that this information exists already in a number of other web sites and has been part of projects in the area of biorisks, some funded by the Commission itself. However, it is of added value for ECDC to compile these sources of information and to "distill" and "disseminate" the relevant information to the appropriate audience. The Biorisk Expert Group is expected to work

with ECDC to ascertain the needs and to develop the content and communication style with our web portal team and Health Communication Unit.

In addition to these activities the Biorisk Expert group will promote the "Sign-up as ECDC expert" to its associated bodies as part of engaging with the larger biorisk community in Europe and globally and to foster collaborations.

Finally this WP should take the scientific work produced in WP2 and support preparations for publication (web based and or traditional paper publications or information pamplets) in an appropriate format to target audiences, such as expert networks and associations in biorisks.

Summary of Work Package 3: COMMUNICATION - BIORISK INFORMATION RESOURCES ARE DEVELOPED AND DISSEMINATED TO THE PUBLIC AND/OR TO A RESTRICTED GROUP	
Activities	- develop, maintain, and update biorisk information resources for ECDC web portal - promote the use of these resources and engage with community of biorisk and other public health experts via the ECDC "sign in as expert" - final production phases of the scientific guidance/studies performed in WP2
Key Milestones/Deliverables year 1	- following agreements made in first meeting of group with ECDC the group will prepare content for web resources in the area of biorisks (D3.1) - keeping biorisk web content up-to-date, dissemination to expert community, and developing future plans (D3.1-3.2) - scientific publications from WP2 completed and communicated (D3.3)
Duration	45 months (M3-M48)
Estimated Budget year 1	15,000 Euros

WORK PACKAGE 4 (WP4) - TRAINING - AN OVERVIEW OF EXISITING TRAINING PROGRAMMES, RESOURCES, AND OPPORTUNITIES IN THE EU IS PROVIDED AND THE ROLE OF ECDC FOR FUTURE IMPLEMENTATION IS RECOGNIZED BY STAKEHOLDERS

Training is one of the key areas in the field of biorisks and biorisk management. Well trained professionals that work in the labs as well as those that have more management responsibilities is part of a robust biosafety programme in the area of infectious diseases. There are a number of Commission bodies and third parties interested to gain an overview of all the training activities in the EU and the curriculum being used. EBSA is one of the key resources in this respect with their unique networking of experts and as

well excellent workshops at their annual meetings. Also, a number of Commssion funded projects have gathered information over the years and made concrete recommendations on the topic of training but the results are not all in one place to interpret. In addition, recommendations need to be translated into implementation plans and to identify roles and responsibilities according to institutional mandates.

ECDC is a recent stakeholder in the field of public health and part of its mandate stipulates training and support to MS in fields that relate to prevention and control of infectious diseases. There is a role for ECDC to play in biorisk training whether it be at a coordinating and information resource level or more specific support for identified target groups in the MS as part of its long term strategy for cooperations with microbiology laboratories. Currently the role of ECDC in the field of training and biorisks needs to be ascertained with stakeholders, working in synergy with the Member states and other bodies to avoid duplications of efforts and to maximise impact. To work on this, WP4 engages the Biorisk Expert Group in activities aimed at bringing together results of past- and –present projects that looked into training issues and to also contribute more up-to-date information that has developed since the close of these projects/studies. From this situational analysis, the Biorisk Expert Group can develop with ECDC a road map and guidance in training needs in the EU that ECDC can promote and implement.

Summary of Work Package 4: TRAINING - AN OVERVIEW OF EXISITING TRAINING PROGRAMMES, RESOURCES, AND OPPORTUNITIES IN THE EU IS PROVIDED AND THE ROLE OF ECDC FOR FUTURE IMPLEMENTATION IS RECOGNIZED BY STAKEHOLDERS	
Activities	- understand the training mandate and work at ECDC - compile information and recommendations past and present on this topic of biorisk training in the EU - build the strategy and implement plans in biorisk training
Key Deliverables - year 1	- situational analysis and road map of role of ECDC in training (specific part of WP2 study and report or separate document) and implementation of plan (D4.1-4.2)
Duration	45 months (M1-M48)
Estimated Budget - year 1	15,000 Euros

2.6. Meetings:

For the meetings (including training), the successful Applicant shall carry out the following tasks:

- Propose the list of participants and seek ECDC input and approval prior to the meeting and provide the scope and purpose of the meeting. Provide a final list of participants, including their affiliation and contact details, at the meeting. Make it available to ECDC in an electronic copy.

- Ensure the delivery of the full meeting, including:
- Organize travel and accommodation for all participants. Cover all costs related to the travel, subsistence and accommodation of all participants. Travel, accommodation and subsistence for ECDC staff, will be covered by ECDC according to its internal procedures.
- For meetings occurring outside ECDC, provide catering for all participants.
- The successful applicant will be paid, for covering the costs of the participants, the country-specific fixed rate indicated in Annex VI Rules on Eligibility of Costs of the draft agreement per participant and per day, after conclusion of the module, upon proof of participation by a participants' list signed by each participant for each meeting day.
- For meetings occurring outside ECDC premises, provide the meeting venue as appropriate, ensuring smooth implementation and ideal working conditions; including all relevant material such as personal computer, overhead projector, video projector, power point and beamer, screens, flip charts (with paper and pens), easy access to printer, photocopier (with sorter and stapler function); and including coffee breaks and water on the table during meetings.
- The meetings are held in English.
- Provide printed material related to the meeting.
- Ensure the relevant support to allow for the smooth organisation and implementation of the meeting.
- Ensure that all participants sign the participants list for each day of the meeting.
- Collect presentations.
- Write a short report of the main discussion points of the meeting, including the recommendations and action points.
- Provide the meeting material and report

2.7. Place of performance of the contract

The implementation of the contract is to be carried out at the successful applicant premises except for some meetings (.

2.8. Characteristics of the agreement object of the call of proposals

ECDC wishes to conclude a framework partnership agreement with one applicant or a consortium of partners. The duration of this agreement is planned to be two years, with another two yearly possible renewals upon agreement of both parties. After the first two years implementation, further implementation is subject to the outcomes of the first two years. The framework partnership agreement establishes the framework of the deliverables and requires an additional step to make the actual implementation. This is in the form of a specific grant agreement specifying the details for each particular implementation, based on the previously signed framework partnership agreement, and

specifying the resources used. Due to calendar planning and in order to group processes, the submission of the first specific grant agreement is already requested with this application (see Section above concerning year 1). The specific agreements after the first renewal will be subject to budget availability confirmation.

The successful Applicant shall coordinate a consortium with other Institutions in all EU/EEA Member States and where appropriate to extend some activities to candidate and accessing EU countries. The successful Applicant must submit the details of institutions involved. A consortium arrangement between partners that will form the core expert group will ensure pooling of existing European knowledge and expertise in this area.

The signature of the agreements shall be by one Lead Institute, the Coordinator of the consortium. Partner institutions give mandate to the Lead Institute for the performance of the agreement.

The coordinator shall ensure that consortium partners complete the formalities for them to accede to the contractual agreement. (see Article I.2 of the model Framework Grant Agreement in Annex II), including the duly completed and signed originals of Form A (set out in Annex III).

If subcontracting is envisaged, the volume/proportion of the tender being subcontracted cannot represent an important part of the grant amount. The parts of the work sub-contracted have to be specified in the application, for each subcontractor. Sub-contractors must satisfy the eligibility criteria applicable to the award of the grant. If the identity of the sub-contractor is not known at the time of submitting the application, the applicant who is awarded the grant will have to seek ECDC's prior written authorisation before entering into a sub-contract. Where no sub-contractor is given, the work will be assumed to be carried out directly by the applicant/consortium.

2.9. Amount available for financial support and provisions about the results

The estimated grant for the first year of the project (covering all activities in WP1-WP4) is 100,000 EUR. For the successive years the grant amount will be determined time by time, contingent on the available budget and on the work plan of ECDC. Funding available for the first two years is indicatively 250,000 EUR, for the next two renewals together indicatively 250,000 EUR. The budget amounts from year two to four are subject to budget availability and the performance on work packages WP1-WP3.

The ECDC contribution covers 90% of the total eligible costs and the successful applicant will co-finance the remaining 10% of the total eligible costs.

Applicant must apply **the Rules on eligibility of costs** (see Annex VI of this Call).

The ultimate aim is an active cooperation between ECDC and the successful Applicant for the duration of the project.

Ownership of the outcomes obtained during and from the project implementation (action, work packages), including industrial and intellectual property rights, and of the reports and other documents relating to it shall be vested in the ECDC.

The owner of all the documentation, all data in databases and all the functionalities to use those data and update them and the working of the database will be the ECDC. No publications can be made without agreement of ECDC. ECDC should have co-authorship of any scientific publication and communication produced by the awarded applicant.

Without prejudice to the previous paragraph, the ECDC grants the partner the right to make use, subject to prior written consent of ECDC, of the results of the project (action), provided it does not thereby breach its confidentiality obligations or existing industrial and intellectual property rights.

ECDC should be acknowledged / mentioned as provider of funding on all communications meaning the ECDC logo and a disclaimer will be put on all reports, web site, bulletins, etc.

2.10. Reporting requirements

The following reports are requested to be submitted:

The reports related to the deliverables of the call for proposal:

The reports related to the financial management of the implementation:

- A financial statement supporting the request for payment: The costs here declared by the partner shall be real, accurately recorded and eligible, in accordance with the framework agreement and the specific agreement. The supporting documents are not requested to be submitted and are kept by the partners, according to their accounting and internal auditing procedures. They must permit direct reconciliation of the costs and revenue declared for the implementation with the corresponding accounting statements and supporting documents, in compliance with Article II.22 - Checks and Audits of the agreement.

- A comprehensive condensed technical report on the implementation

- Relevant written correspondence, including ECDC's approval on any item mentioned above

2.11. Payments

Payments for the year 1 Specific Grant Agreement will be performed as follows:

- 25% pre-financing upon receipt of a request for pre-financing that can also be submitted together with the agreement for signature.
- Up to 35% interim payment, based on actual costs (25% covered by the previous pre-financing) by mid-November 2009.
- Interim payment to reach up to 75% of the project by month 7 after the kick-off meeting, based on actual costs and implementation of deliverables.
- Balance final payment upon receipt and approval of a final invoice, final financial and technical report, the related supporting documents, all the deliverables and scientific paper ready for submission.

For specific grants agreements for the successive years, the payment schedule will be established when there is the request for resources allocation and budget.

2.12. Indicative time frame 1st year

Please propose a detailed work plan and timeline (i.e. Gantt chart) for the implementation of year 1, considering that a big part of the implementation is expected by mid November 2009, and the finalization by the first half of 2010.

	months	1	2	3	4	5	6	7	8	9	10	11	12
Activity	**WP n** (title of work package)												
1.1	(name of activity)												
1.2	...												
1.3	…												
	…												

2.13. Implementation of the Work Packages in years 2 to 4

By the end of May 2010, the successful applicant is requested to present a detailed description of the planned activities and deliverables for each of all the Work Packages, concerning each next year, including the relative budgets and workplan, with timeline, approach and list of milestones and deliverables.

3. CONTENT OF THE APPLICATION

3.1. THE DEADLINE FOR APPLICATION IS 8 SEPTEMBER 2009

3.2. The proposal to submit to ECDC should include:

- **An outline of the whole project.**
- **A detailed description of the year 1 activities for Work Packages 1-4. For year 1** project plan, a Gannt chart for the main milestones of the project should be provided plus a description of the approach and the allocation of resources (individuating resources of consortium partners involved) and expertise to be used to achieve the deliverables. The number of person months envisioned should be estimated and a budget provided thereof.
- **An outline of the activities for year 2-4 of these same work packages.**

Detailed description of activities (i.e. key topic, deliverables, and timeline) for year 2-4 of the project will only be discussed and negotiated after completion of preceding activities, based on an invitation by ECDC to submit a proposal in accordance with Article I.4 of the framework partnership agreement and taking into account the outcome of previous work package activities as well as the budgetary context at that time.

The proposal from an Applicant should include a technical and budget proposal for each Work Package.

Submission of a proposal implies acceptance of all the terms and conditions set out in the call for proposal, in the annexes and in the draft framework grant agreement and specific grant agreement. In drawing up your proposal, you should bear in mind the provisions of the draft agreement (see Annex II and III). All documents presented by the applicant become the property of the ECDC and are deemed confidential.

3.3. Management and Communication Plan

A preliminary project Management plan should be designed and submitted as part of the proposal for this grant.

The **Management plan** should describe the project management organisation (i.e. see details above regarding the description of main project management actors) and include the interaction with the Steering Committee. The decision making process for the project should be elaborated on including the interactions of the consortium with the management team and with ECDC. The proposal provided will be adapted where necessary to fit to the ECDC procedures of clearance through ECDC Chief Scientist. A project organigramme showing links between participating partners can be included in the descriptions.

The Management Plan should also include a **Communication Plan**, which should outline both internal and external communication.

(a) The internal component of the Communication Plan should include organising, conducting and chairing meetings of the Management Team.

(b) The external component of the Communication Plan relates to the dissemination of the final results and should be further detailed.

3.4. Estimated budget

Within the total budget, the applicant is free to propose particular implementations with the corresponding budget allocation to the activities, providing that the project proposal remains focussed on the main objectives and deliverables. As the project progresses, eventual updates shall be discussed with ECDC and as indicated by the agreement.

4. EVALUATION OF THE PROPOSALS

After having verified the compliance with all **the submission requirements** (see 4.1), ECDC selects the admissible proposals through a procedure that involves 4 types of **evaluation criteria in this order**:
(1) eligibility criteria (see 4.2),
(2) exclusion criteria (see 4.3),
(3) selection criteria (see 4.4),
(4) award criteria (see 4.5).

If the submission requirements are not met, the proposal is not passed to the next step of the evaluation criteria. **If one of the evaluation criteria** is not met, the proposal is not passed to the next steps of the evaluation criteria. It is therefore essential to complete the

proposal in full and provide all the supporting documents requested. The proposal proposed for award is the one, among those evaluated with the award criteria, which has the best score.

An Evaluation Committee will be established in accordance with article 116 of the Financial Regulation and article 178 of its Implementing Rules in order to evaluate the submitted proposals. ECDC intends to finalise the evaluation of proposals within one month since the final deadline for submission of proposals. In compliance with article 116 (3) of the Financial Regulation, the applicant will be informed in writing of the decision on their proposal. Please note that ECDC has the right not to award a grant and to cancel the procedure at any time before the signature of the agreement without any compensation to be paid to the applicant.

General principles:
In compliance with the Financial Regulation and its Implementing Rules, the proposals must comply with the following principles:
• **Co-financing rule**: external co-financing from a source other than EU budget is required as indicated in part 2.7.
• **Non-profit rule**: the grant may not have the purpose or effect of producing a profit for any of the applicant;
• **Non-retroactivity rule**: the costs eligible for financing must be incurred after the starting date stipulated in the agreement;
• **Non-cumulative rule**: only a single EU grant may be awarded for a specific project carried out by a given beneficiary in one financial year.
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4.1. Verification of submission requirements

The following will be assessed:

• **The final deadline for submission of proposals:** If this deadline has not been respected the proposal **will automatically be rejected**.
• The proposal is **duly signed** by the duly authorized representative of the consortium.
If the proposal is not signed then it may be rejected on that sole basis.
• **The proposal is complete, including all supporting documents and in accordance with the model structure (Annex I)**. If any of the requested information/documents is missing or is not complete the proposal may be rejected on that sole basis.

The proposal which meets all the submission requirements will be considered admissible and will pass to the next stage of evaluation process – verification of eligibility criteria.

4.2. Eligibility criteria

Consortia consisting of at least two partners (natural/legal persons, private or public), these partners being established in different ECDC member countries (the 27 EU Member States and EEA/EFTA counties which are Iceland, Liechtenstein and Norway), are eligible.

A **LEGAL ENTITY FORM has** to be completed and signed separately by the applicant (each partner of the consortium). This legal entity form should be returned together with a copy of the public legal act establishing the entity in question or failing that, any other

official document attesting to the establishment of the entity, clearly indicating it pursues public interest objectives. ECDC provides a template to be used – Annex V.

4.3. Exclusion criteria

Article 114(2) of the Financial Regulation states that "Grants may not be awarded to applicant who are, at the time of a grant award procedure, in one of the situations referred to in Articles 93 and 94". Accordingly, applicant and possible partners must certify that they are not in one of the following exclusion situations:

- (a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

- (b) they have been convicted of an offence concerning their professional conduct by a judgment which has the force of *res judicata*;

- (c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;

- (d) they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the implementation is to be performed;

- (e) they have been the subject of a judgment which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;

- (f) following another procurement procedure or grant award procedure financed by the Community budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations.

In addition, grants may not be awarded to applicant who, at the time of the selection procedure:

- (a) are subject to a conflict of interest;

  (b) are guilty of misrepresentation in supplying the information required by ECDC as a condition of participation in the award procedure or fail to supply this information.

- (c) find themselves in one of the situations of exclusion listed above.

Applicant must certify that they are not in one of the situations listed above by signing the attached Declaration on Honour (Annex IV). The Declaration on honour is to be completed and signed separately by each consortium partner.

The *consortium with which the partnership agreement will be signed* must provide evidence confirming the declaration referred to in the previous point.

4.4. Selection criteria

In the case of a consortium submitting an offer, each member of the consortium must provide the required evidence. For 'technical capacity' the evidence provided by each member of the consortium will be checked at consortium level to ensure that the consortium fulfils the criteria.

Financial capacity:

Evidence of the *consortium's* economic and financial capacity shall be furnished by the following documents:

- Commitment to provide the necessary financial coverage for the project implementation cash flows and for the 10% co-finance requirement, in order to maintain the consortium's activity throughout the 4 year partnership period;

- for private partners: profit and loss accounts, balance sheet for the last financial year for which the accounts were closed (and audit reports by an approved external auditor certifying the accounts for the last available financial year).

If, for any valid reason, the service provider is unable to provide the references requested by the contracting authority, he may prove his economic and financial standing by any other document which the contracting authority considers appropriate.

Technical and professional capacity

The Applicant must have the following technical capacity to perform the contract:

The group should have a broad knowledge in the biorisks area and appropriate links to EU and global initiatives to give some strategic directions to the activities performed in the workpackages, particularly for development of years 2-4 of the project.

It would be necessary to have high representation in the core group from those experts that work in areas relevant to public health, risk of infectious diseases, and with human focus. But it is advantageous to have representatives that also can cover the animal health area, particularly those that fall into the category of zoonotic pathogens.

It is preferable that the consortium includes partners from different EU MS and EEA/EFTA countries in order to assure wide EU research collaboration between the countries. It is important to have collaborators from different EU MS and EEA/EFTA countries who could provide data and collaborate on national and regional level to achieve the project objectives.

Evidence of the *consortium's* technical and professional capacity to carry out the envisaged project shall be furnished on the basis of the following documents:

1. Detailed CVs (indicating the level of English/other language skills[7]) as well as letters of intent of the core staff and key experts of all consortium partners assigned proposed for the

[7] Languages abilities: statement of the candidate's language abilities. Most of the work will be performed in English. The core staff/key experts must demonstrate a strong ability to draft and operate in this language and provide examples of previous work

project, proving that the *consortium* as a whole has sufficient technical, scientific and management (including financial) experience to implement the project.

2. Examples of work done in the areas covered by this call for proposals in the past three years; clearly indicating the role of the contributors.

3. A presentation of the organisation of consortium and its internal organisation. Proposals must specify the role, qualifications and experience of each of the members of the consortium.

Every *consortium* submitting a proposal shall nominate a Coordinator who will alone interface with the Centre.

Letters of intent of all consortium partners to participate to the project and to provide co-financing to the project for at least 10 % of the total eligible costs of the work packages[8]. The 10%-rule of minimum co-financing is applied towards the consortium as a whole. To what extent partners contribute to this co-financing is an internal consortium matter. Before awarding any grant through Specific Agreements (SAs) based on Framework Partnership Agreements (FPA(s)), (the) consortium(a) must furnish proof of the amount of co-financing to be provided (Article I.6.2 FPA).

5. Language abilities: statement of the candidate's language abilities. Most of the work will be performed in English. The core staff/key experts must demonstrate a strong ability to draft and operate in this language and provide references to previous work.

The Applicant must have the following professional capacity to perform the contract:

- The Applicant must be registered in a relevant commercial or trade register. This condition does not apply for public bodies.

Evidence of this capacity must be provided by:

- The Applicant must provide evidence of enrolment (declaration or certificates) in one of the professional trade registers in its country of establishment.
- If the Applicant is not required or permitted to enrol in such a register for reasons of his statute or legal status, an explanation should be provided.

[8] The 10%-rule of minimum co-financing is applied towards the *consortium* as a whole. To what extent partners contribute to this co-financing is an internal *consortium* matter. Before awarding any grant through Specific Agreements (SAs) based on Framework Partnership Agreements (FPA(s)), (the) *consortium(a)* must furnish proof of the amount of co-financing to be provided (Article I.6.2 FPA).

4.5. Award criteria

The framework agreement will be awarded to the proposal which will obtain the highest score, taking into account the following criteria; no award criteria and sub criteria others than these will be used to evaluate the proposal.

Award criterion 1: Technical implementation i) Understanding of the context ii) Degree to which the proposed implementation responds in a credible way to the call for proposals iii) How the deliverables are apt be disseminated and have an impact *(The above aspects are of the same relative value)*	**25 points**
Award criterion 2: Methodology i) Soundness of the proposed technical aspects of the project - i.e. Content and quality of the proposed methods for carrying out the deliverables of the WP1-4 ii) Use of the appropriate resources for carrying out the planned tasks *(The above aspects are of the same relative value).*	**30 points**
Award criterion 3: Project team and management i) Allocation and management of resources and expertise ii) Coordination and mobilization of the team and possible subcontractors iii) Realistic time deadlines for completion of tasks and work plan iv) Verifiable objectives and milestones v) A group of relevant partners who work together as a multi-disciplinary team *(The above aspects are of the same relative value)*	**25 points**
Award criterin 4: Cost effectiveness The extent to which the estimated budget is cost-effective (comparison between estimated cost and anticipated achievement of objectives/results).	**20 points**

<u>Minimum attainment per award criterion</u>

Proposals scoring less than 60% for any award criterion will be deemed to be of insufficient quality and eliminated from further consideration.

<u>Minimum attainment overall</u>

Proposals scoring less than 60% after the evaluation process will be considered to be of insufficient quality and eliminated from the following phase.

5. ANNEXES

I. Model proposal (structure)
II. Model of Framework Partnership agreement
III. Form A – Form B – Model of Specific grant agreement
IV. Declaration on honour on exclusion criteria
V. Financial identification and legal entity forms
VI. Rules on eligibility of costs
VII. List of previous/current EU grants
VIII. Estimated Budget