Instrument for Stability

ANNEX II
TERMS OF REFERENCE
for

Sharing experience between EU and South East Asian countries on the reinforcement of legislations and regulations in the field of biosafety and biosecurity, as well as relevant laboratories management systems through Regional Centre of Excellence

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ATTACHMENT "TOWARDS A GLOBAL APPROACH: THEORITICAL CONCEPTS AND KEY DEFINITIONS"

1. BACKGROUND INFORMATION

1.1. Partner countries and territories

South East Asia countries (list of countries to be defined during the inception phase)

1.2. Contracting Authority

European Union, represented by the European Commission (implementation by the EuropeAid Cooperation Office (AidCo))

1.3. Background

The new Instrument for Stability (IfS)[1], created as part of the reform of the Community external financing instruments in 2006, has been designed to provide the Union with a strategic tool to address a number of global security challenges.

One of the objectives of this instrument consists in developing **longer-term Community actions to counter global and trans-regional threats** arising from organised crime, trafficking, radiological, nuclear, biological and chemical risks mitigation and also threats to critical infrastructure and public health, while at the same time contributing to broader Community development and external policy objectives.

Strengthening capabilities against biological threats has been identified as a priority area in the Strategy 2007-2011 and Indicative Programme 2009-2011 (Project area 3) of the Instrument for Stability.

Experience has shown that Community programmes can play an important role in the area of risks mitigation. In the course of its cooperation with Russia and other CIS countries, and through the enlargement process, the Community has acquired considerable experience in combating the trafficking of illicit nuclear material. It is clear however that in the field of CBRN threats mitigation, the approach taken must necessarily be global and trans-regional, although many of the measures may be implemented at national or regional levels. Adopting a regional approach with regard to Biosafety and Biosecurity is a manner to enhance cooperation and the experience shared between countries and building a common culture of Bio risks managements.

1.4. Related programmes and other donor activities

In fulfilment of Art. 4.2 of the Instrument for Stability (IfS), the IfS Indicative Programme 2009-2011 identifies "capacity building against CBRN threats" as a necessary condition for risk mitigation and preparedness relating to CBRN materials or agents.

The first phase (under Annual Action Plan 2009) is being implemented. In the action fiche relating the CBRN Centres of Excellence, pilot projects have been

[1] Regulation (EC) No 1717/2006 of the European Parliament and of the Council of 15 November 2006 establishing an Instrument for Stability (OJ L 327/1)

earmarked under 4.3. The first establishment of a CoE Secretariat is expected early 2011 in the South East Asia region.

In the field of the CBRN threat, a number of initiatives and projects are being conducted by international/regional organizations, including the EC's TACIS/PHARE and IfS programmes, the IAEA, including its Illicit Trafficking database, WHO, EUROPOL's Counter-Proliferation Programme (CPP), US Department of Energy and Department of State, Biological and Toxin Weapons Convention (BTWC), OPCW, the WCO's Programme on Nuclear and Radiological Materials, INTERPOL's bioterrorism project and Organization for Security and Co-operation in Europe (OSCE).

2. OBJECTIVE, PURPOSE & EXPECTED RESULTS

2.1. Overall objective

Through the Regional Asian Centre of Excellence, the main objective is to share a common understanding between European Union and Asian countries on the main Biosecurity and Biosafety concepts, and then studying the legislations, regulations as well as relevant standards, especially those that deal with laboratory management systems.

2.2. Specific objectives

Taking into account the global scope of the Instrument for Stability, and especially the topics of interest described above, it is necessary, as a first step, to define a list of Asian countries to be covered; to reach a "regional approach", it could be useful to start with at least three Asian countries (South East Asia). This choice should be based on various criteria, such as:

- Need of laboratories' Biosafety/Biosecurity reinforcement;
- Geographical situation of the country and its relationships with its neighbourhoods;
- Political stability;
- Amount and type of international cooperation;
- Willingness of the country to cooperate with the EU, in particular in the area of bio-safety / bio-security, and to adopt WHO, EU and relevant international standards;
- Participation of the country to international organization dealing with international standardization such as ISO (International Organization for Standardization);
- Existence in the country of residual facilities, materials and agents.

Thus, the previous results of the field missions already conducted through the EU "Expert Support Facility" in South-East Asian countries must be taken into account (see "Expert Support Facility" project Lot 4 reports); e.g. Malaysia and Thailand have already expressed their interest, nevertheless, others countries belonging to ASEAN could also express their willingness to join this project through the CBRN centres of excellence initiative.

2.3. Results to be achieved by the Contractor

The implementation of the road map described hereafter should be facilitated by the creation of **a Joint Working Group (JWG),** involving **experts from the EU and from the South-East Asia partner countries**, such as: scientists, experts, head of institutes and laboratories, people coming from ministries and organisms that are responsible for elaboration and application of laws, regulations and standards.

The aim of this **Joint Working Group** would be to carry out and coordinate the different steps described hereafter, first by sharing common understandings on the main Biosecurity and Biosafety concepts, and then by studying the legislations, regulations, as well as relevant standards already in place and how they are implemented.

Thus, at the final stage, the **Joint Working Group** should be involved in the elaboration of a set of concrete and adapted recommendations, in order to reinforce if needed and as needed, legislations, regulations as well as relevant standards applying to laboratories, but also taking into account all the security of the biological pathogens' exchanges of strains between the laboratories and countries.

A team of high level experts from EU Member States (Team of European experts --TEE--), led by an experienced project manager, familiar with the EU's external assistance programmes, having a technical background and aware of the international procurement rules, shall provide services as listed below.

The activities under this project shall be implemented in close coordination with AidCo A.4 Project manager, and with the CBRN CoE's Implementing Body and Coordinating Committee. The Team of European experts shall regularly brief the EU on the state of play and shall provide for documents in draft and final forms for the EU review and approval. Frequent contact with the AidCo by email and/or telephone is required, as well as occasional meetings to enable AidCo to have a full understanding on the development of the project.

At the beginning of the project, a realistic project schedule shall be developed and agreed with the EU contact point.

The project schedule should take into account the following goals:

- The first goal is to reach to a regional approach through the Regional Asian Centre of Excellence and mainly, by the implementation of a Joint Working Group (JWG) both including the Team of European experts --TEE-- but also the experts from at least 3 Asian countries, (task 1).
- The second goal is to share the culture of biological risks assessment (tasks 2 and 3)
- The third goal is to share the culture of biological risks management (tasks 3 and 4)
- The fourth goal is to finalize the fine assessment of the Biosecurity and Biosafety improvement needs through a sound analysis of the laws and regulations, as well as the relevant standards, in close cooperation with Asian countries (task 4).
- At the final stage, the strong point is the sharing methodology for strengthening Biosafety and Biosecurity guidelines, regulations and

legislations if needed and as needed (during last years the regulations on Biosafety and Biosecurity have changed several times within EU countries due to a strong need of pragmatically applicability field level), (tasks 2,3 and 4).

3. ASSUMPTIONS & RISKS

3.1. Assumptions underlying the project intervention

The Contractor will benefit from the support of the CBRN Secretariat in the region.

The Contractor ill also benefit from the support of the UNICRI (United Nations Interregional Crime and Justice Research Institute) and the JRC (Joint Research Centre), both in charge of the establishment of the regional CBRN Secretariats.

The proposed project will build on UNICRI/European Commission (EuropeAid & JRC) experience in IfS 2007 and 2008 projects on CBRN Knowledge Management System, exchanges of information, collection and management of data and coordination of agencies at national and regional levels, which has demonstrated the advantages lying in the development of the CBRN CoE as a platform for the implementation of future national and regional projects, in close coordination with other international initiatives.

3.2. Risks

There are few risks resulting out of the complexity (from political to social dimension, big and heterogeneous area etc.), that are common to the all tasks of the project. The set-up of the CBRN Centre of Excellence could entail the following implementation risks and difficulties:

- Gaining access to reliable data and access to information from the recipient and/or other organisations that are involved, if the information is not available and/or if the data provided by the partners are incorrect.;
- Addressing countries' requirements;
- Engaging national agencies responsible for dealing with the CBRN threat;
- The much extended network, the big number of partners and the large territory may affect the project implementation with respect to provision of sufficient funding, the compliance of the working plan in terms of completeness and time and the danger not to get all the partners involved in the foreseen way

To meet these challenges will first of all require the development of strong management tools and methods in order to:

- Come to an effective and coordinated involvement of all key players to meet a broad variety of partners' interests and to generate synergies, enhance complementary actions and avoid unnecessary overlapping;
- Establish working principles like enhanced co-ownership, particularly due to shared responsibilities, pro-active participation of all partners in the

planning and implementation and result oriented activities with more common consensus regarding priorities;

- Provide a clear understanding to all actors inside the Project regarding goals, deliverables, schedule and interrelationships, financial and technical resources opportunities and restrictions, schedules, and deadlines that should be reached;
- In light of the particular sensitivity of some countries to collaborate in a program CBNR and in light of the extreme importance of the communication in the management of events relating to CBNR threats, the Contractor will add the figure of communication expert In this context, communication plays a crucial role to ensure coordinated and comprehensive responses by the institutions involved. To face to CBNR risk integrated responses are needed. Planning process, together with coordination and sharing should be promoted and reinforced by effective internal and external communication processes.

4. SCOPE OF THE WORK

4.1. General

Effective response to CBRN risk depends on cooperation and co-ordination between all levels of government, response organizations and international partners. An effective strategy to deal with the CBRN threat requires a very high level of co-operation and co-ordination among many different authorities within and among countries. Lack of harmonised national preparedness and fragmentation of responsibilities within the regional or international anti-trafficking network may be easily exploited by non-state actors to traffic and develop CBRN weapons.

The creation of CBRN Centres of Excellence (CoE) aims at improving national CBRN policies in the targeted third countries by defining comprehensive tailored assistance packages in the areas of export control, CBRN illicit trafficking, redirection of scientists, emergency planning, bio-safety and security, crisis response and a culture of safety and security. This process will be developed with the help of EU Member States in a coherent and effective combination of national and regional capabilities.

4.2. Specific activities

Task # 1 – Implementation of a Joint Working Group (JWG), work schedule and inception report

- subtask A1: identification of team leader and preparation of work plan
- subtask A2: creation of a high-level expert team with the involvement of Southeast Asian and the EU countries

The Team Leader, after having familiarised himself with the current procedures of the EC, but also with the Strategy and Indicative 2009-2011 programme, the content of the on-going AAPs (2007-2009) of the Instrument for Stability and with other relevant documentation on the main issues of interest, like the "Expert Support Facility" project Lot 4 reports, shall prepare the work schedule in close coordination with other team members and the EC project officer.

In preparation of the schedule, notably by a political action by getting in touch with the countries of interest at an high political level (top-down approach of ASEAN), the European Union will help the Team of European experts (TEE) to take contacts at political level in order to identify the suitable counterparts in the selected countries as well as to prepare a draft schedule of visits and interactions.

The main purpose is to set up a Joint Working Group, involving experts from the EU (TEE) and those from the Asian partner countries that have to be:

- Scientists,
- Experts
- Head of institutes and laboratories,
- People coming from ministries and organisms that are responsible for elaboration and application of laws, regulations and standards.

The aim of this Joint Working Group would be to carry out and coordinate the different steps described hereafter, first by sharing common understandings on the main Biosecurity and Biosafety concepts, and then by collecting and studying the legislations, regulations, as well as relevant standards already in place and how they are implemented. On this basis, the implementation of the road map described hereafter should be facilitated by the Joint Working Group.

The Joint Working Group is also a mean to build confidence between countries, to reach a mutual and reasoned understanding of Biosafety and Biosecurity concepts and to promote recommendations that can be adapted to the situation of the partner country.

At a final stage, the Joint Working Group should make concrete and adapted recommendations, if needed and as needed, (including on legislations, on standards, and if possible, until laboratory's operating procedures).

Required output:

Deliverable # 1 – Inception report including description of the methodology, identification of at least 3 Asian countries to be covered, detailed time schedule of the activities, and names of Asian experts of the Joint Working Group (JWG).

Task # 2 – Mapping of relevant regulation

- subtask B1: mapping of the international treaties;
- subtask B2: collecting and mapping of the most important EU legislation, regulation, international good practices and international quality management systems standards;
- subtask B3: collecting and mapping of the national texts such as bio-safety regulations, lab policy, standards and internal law.

The Team of European experts (TEE), with close links with the CoE secretariat, has to establish a mapping of the international treaties and of the most relevant EU legislation and regulation in Biosafety and Biosecurity, as well as international good practices, such as WHO manuals and recommendations and international quality

management systems standards. Sometimes, some relevant legislations and regulations coming from some EU member states will be used as well.

This approach allows identifying and defining a set of texts that could be used as references.

Thus, a mapping of relevant laws, decrees, regulations and standards should be established by the TEE taking into account the type of text, responsible ministries, and the scope of the relevant texts. The mapping should include texts from EU, as well as international good practices, such as WHO manuals and recommendations and international standards of quality management systems.

In parallel, the Joint Working Group, through the strong help of its Asian experts, has to establish the collect and mapping of the national texts of at least 3 Asian partner countries, taking into account the type of text, responsible ministries, and the scope of the relevant texts.

Required output:

Deliverable # 2 – the mapping of the texts of reference, taking into account a prioritization of the relevant main texts and the needs of the partner countries with regard to the type of Bio risks that they have to face.

Task # 3 – Glossary

A glossary will be built taking into account the previous identification of the main texts of reference at European level as well as at the international one.

A glossary should be elaborated in the language of the partner countries and in English in order to avoid the obstacle of the languages in this regional approach. This quite important work should be carried out by the Joint Working Group including both experts from the partner country and experts from the EU (TEE) in order to identify the most relevant words and concepts that need to be defined and translated.

Required output:

Deliverable # 3 – A practical glossary with practical examples.

Task # 4 – Recommendations

Starting from the mapping and glossary described above, the Joint Working Group should establish a reasoned comparison of the different texts (overlaps, main gaps) and write recommendations in order to reach a well balanced approach in terms of Biosafety and Biosecurity. This comparison has to be conducted through an analysis of the legislations and regulations, but also standards.

Required output:

Deliverable # 4 – Report on a reasoned comparison of the different texts (overlaps, main gaps) and suitable reinforcement recommendations if needed and as needed for the laws, the regulations and the standards. In some countries however, there is a merging of laws and standards; In this case, it's necessary to separate the requirements coming from laws from those coming from standards. At the final

stage, the strong point is the sharing methodology for strengthening Biosafety and Biosecurity guidelines, regulations and legislations if needed and as needed

Task # 5 Completion report

In this task the Contractor is expected to prepare the completion report that will summarize the work done but also recap the recommendations that were obtained during the implementation.
The completion report shall, as appropriate, document frequently problem issues, major constraints encountered in the course of the project and suggestions given for overall improvement.

Required output:

Deliverable #5 Completion report

The report needs the approval of the Commission (Mr Philippe Servais, AIDCO A4); if within twenty working days no comments have been made, the approval is deemed being given.

4.3. Project management

4.3.1. Responsible body for this action

The Contracting Authority is the European Commission, EuropeAid Cooperation Unit AIDCO/A4.

4.3.2. Management structure

The Management structure will be developed by the Contractor in the "Organization & Methodology" (Annex III).

4.3.3. Facilities to be provided by the Contracting Authority and/or other parties

None

5. LOGISTICS AND TIMING

5.1. Location

The main office of the programme is located at the Faculty of Medicine and Surgery “Luigi Sacco” University Hospital Milan which is the site of the Contractor and it will be main operational base for the Project.

5.2. Commencement date & Period of implementation of tasks

The date for commencing implementation shall be 15 January, 2011. The period of implementation of the contract will be 18 months from the commencement date.

5.3. Planning

The following provisional time schedule is envisaged for different tasks:

Task No.	Description	Start period
Task1	Implementation of a Joint Working Group (JWG), work schedule and inception report	T_0 + 3 months
Task 2	Mapping of relevant regulation	T_0 + 12 months
Task3	Glossary	T_0 + 14 months
Task4	Recommendations	T_3 + 3 months
Task5	Completion Report	T_0 + 18 months

The Contractor in his detailed work plan in Task1 shall propose the final and more detailed time schedule for the various activities on this project.

6. REQUIREMENTS

6.1. Personnel

6.1.1. Key experts

The Contactor Team will have the following key expert profiles to implement the project:

- Team Leader : public health expert with consolidated experience in project management and networking with the following qualifications and skills:
    - University Degree
    - Post-graduate diploma/education in public health or equivalent
    - Very good English knowledge. Knowledge of a second language (French or Arabic) is an additional asset.
    - At least 10 years of experience in the management of public health research and/or public health interventions.
    - Knowledge of the geographical area addressed by the project acquired with missions and works in the countries involved.
- Expert in legislation and regulation: consolidated experience on legislation and regulation in the domain of life sciences with the following qualifications and skills:
    - University Degree
    - Post-graduate diploma/education in International Cooperation or Public health covering the Biosafety and Biosecurity domains or equivalent
    - Very good English knowledge. Knowledge of a second language (French or Arabic) is an additional asset.
    - At least 5 years of experience in the public health sectors with focus on legal aspects

- Knowledge of the geographical area addressed by the project acquired with missions and works in the countries involved.

The Contractor's key experts shall have appropriate qualification, language skills and professional experience relevant to their specific area of work. Additional advantage will be given to the Team of European expert (TEE) having the necessary contacts and knowledge to access local relevant authorities in the target countries.

6.1.2. Other experts, support staff & backstopping

The Contractor shall select and hire other experts as required according to the project needs. The selection procedures used by the Contractor to select these other experts shall be transparent and shall be based on pre-defined criteria, including professional qualifications, language skills and work experience.

The experts should have proven:

- In-depth knowledge of issues relating to bio-safety & bio-security; especially experts coming from agencies who are responsible for the elaboration and application of the relevant legislations and regulations in the biosafety and biosecurity; and experts coming from standardization association, member of ISO, that deal with quality management systems.
- At least 2 European experts with an experience of work in a Bio Safety Level 3 (BSL-3) laboratory which activities are compliant with international standard such as ISO IEC 17025.
- Specific knowledge related to animal diseases and epidemiology (avian influenza etc.);
- Experience in the field of non-proliferation of WMD, especially a general and in-depth understanding of illicit trafficking and export control issues, supported by academic or professional titles, as required by their category.
- Experience in needs-assessment and programme preparation within EC and other external assistance programmes;
- Experience in working in a multi-cultural environment;
- Good knowledge of English language, both written and spoken;
- At least 1 expert in communication with international experience;
- Working experience in Asian countries is welcome.

Expertise in elaboration and application of the relevant legislations and regulations in the Biosafety and Biosecurity, expertise of work in a BSL 3 laboratory which activities are compliant with the requirements of international standard such as ISO IEC 17025 and expertise got from standardization association, member of ISO, which deal with quality management systems are also assets.

Cost for backstopping and support staff, as needed, are considered to be included in the financial offer of the Contractor in the fee rates of the experts.

6.2. **Office accommodation**

Office accommodation for each expert working on the contract is to be provided by the Contractor.

6.3. Facilities to be provided by the Contractor

The Contractor shall ensure that experts are adequately supported and equipped. In particular it shall ensure that there is sufficient administrative, secretarial and interpreting provision to enable experts to concentrate on their primary responsibilities. It must also transfer funds as necessary to support its activities under the contract and to ensure that its employees are paid regularly and in a timely fashion.

6.4. Equipment

No equipment is to be purchased on behalf of the Contracting Authority / partner country as part of this service contract or transferred to the Contracting Authority / partner country at the end of this contract. Any equipment related to this contract which is to be acquired by the partner country must be purchased by means of a separate supply tender procedure.

6.5. Incidental expenditure

The provision for incidental expenditure covers the eligible incidental expenditure incurred under this contract. It cannot be used for costs that should be covered by the Contractor as part of its fee rates, as defined above. Its use is governed by the provisions in the General Conditions and the notes in Annex V of the contract.

It covers:

✓ costs involved in organizing events (such as printing material; translation and the interpretation costs, catering, renting costs);
✓ cost related to dissemination;
✓ teleconferences;
✓ travel costs and subsistence allowance for participants in project event (missions, seminars, conferences, technical meetings);
✓ travel costs and subsistence allowance for participants in training activities (workshops, simulation exercises, stages);
✓ travel costs and subsistence allowance to carry out specific assessments, costs related to missions of experts to the Beneficiary Countries to support the capacity building, coordination and supervision in the beneficiary countries;
✓ travel costs and subsistence allowance for missions to EC Bodies

It also covers:

- Any subsistence allowances to be paid for missions undertaken as part of this contract must not exceed the per diem rates published on the Web site: http://europa.eu.int/comm/europeaid/index_en.htm at the date of the signature of the specific contract.

- Any long distance air travel must be by economy class while long distance train travel may be by 1st class

Maximum budget for the incidental expenditures is **252,700 EUR**.

6.6. Expenditure verification

The Provision for expenditure verification relates to the fees of the auditor who has been charged with the expenditure verification of this contract in order to proceed with the payment of pre-financing instalments if any and/or interim payments if any.

The provision for expenditure verification for this contract is **3,000 EUR.** This amount cannot be decreased but can be increased.

6.7. Working language

The working language for documents to be provided by the Contractor as reports and other deliverables shall be English.

7. REPORTS

7.1. Reporting requirements

The reports that have to be provided to the EC include:

- The administrative reports;
- The technical Delivery documents, described in section 4.2 Specific activities;
- Other communication documents.

For each report, paper and electronic versions will be distributed.

The Contractor shall provide the final version of all the reports and other documents issued during the Project in English. All Deliverables shall be submitted by e-mail or on CD (2 copies) and in 2 paper copies.

7.1.1. The administrative reports

This section only deals about the administrative reports. The other documents are considered as Deliverables, and described in section 4.2.

Please refer to Article 26 of the General Conditions. Interim reports must be prepared every 6 months during the period of implementation of the tasks. They must be provided along with the corresponding invoice, the financial report and an expenditure verification report defined in Article 28 of the General Conditions. There must be a final report, a final invoice and the financial report accompanied by an expenditure verification report at the end of the period of implementation of the tasks. The draft final report must be submitted at least one month before the end of the period of implementation for the tasks.

Each report shall consist of a narrative and a financial section. The financial section must contain details of the time inputs of the experts, of the incidental expenditure and of the provision for expenditure verification.

Progress reports

Biannual progress reports are to be prepared for the duration of the project. Those reports are administrative reports.

Progress reports are to inform the EC on progress of the activities, problems encountered, recommendations, requests, etc. Progress reports could be submitted per e-mail.

Inception Report

The Inception Report shall be produced no later than three months after the commencement of the implementation. In the report the Contractor shall describe e.g. the first findings, the progress in collecting data, the encountered and/or foreseen difficulties in addition to the work programme and staff mobilization The Contractor will send the final version to the EC Programme Manager for approval. The Contractor is advised to proceed with his/her work also in absence of comments by the Contracting Authority to the inception report.

Completion Report

The administrative progress report which will accompany the last invoice is called the Completion Report. This report must be accompanied by the final invoice, the financial report and an expenditure verification report.

7.1.2. The Delivery of technical documents

Deliverables are the technical outputs, products and services that are produced because of the project activities to match the expected Results, as outlined in section 4.2. At the end of each task, the Contractor is expected to deliver a technical Report.

Production of the end of task reports is responsibility of the Contractor.

Each end of task report will include the entire task's technical data:

- All the input data (understood in its broadest meaning);
- Possibly, the description of the observed local non-compliance situation;
- All the written outputs of the related task;
- The used methodology, including Quality Assurance aspects.

At the end of the project, the Contractor will prepare the **Final Technical Report**, which will contain the Executive summary, presentation of results of the each WP, and important project insights.

7.2. Submission & approval of reports

All reports referred to above must be submitted to the EC Programme Manager (AidCo A4 - Mr Ph. Servais) as identified in the contract. The language of these reports shall be English. The Programme Manager is responsible for approving the reports.

All Deliverables shall be submitted on CD (2 copies) and in 2 paper copies.

8. MONITORING AND EVALUATION

8.1. Definition of indicators

The project will be monitored in accordance with the standard EC procedures, i.e. result-oriented monitoring (ROM).

The activities described in Section 3.2 will be monitored on the basis of the deliverables to be defined during the detailed project definition phase before contracting.

Key performance indicators will be defined accordingly, and the project will be monitored with reference to them.

In addition, the progress of the project will be assessed through regular reporting and information provided by the Contractor about political, economic or institutional developments of relevance to the project.

8.2. **Special requirements**

N/A

ATTACHMENT 1.

TOWARDS A GLOBAL APPROACH: THEORITICAL CONCEPTS AND KEY DEFINITIONS

Hereafter is a reminder of some definitions of keys words, agreed at the international level.

- Biosafety (adapted from: WHO/CDS/EPR/2006.6)
Laboratory Biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release. In other terms, laboratory Biosafety includes all types of measures that have to be taken into account in order to prevent any kind of unintentional exposure to biological agents and toxins, or their accidental release for the workers, the population and the environment.

- Biosecurity (adapted from: WHO/CDS/EPR/2006.6)
Laboratory Biosecurity describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorised access or intentional release whether the Bio risk(s) is acceptable or not.

- Biorisk (adapted from OHSAS 18001:2007)
Combination of the likelihood of the occurrence of an adverse event involving exposure to biological agents and toxins and the consequence (in terms of accidental infection, toxicity or allergy or unauthorized access, loss, theft, misuse, diversion or release of biological agents or VBMs) of such an exposure.

- Biorisk assessment (adapted from OHSAS 18001:2007)
Process of evaluating the Bio risk(s) arising from biohazard(s) or VBMs, taking into account the adequacy of any existing controls, and deciding whether or not the Bio risk(s) is acceptable.

- Biorisk management system (adapted from OHSAS 18001:2007)
Part of an organisation's management system used to develop and implement its biorisk policy and manage biorisks.

On the long term and first of all, the objectives of the Biosafety and Biosecurity concepts' implementation by the different countries at world scale are public health concerns. Thus, Biosafety and Biosecurity are deeply responding to the need to ensure global public health. For the population, the workers, and the environment, the goal is to prevent their exposure to harmful biological agents and toxins.
This exposure could be unintentional, coming from accidental release. That is the reason why the World Health Assembly 58.29 outlines "…that the release of microbiological agents and toxins may have global ramifications, acknowledges that the containment of microbiological agents and toxins in laboratories is critical to preventing outbreaks of emerging and re-emerging diseases such as acute respiratory syndrome (SARS), … and notes that an integrated approach to

laboratory Biosafety, including containment of microbiological agents and toxins, promotes global public health".
The exposure of the population could be also deliberated, coming by loss, theft, misuse, diversion of, unauthorised access or intentional release of biological pathogens. In October 2001, several letters containing highly infectious anthrax spores were mailed in the United States to news media offices and two US senators. Among transporters and receivers, the letters killed 5 people and infected 22 others, rapidly spreading panic among the population. As a consequence, extensive public health measures were taken for the treatment and care of thousands who were potentially exposed to anthrax. The decontamination of the government buildings and postal offices took years. These overall damages cost USA more than 1 billion of USD.

Biorisk encompasses both Biosafety and Biosecurity. The term came about as a result of the different uses and schemes that have been established for laboratory Biosafety and Biosecurity. Distinctions between the two terms, Biosafety and Biosecurity, are quite academic - in practice, when one actually works hands-on in a laboratory, it is much more difficult to draw such distinctions. At the operational level, there are many similarities between the two.

There is thus a continuum between Biosafety and Biosecurity, with two driving forces: Bio risk assessment and Bio risk management.

For an overall view of the biological risks, and from a technical and pragmatic point of view, the following step by step approach has to be considered:

1. **The first step is the assessment of the biological risks currently existing both within and outside the laboratories**. This approach allows the identification of the gaps and to understand the failings. Without a proper assessment of what the risk is, it is not possible to identify the needs to protect ourselves or to identify gaps in the system. Thus, it is not possible to implement suitable Biosafety and Biosecurity measures so that to manage the previously identified risks. A proper assessment of the risk will allow the development of a proper management strategy.

2. **The second step is the implementation of an effective Bio risk management system.**

   Such a management strategy will likely make use of existing standards, require a national legislative and regulatory framework as well as a proper quality management system. Thus, there is not “one size fits all” comprehensive response to Bio risk.

Biorisk management system is often dealt with, through a number of interconnected and complementary responses, taking advantage of different types of measures and requirements coming from international standards, international best practices and recommendations (e.g. WHO manuals), as well as laws and regulations (e.g.

European or national), which deal with specific aspects of the risk within the laboratories as well as outside the laboratories (e.g. during the exchanges of pathogens between laboratories). That is the reason why, it is mandatory to adopt a global approach --such as an integrated management system (IMS) -- taking into account the different types of measures and requirements that have to be applied at the laboratory scale, and for the activities that occur between the laboratories.

Some measures deal with the prevention of the Bio risks within laboratories, others deal with those derived from exchanges of biological agents and toxins between laboratories. Each country needs to develop its own laws and regulations for dealing with Biosafety and Biosecurity. Both Bio risk assessment and management strategies will depend on national situation, should take advantage of existing standards and guidance, and provide practical tools at the operational level.

The requirements are legally binding when they come from legislations and regulations; others are applied on a voluntary basis by the laboratories, when they come from standards, or international recommendations.

An effective laboratory Bio risk management system applied to laboratory is based on a quality management system with two main driving forces enforced by an international standard such as ISO IEC 17025: exhaustive traceability of the "resources" (that is to say: personnel, premises, operations --which have to be conducted in compliance with validated methods--, equipments, biological materials) used by laboratory to conduct its activities, **and the requirements regarding the staff competence** (because ISO IEC 17025 is an accreditation international standard, that is to say that the competence of the staff constitutes a main requirement of the standard). **If the staff is competent, he is knowledgeable, owns knowledge and is aware of what he does; qualities which are crucial both for Biosafety and Biosecurity.** Regarding Biosecurity, the requirement of traceability of the staff is one of the strong points; among these last ones, also, the staff can obtain a security clearance.

Moreover, an effective Bio risk management system has to be an Integrated Management System (QSE: Quality-Security-Environment). Integrated means combined; merging all the internal management practices into one single system (not into separated components).

The complementarities of responses facing Bio risks, which are different in nature, could be measures:

1 - WITHIN THE LABORATORIES (e.g. through the compliance to standards such as ISO IEC 17025 taken as a general framework that needs to be supplemented by specific measures to the biological applicability), measures with regard to:

a. the personnel - defining who is doing what activities and defining relevant responsibilities, ensuring competencies of the staff through training programmes, ensuring the availability of personal protective equipment,…

b. the premises - e.g. Biosafety Level of the laboratory, the hygiene and cleaning procedures, the waste management, flow of samples, traceability, access control, site security,…

c. the operations - including animal experimentation, the transportations of the strains and samples, the reception and storage of the initial samples, the preparation's generation of the handling and processing further samples, the preparation and sterilisation of culture medias and equipments, the biological materials' storage, and the supply, delivery and sale of samples equipment,…

d. the equipment - full traceability, maintenance, effective cleaning and decontamination, contamination monitoring programme, material detection equipment,…

e. the biological material -full life cycle traceability such as acquisition criteria, registration of each operation involving the material, quality controls based on CABRI guidelines --including preservation of samples, distribution, stock control, storage and recording of data, packaging requirements that comply with current rules of transport of dangerous goods, postal, quarantine and International Air Transport Association regulations,…

AS WELL AS

2- DURING THE EXCHANGES OF BIOLOGICAL PATHOGENS BETWEEN THE LABORATORIES (measures regarding transport and types of transport, import/export control, and criminalization if laws and regulations are not applied…).

Moreover, it is a clear demonstration that Biosafety and Biosecurity go hand by hand with each other and participate of the same logic of the Bio risks management. A global approach regarding Bio risk management systems is thus mandatory and must take into account of:

any kind of activities (within the laboratory but also outside the lab during the exchange of biological materials);

the requirements coming from the legislations and regulations recognized and already validated by many countries, but also those coming from international standards.

Taking into account the considerations above mentioned, and in order to illustrate the purpose, it’s possible to define a preliminary set of reference documents, but which is not exhaustive:

BIOSAFETY

- Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC) [European Union]

- International standards such as:

- ISO CEI 17025,
- ISO 15189,

- CWA 15793

and those coming from WHO manuals:

- Laboratory Biosafety Manual, Third Edition (WHO/CDS/CSR/LYO/2004.11, 2004)
- WHO Biorisk Management: Laboratory Biosecurity Guidance (WHO/CDS/EPR/2006.6, Sept. 2006),

without forgetting the best practices and recommendations such as:

- OECD best practices guidelines for biological resources centres (2007 & related bibliography),
- CABRI guidelines (http://www.cabri.org/guidelines.html).

BIOSECURITY

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

- Council Regulation (EC) No 428/2009 of 5 May 2009, setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

- The Convention on the prohibition of the Development, production and stockpiling of bacteriological (biological) and toxins weapons-1972.

Some texts coming from EU members states: for biosafety and biosecurity, for example:

- « Décret no 2010-736 du 30 juin 2010 relatif aux micro-organismes et toxines » ;

- « Arrêté du 30 juin 2010 fixant la liste des micro-organismes et toxines prévue à l'article L. 5139-1 du code de la santé publique ».