



PAN AMERICAN HEALTH ORGANIZATION  
WORLD HEALTH ORGANIZATION



## **50th DIRECTING COUNCIL**

### **62nd SESSION OF THE REGIONAL COMMITTEE**

*Washington, D.C., USA, 27 September—1 October 2010*

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*Provisional Agenda Item 4.16*

CD50/20, Rev. 1 (Eng.)  
31 August 2010  
ORIGINAL: SPANISH

### **STRENGTHENING NATIONAL REGULATORY AUTHORITIES FOR MEDICINES AND BIOLOGICALS**

#### **Introduction**

1. Strengthening the steering role of the health authority as part of the essential public health functions has been recognized in different forums, such as the Directing Council of the Pan American Health Organization (PAHO) and the World Health Assembly. Since 1992, the PAHO Directing Council, the World Health Assembly, and the Executive Board of the World Health Organization (WHO) have adopted a number of resolutions (1-4) related to strengthening the health authority at all levels of government to ensure access to quality-assured medicines and biologicals.

#### **Background**

2. Medicines and biologicals have traditionally been subject to control by national regulatory authorities, particularly because of their indisputable impact on health and the public health risk they pose, and because consumers are ill-equipped to evaluate the quality of the products they purchase. The State, therefore, assumes responsibility for defending patients' interests and regulates in detail all activities involving research and development, and the production, promotion, prescription, dispensing, and rational use of medicines, as well as the quality and safety of these products.

3. As a government function with clear social objectives, the regulation of medicines and biologicals should be subject to social analysis, and it is imperative to determine whether this regulation is effective and meets the objectives of protecting and promoting the public health. However, effectiveness is not the only quality that a society demands of a national regulatory authority: efficiency, accountability, and transparency also are indispensable characteristics of a responsible authority.

4. Governments, through their national regulatory authorities, establish and maintain the necessary standards, laws, and policies for guaranteeing that medicines, including pharmaceutical products, vaccines, and other biologicals, such as those biotechnology products, and antivenins, are safe, effective, and of high-quality.

5. The principal regulation and enforcement<sup>1</sup> functions for medicines and biologicals range from the authorization of clinical trials prior to registration, the granting of authorization to market the products, inspection and licensing of manufacturers and distributors, postmarketing surveillance, and control over advertising and rational use.

6. WHO has systems and procedures for the initial approval of pharmaceutical products and vaccines (prequalification) to safeguard the quality of products procured through United Nations agencies (5, 6). Although these prequalification systems involve the participation of national regulatory authorities, their main purpose is not to strengthen the authorities but to guarantee the quality of products funded by the principal donors and procured through international purchasing mechanisms for requesting countries.

7. Drug regulatory harmonization processes are an essential tool for correcting differences among regulatory systems and offer countries, especially lesser developed countries, health, economic, and technical advantages. The countries of the Region of the Americas have addressed this issue through several integration mechanisms with different degrees of development and different strategies, and also at the regional level through the Pan American Network for Drug Regulatory Harmonization (PANDRH) (7).

## **Analysis**

8. Some national regulatory authorities in the Region of the Americas have well-developed functions characteristic of a regulation and enforcement agency, while others have marked weaknesses in their structure, legal underpinnings, and processes for adequately performing these functions. The extent of the development of the pharmaceutical sector, the availability of trained human resources and financial resources, and the existence of adequate infrastructure influence the performance of these functions.

9. Deficient or inadequate regulatory capacity can mean that harmful, ineffective or substandard medicines become available on the market.. Thus, the steering capacity of

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<sup>1</sup> Understanding regulation and enforcement as Essential Public Health Function 6, described in document CD42/15, Essential Public Health Functions, 42nd Directing Council, 52nd Session of the Regional Committee of the World Health Organization for the Americas, 25-29 September 2000. Washington (DC): PAHO; 2000.

national regulatory authorities needs to be strengthened. Each country should establish its regulatory framework, prioritizing and developing standards, laws, and policies that help prevent these irregularities from occurring.

10. The Pan American Health Organization supports technical cooperation aimed at strengthening national regulatory authorities as part of its strategic and programmatic orientations including the strengthening of health systems based on primary health care. It recognizes the importance of promoting equity in health and human development. It incorporates the principles of primary health care and seeks to meet the health needs of the population and promote quality, responsibility, and accountability of the part of governments; social justice; sustainability and participation; and the health promotion, gender, and intercultural approach.

11. In 2006, the national regulatory authorities of some countries proposed the development of a qualification system, to be coordinated by the Pan American Health Organization. The objective of this system is to facilitate the establishment of mechanisms for cooperation among regulatory authorities in the Region and progress toward possible interinstitutional recognition, with the consequent optimization of human and financial resources. The proposal for a qualification system for national regulatory authorities was studied at subsequent meetings attended by the national regulatory authorities and the PANDRH Steering Committee in Buenos Aires, Argentina, São Paulo, Brazil, and Mexico City, Mexico, including the Fifth Conference for Drug Regulatory Harmonization (8).

### **Proposal for strengthening national regulatory authorities for medicines and biologicals**

12. The Pan American Health Organization has developed an initiative to strengthen the regulatory capacity and the steering role of the national regulatory authorities in the area of medicines and biologicals, with a view to guaranteeing the quality, safety, and efficacy of all products (see procedure in Annex A). The aim of the initiative is to:

- a) Establish and support regulation and enforcement harmonization mechanisms such as PANDRH.
- b) Develop and implement a process for evaluating national regulatory authorities' performance in terms of the basic functions established by WHO (9-11). This process will use the *Guía para conducir una evaluación de sistemas reguladores de medicamentos y productos biológicos* [Guide for Evaluating Regulatory Systems for Medicines and Biologicals] (12) and the *Indicadores básicos para la evaluación de sistemas reguladores de medicamentos y productos biológicos* [Basic Indicators for the Evaluation of Regulatory Systems for Medicines and Biologicals] (13).

- c) Create mechanisms to provide technical training for the Region's national regulatory authorities.
  - d) Promote interaction and technical cooperation among countries.
13. The regulatory authorities of regional reference will:
- a) Participate in processes for guaranteeing the quality, safety, and efficacy of products procured by the Pan American Health Organization on behalf of the countries.
  - b) Collaborate as reference centers in implementing and monitoring the recommendations of PANDRH.
  - c) Collaborate with the Pan American Health Organization in activities to strengthen other national regulatory authorities in the Region so they can be designated as regulatory authorities of regional reference.
  - d) Share public information online within the framework of current national legislation on the products approved by the regulatory authorities of regional reference. This will give authorities with less capacity tools for making decisions about their own products, as the products registered and marketed in countries with regulatory authorities for regional reference will meet WHO's recommended quality standards.

**Action by the Directing Council**

14. This document is submitted for consideration by the Directing Council with a view to presenting a resolution to the Member States on strengthening national regulatory authorities in the areas of medicines and biologicals to guarantee the quality, safety, and efficacy of these products, in addition to describe the mechanisms or tools necessary for strengthening the regulation and oversight of public health functions.

15. The Directing Council is requested to review the information in this document and study the possibility of adopting the proposed resolution in Annex B.

## References

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Annexes

## **PROCEDURE FOR DESIGNATING REGULATORY AUTHORITIES OF REGIONAL REFERENCE FOR MEDICINES AND BIOLOGICALS**

1. This procedure describes the process intended to plan and organize the qualification of regulatory agencies applying to become regulatory authorities of regional reference. It applies to all qualification activities for national regulatory authorities as part of the system for their designation as regulatory authorities of regional reference in medicines and biologicals.
2. The purpose of this procedure is to establish a uniform, transparent methodology for evaluating the performance of national regulatory authorities in the Americas in terms of their regulatory and enforcement functions. Qualifying regulatory authorities can:
  - a) Participate in quality, safety, and efficacy assessment processes for products procured by the Pan American Health Organization on behalf of the Member States.
  - b) Collaborate as reference authorities in the implementation and monitoring of recommendations made by PANDRH.
  - c) Support the Pan American Health Organization in activities to strengthen other national regulatory authorities in the Region so that they too can move towards designation as a regulatory authority of regional reference.
  - d) Share public information online, and within the framework of current national legislation, on products approved by regulatory authorities of regional reference to enable authorities with less capacity to have the tools for making decisions regarding their own products, recognizing that products registered and marketed in countries with regulatory authorities of regional reference will meet WHO's recommended quality standards.
  - e) Establish mechanisms by agreement with the Pan American Health Organization that facilitate processes for the mutual recognition of drug regulatory authority functions.
3. The proposed procedure for qualification of the development and performance of the functions under the purview of the national regulatory authority consists of three stages: prequalification, qualification, and follow-up to qualification. This procedure involves the use of a data collection tool, consisting of indicators reflecting WHO norms in good manufacturing practices (GMP), good laboratory practices (GLP), good distribution practices (GDP), and good clinical research practices (GCP). Each indicator is classified as detailed below in order to provide objective, uniform evaluation criteria for its use in the assessment of the national regulatory authorities.

### Criteria for Classifying Indicators

- a) **Critical:** abbreviated as “C.” This designates the indicators in the data collection tool that, if not achieved, could critically affect the regulatory system and/or adequate performance of critical control functions. Achievement of these indicators should be absolute and unquestionable for a national regulatory authority to obtain a positive evaluation. Failure to achieve one of the critical factors or partially achieving it will result in a negative evaluation for that indicator and for the overall results of the national regulatory authority. Thus, a new application for qualification will have to be submitted by a given deadline, responding to the critical problem identified.
  - b) **Necessary:** abbreviated as “N.” This is assigned to indicators in the data collection tool that, if not achieved, will affect the performance of the regulatory system and/or the adequate performance of critical control functions. Achievement of these indicators should be absolute and unquestionable to obtain a positive evaluation. Therefore, they are scored as Yes or No. Failure to achieve them will be assessed as negative and will require their inclusion in the Institutional Development Plan with a deadline for remedying the situation.
  - c) **Informative:** abbreviated as “I.” This designates indicators in the data collection tool that provide descriptive complementary information. Failure to achieve them or partially achieving them does not affect the regulatory system and/or the adequate performance of critical control functions. However, this information should be provided by the National Regulatory Authority at the time of the visit.
4. The qualification of national regulatory authorities depends on satisfactory achievement of the critical indicators in the data collection tool for both the Regulatory System and the enforcement and regulatory functions of the regulatory agency, following the guidelines for the qualification of a national regulatory authority.
  5. National regulatory authorities that attain level IV according to the following qualification table will earn designation as a regulatory authority for regional reference.



### Functional Level of the National Regulatory Authority

- Level IV: defined as *a competent and efficient national regulatory authority that performs the health regulatory functions recommended by PAHO/WHO for guaranteeing the quality, safety, and efficacy of medicines and biologicals. Regulatory authority of regional reference.*
- Level III: defined as *a national regulatory authority that needs to improve its performance of certain health regulatory functions recommended by PAHO/WHO for guaranteeing the quality, safety, and efficacy of medicines and biologicals.*
- Level II: defined as *structures or organizations with a national regulatory authority mandate that perform certain health regulatory functions recommended by PAHO/WHO for guaranteeing the quality, safety, and efficacy of medicines and biologicals.*
- Level I: defined as *divisions of health institutions that perform certain health regulatory functions for medicines and biologicals.*

**Table 1: Performance qualification level of national regulatory authorities, based on the data collection tool for the designation of regulatory authorities for regional reference**

Level	Achievement of critical indicators			
	Not achieved	In the process of achieving	Partially achieved	Achieved
I	Up to 50%	50-75%		0-24%
II	Up to 25%	25-50%		25-49%
III	Up to 15%	25-50%		50-74%
IV	0%		0-25%	75-100%

6. Each indicator contained in the data collection tool is evaluated according to its degree of achievement, as follows: a) Not achieved, when there is no evidence on the indicator; b) In the process of achieving, when there are documents or activities at the development stage and/or there are preliminary results; c) Partially achieved, when there is evidence of some results regarding documents or activities recently implemented; or d) Implemented, when there is proof that the activity, procedure, or guideline is being carried out and its results are available.

## **Evaluation Team**

7. The Pan American Health Organization shall provide coordination and leadership for the qualification process. The dates of the mission, the program, and the composition of the evaluation team, including the leader, shall be proposed to the national regulatory authority for their prior approval.

8. The evaluation should be conducted by a multidisciplinary team with expertise in the basic functions of national regulatory authorities for medicines and biologicals.

9. The team will usually consist of six experts for the qualification stage; at least two members, together with the team leader (a staff member of the Pan American Health Organization), shall conduct the follow-up visit.

10. The experts on the evaluation team shall come from a panel of expert advisors/consultants registered in a database shared by the team that will carry out the activity in the Pan American Health Organization, which shall be systematically updated. Consultants shall be recruited and selected through public procedures published on the Pan American Health Organization's website.

11. Prior to the mission, the résumés of the Pan American Health Organization's staff members and the outside experts involved in the mission shall be sent to the national regulatory authority, which may reject any technical adviser or external consultant, indicating the reasons for its objection. The entire examining team should adhere to the pertinent codes of ethics, following the guidelines in their contracts relative to the absence of conflicts of interest and the confidentiality of the information to which they have access.

12. At least 75% of the members of the teams that will carry out the qualification activities shall always be expert staff from the Region's regulatory authorities who have been preselected and are in the Pan American Health Organization's database. The remaining 25% shall be made up of the leader representing the Pan American Health Organization and invited members from other national regulatory authorities outside the Region or academic experts from the Pan American Health Organization's database. Representatives of the pharmaceutical industry or its advisers or consultants may not participate in this process as outside experts.

13. A letter of invitation shall be sent to the selected experts and the highest ranking executive of their institutions to obtain approval for their participation in the international qualification activity on the suggested date.

14. During the visit to the national regulatory authority, the examining team's members shall be in charge of preparing recommendations for the national regulatory authority and providing the preliminary report for the debriefing. The final version of the report will be sent to the national regulatory authority within 30 days of the visit.

## **Qualification Stages**

### ***Prequalification***

15. At this stage the selected team issues a preliminary qualification, based on the activities documented and accessible online or other official documents from the national regulatory authorities to be evaluated. This consists of collecting data through online research and existing publications, using the indicators of the data collection tool.

16. This exercise is useful for obtaining pertinent information on the functions of the national regulatory authorities. It will help reduce time spent in the country being evaluated, which will have an impact on costs. It is recommended that prequalification be carried out at least two months prior to the visit to the national regulatory authority.

17. Before visiting the regulatory authority, the examining team's members should hold a telephone conference or *Illuminate* session to give all participants general information about the national regulatory authority, setting the work agenda, and defining the role of each expert and his or her responsibilities during the mission.

### ***Qualification***

18. At this stage, the visit to the national regulatory authority is made in order to administer the data collection tool. This includes the visit to the national regulatory authority and all other institutions directly or indirectly related to it, which shall be evaluated using the respective indicators mentioned in the data collection tool used in the prequalification.

19. At the opening meeting at the national regulatory authority, the mission's objectives shall be described to clarify any confusing points, if necessary, and the proposed program for the visit shall be presented and approved and appointments scheduled with key people and institutions.

20. The team can be divided up to save time and make the most of each member's expertise regarding the functions to be evaluated. The national regulatory authority shall provide the information requested, as well as a site where the team can at a minimum conduct interviews and prepare its reports.

21. The team shall meet and discuss the findings, conclusions, and recommendations and shall prepare a summary report to be presented publically on the last day of the visit to the national regulatory authority to be qualified, via an oral presentation and debriefing. If possible, the presentation should be in *PowerPoint*, indicating the examining team's conclusions and recommendations regarding the system in place and the performance of functions. A hard copy of the summary report and presentation shall be distributed to the attendees for discussion and the correction of any errors in the draft document.

22. The format for the qualification report shall be provided by the leader of the examining team.

23. The first report written for the debriefing is a summary document covering the regulatory system and each function reviewed, which includes the categorization of the indicators, the recommendations of the examining team, and a proposal for an institutional development plan to which the respective Ministry of Health should be committed. This draft shall be distributed at the closing meeting and revised to produce the final version, based on the comments and corrections requested by the national regulatory authority, if the examining team considers them justified.

24. This report shall subsequently be completed by the team leader using the information compiled by each team member, and the final report shall be sent to the national regulatory authority directly or through the Representative Office of the Pan American Health Organization, within no more than 30 days of conclusion of the visit.

25. If the results of the evaluation indicate that the regulatory authority can be considered as a regional reference, this designation shall be published on the Pan American Health Organization's website in a notice signed by the representatives of the examining team and team leader. If not, an institutional development plan shall be presented, whose execution will be monitored to ensure that missing activities are carried out, and these activities, in turn, will be monitored to strengthen the regulatory system.

26. The institutional development plan shall be proposed to the national regulatory authority so that any missing activities are carried out, and thus fill any gaps or improve underperformed functions. The team from the Pan American Health Organization can help institutions with deficiencies by providing training or facilitating contact with other national regulatory authorities.

27. The hard copies of the final report, marked “Confidential” on each page, shall be sent to the key people in the national regulatory authority that was visited; other copies are limited to the coordinators of the Pan American Health Organization, the examining team’s leader and members, and Pan American Health Organization’s Representative in the country where the national regulatory authority evaluated. Upon request, a copy can be provided to World Health Organization personnel after their acceptance of the confidentiality of the information.

***Qualification follow-up***

28. A visit shall be made to the national regulatory authority no more than two years after the presentation of the institutional development plan prepared by the authority based on the recommendations and gaps identified during the assessment process. On that occasion, the data collection tool and the plan of action proposed by the institution shall be used as basis for the assessment. Follow-up shall be at the express request of the national regulatory authority.



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Annex B  
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**ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES**

- 1. Agenda item:** 4.16 Strengthening National Regulatory Authorities for Medicines and Biologicals
- 2. Responsible unit:** Essential Medicines and Technologies
- 3. Preparing officer:** Dr. James Fitzgerald.
- 4. List of collaborating centers and national institutions linked to this Agenda item:**
  - National Regulatory Agencies (ANMAT, Argentina; CECMED, Cuba; ANVISA, Brazil; INVIMA, Colombia; INS, Chile; COFEPRIS, Mexico; and others to be included in the project).
  - Pan American Network for Drug Regulatory Harmonization (PANDRH).
- 5. Link between Agenda item and Health Agenda for the Americas 2008-2017:**

Within the areas of action of the Health Agenda for the Americas 2008-2017, Area a), Strengthening the National Health Authority (paragraph 35), establishes the need to strengthen regulatory capacity as one of the essential public health functions.

Health Agenda for the Americas 2008-2017, Pg. 13, Paragraph 35:  
*Ministries of Health must fully carry out the essential public health functions and efficiently perform their role in the guidance, regulation, and management of health systems*
- 6. Link between Agenda item and Strategic Plan 2008-2012:**

Related to SO12, RER 12.2.1: Number of countries evaluated in their regulatory functions for medical products.
- 7. Best practices in this area and examples from countries within the Region of the Americas**

The Pan American Network for Drug Regulatory Harmonization (PANDRH) is an example of best practices involving the participation of experts from the regulatory authorities of the Region, with PAHO serving as the secretariat for each of the 13 Expert Working Groups created in this network.
- 8. Financial implications of this Agenda item:**

\$ 600,000.00 for a two-year period in which the evaluation of six regulatory agencies is planned.



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## **50th DIRECTING COUNCIL**

### **62nd SESSION OF THE REGIONAL COMMITTEE**

*Washington, D.C., USA, 27 September - 1 October 2010*

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*Provisional Agenda Item 4.16*

CD50/20, Rev. 1 (Eng.)  
Annex C  
ORIGINAL: SPANISH

### ***PROPOSED RESOLUTION***

#### **STRENGTHENING NATIONAL REGULATORY AUTHORITIES FOR MEDICINES AND BIOLOGICALS**

***The 50th DIRECTING COUNCIL,***

Having reviewed Document CD50/20, *Strengthening National Regulatory Authorities for Medicines and Biologicals*;

Considering resolutions WHA45.17 (1992) and WHA47.17 (1998) of the 45th and 47th World Health Assemblies, respectively; document EB113.10 (2004) of the 113th Executive Board of the World Health Organization (WHO); and document CD42/15 (2000) of the 42nd Directing Council of the Pan American Health Organization, on the essential public health functions and strengthening the steering role of the health authority at all levels of the State;

Considering that strengthening the regulatory capacity of the national regulatory authorities and designating regulatory authorities of regional reference can lead to recognition of the existing capacity in the Region of the Americas and to the establishment of cooperation mechanisms that will make it possible to strengthen the steering role of other national regulatory authorities;

Recognizing the initiative of the Member States and PAHO/WHO in the preparation of a consensus-based instrument and the creation of a procedure for the qualification of regulatory authorities for regional reference;

Recognizing the possibility of having regulatory authorities of regional reference participate in product evaluation processes as part of the Pan American Health Organization's procurement mechanisms,

***RESOLVES:***

1. To urge the Member States to:
  - a) strengthen and evaluate their regulatory capabilities with respect to the functions characteristic of a regulatory and oversight agency for medicines and biologicals, through an examination of the performance of their essential functions;
  - b) use the results of the qualification activity and the designation of the regulatory authorities of regional reference to strengthen their performance in terms of the steering role of the health authority;
  - c) support national regulatory authorities so they can benefit from the processes and information from national regulatory authorities of reference;
  - d) promote the dissemination of information on the results and processes for the regulation and oversight of medicines, biologicals, and other health technologies;
  - e) promote interaction and technical cooperation among countries;
  - f) actively participate in the Pan American Network for Drug Regulatory Harmonization (PANDRH).
2. To request the Director to:
  - a) support initiatives for the strengthening and qualification of national regulatory authorities to guarantee the quality, safety, and efficacy of medicines, biologicals, and other health technologies;
  - b) widely disseminate in the countries of the Region of the Americas the available tools and procedures for qualification of the competencies of national regulatory authorities in medicines and biologicals and support development of the system for the qualification of national regulatory authorities and their designation as a regulatory authority of regional reference;



- c) maintain and strengthen the collaboration of the Pan American Health Organization with the Member States in the area of medicines and biologicals regulation;
- d) promote technical cooperation among country regulatory authorities as well as recognition of the existing capacity in the Region;
- e) ensure that the Pan American Health Organization's procurement procedures for medicines and biologicals are based on the existing capacity of the national regulatory authorities of reference to guarantee the quality, safety, and efficacy of these products.



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Annex D  
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<b>Report on the Financial and Administrative Implications for the Secretariat of the Proposed Resolution</b>
<b>1. Agenda item:</b> 4.16 Strengthening National Regulatory Authorities for Medicines and Biologicals
<b>2. Linkage to Program Budget:</b>  a) <b>Area of work:</b> HHS/MT  b) <b>Expected result:</b> Regulatory Authorities for Regional Reference that facilitate regional processes to guarantee product quality and facilitate regional strengthening of regulatory capacity, contributing to the strengthening of regulatory agencies with lesser capacity though the processes carried out by agencies with greater capacity.
<b>3. Financial implications</b>  a) <b>Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US\$ 10,000, including staff and activities):</b> \$600,000.00 over a two-year period, during which the evaluation of six Regulatory Agencies is planned  b) <b>Estimated cost for the biennium 2010-2011 (estimated to the nearest US\$ 10,000 including staff and activities)</b> \$600,000.00 over a two-year period, during which the evaluation of six Regulatory Agencies is planned.  c) <b>Of the estimated cost noted in (b), what can be subsumed under existing programmed activities?</b> Payment of the salary of the technical professional involved in the visits (\$200,000.00).

**4. Administrative implications****a) Indicate the levels of the Organization at which the work will be undertaken:**

Regionally, subregionally and by countries.

**Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):** One technical professional is needed who is involved in regulatory matters, has participated in evaluation visits to regulatory agencies, and is familiar with World Health Organization standards. Requires leadership capabilities for representing PAHO during visits to Regulatory Agencies. One administrative support professional to support all activities involving issuance of reports and online communications.

**b) Time frames (indicate broad time frames for the implementation and evaluation):**

Two years are estimated for conclusion of this project and its evaluation.