

Standard Summary Project Fiche

1. Basic Information

- 1.1 CRIS Number (Year 1): **BG2004/016-711.05.02**
- 1.2 Title: **Strengthening of the National Surveillance System for Communicable Diseases**
- 1.3 Sector: Employment, Social Policy and Education
- 1.4 Location: **Bulgaria**
- 1.5 Duration: **Phase 1/ Programming year 2004 and Phase 2/ Programming year 2005**

2. Objectives

2.1 Overall Objective(s):

To strengthen the CD surveillance system and to establish national early warning system assuring better control of CD in Bulgaria

2.2 Project purpose:

To ensure the integration of the national CD surveillance system into the EU surveillance networks through adopting the EU legislation and strengthening the administrative capacity of the involved institutions.

2.3 Accession Partnership (AP) and NPAA priority (and implementing measures envisaged by the Action Plan for AP priorities related to strengthening administrative and judicial capacity)

The following are quotations from the Accession Partnership

Employment and Social Policy

“Continue to establish a system for the surveillance and control of communicable disease in line with the Community requirements and for health monitoring and information in line with EU standards”

Roadmap for Bulgaria

“Set up a system for surveillance and control of communicable disease in line with the acquis”

2003 Regular Report on Bulgaria’s Progress towards Accession

“With regard to public health, a national communicable disease surveillance and control plan should be developed with a specific focus on building epidemiological capacity. A revision of legislation relevant to communicable diseases surveillance and control is required to align with the principles and methodology of the Community network for the epidemiological

surveillance and control of communicable diseases. The existing reference laboratory is outdated and lacks resources. Significant capacity building efforts are needed in order to ensure incorporation into the EU system of surveillance and control of communicable diseases.”

2.4 Contribution to National Development Plan (and/or Structural Funds Development Plan/SDP)

Not applicable

2.5 Cross Border Impact

Not applicable

3. Description

3.1 Background and justification:

The principle health policy visions, as adopted in the Amsterdam Treaty of the EU member states, as well as the Decisions and Directives of the Council of Ministers of the EU have been laid down in the Bulgarian Health Strategy. The National Health Strategy also covers the aims of the EU public health policy: improving the information related to public health development, rapid response to threats to the health system, health promotion and disease prevention and is complying with the aims and values of WHO/EURO “Health for All in the 21st century” Strategy.

All common priority areas of collaboration in the field of public health identified by EC and WHO in December 2000 (health information, communicable diseases, tobacco, mental health, environment and health, nutrition and alcohol) are considered in Bulgarian National Health Strategy.

Public health services are organised, supervised, financed and controlled by the Ministry of Health (MoH). The system retains the basic structure that has existed since the 1950s, when public health concentrated upon eradicating communicable diseases. Since 1992 they are called Hygiene and Epidemiological Inspectorates (HEI) and they exist one for each district. Ministry of Defence and Ministry of Internal Affairs manage and finance their own health care facilities, including PH services. The Ministry of Health recently absorbed their parallel hygiene and epidemiological services.

Each of 28 District HEI has five operational structures: state sanitary control; communicable diseases control (CDC); disease prevention and health promotion; laboratories (bacteriology, virology and parasitology, which covers the etiological diagnosis); radiology and radiation protection.

In 1999 a functional and structural reorganization was implemented in the HEI system, which defined its current functions as follows:

- implementation of state sanitary control;
- coordination and implementation of surveillance, control and preventive measures of infectious and parasitic diseases;
- disease prevention and health promotion;
- Consultations on activities for the protection and promotion of personal and public health.

Actual the CDC Departments represents the operational core of communicable disease surveillance and control.

The structure of the CD surveillance in Bulgaria is based on a vertical exhaustive compulsory notification. Parallel, vertical systems exist for Tuberculosis, Influenza and Acute Respiratory Syndrome, sexual transmitted diseases (including HIV/AIDS), nosocomial infections, immunization coverage and antibiotic resistance. The parallel systems have other flow of information and use other forms and deadlines/timelines. Fifty-three diseases are under compulsory notification (food-borne, air-borne, water-borne, viral hepatitis, diseases of

environmental origin, vaccine preventable diseases, diseases covered by the international health regulations, STD, TB etc., including all diseases listed in Annex I of Decision 2003/542/EC). The list of the diseases is fully harmonised with the EU. Introduction of CD case definitions in the national legislation is forthcoming.

The general flow of information is simple and direct – GPs/specialists in outpatient and inpatient health care sector are obliged to report within 24 hours every probable, possible or confirmed CD case to the district HEI by phone, telex, e-mail and every time also on paper by courier or mail. The information includes individual nominative information (name, age, address, profession and workplace, probable source of infection, immunization status and available laboratory results).

HEI immediately start investigation and when is necessary, undertake measures. HEI transmit to the National Centre for Health Information (NCHI) daily aggregated number of cases by disease and place of origin. There is also monthly report from HEI to NCHI based on confirmed diagnosis and is composed of aggregated number of cases and deaths by disease and place of origin. The primary information by the parallel systems comes also from district Tuberculosis and Sexually Transmitted Diseases (STD) Dispensaries and their laboratories. NCHI reports to MoH daily, weekly and monthly aggregated data. HEI is obliged to provide information to MoH immediately at the beginning of a CD outbreak.

The structures involved in the CD surveillance at central level are MoH, National Center of Infectious and Parasitic Diseases (NCIPD) and NCHI.

NCHI only transmitted data regarding CD from HEI to the MoH.

NCIPD is responsible for all referral laboratory services for bacteriology, virology and parasitology, research and technological development in the field of CD, development surveillance analyses, priority setting, planning and implementation of preventive programmes, elaboration and dissemination of guidelines, standards, instructions, manuals. The reference laboratory system strives to achieve quality work, but is outdated and lack resources, computerized archives, specimen bank. NCIPD must pay for the information, coming from NCHI. Only MoH received information for outbreaks and potential outbreaks.

Since January 2003 within the NCIPD is established a new Department of epidemiological surveillance and early warning (ESEW), witch isn't equipped with appropriate software. The staff do not have functions in general sanitary control, but deal only with surveillance. They are three epidemiologists and one biostatistician. The role and the responsibilities of the Department are not clear yet.

The central operative levels (MoH and NCIPD) are with limited administrative capacity.

At this stage there is absence of a training programme and appropriate PC software for specialists at all levels, especially in the field of prognosis elaboration which could permit the early detection of an important event for the health of the population.

The main problems identified in the current CD surveillance system are as follows:

Legislation

- The regulations on CD surveillance are very old and do not respond to the existing EU regulations regarding CD surveillance
- There is no regulation on confidentiality issues related to CD
- There is no separate budgetary line for emergency situations, epidemic preparedness and response at all levels
- There is lack of legislation for laboratory accreditation according to the National Standards of Clinical Microbiology, Medical Parasitology and Medical Virology

- Private labs are not involved in CD surveillance as well as in surveillance of antimicrobial resistance
- There are insufficient funds for sending diagnostic samples and isolated strains to the National Reference labs

Structure

- The roles and responsibilities of MoH, NCIPD and NCHI for surveillance are not well defined
- The Department of CD control within MoH and responsible department in NCIPD are inadequately staffed and can not cope with implementation of all surveillance activities at national level
- District epidemiologists are over burdened with control activities and they lack of time for real CD surveillance
- There is insufficient communication between epidemiologists and microbiologists at all levels
- The laboratories are not enough involved in the surveillance process
- The TB and STD labs do not meet the medical standard for clinical microbiology
- There is no National Reference Laboratory for Tuberculosis.

Standards

- There isn't national standard protocol on epidemiological and laboratory surveillance
- All health service providers (GPs and other specialists) lack guidelines and standards for CD surveillance and control and there is poor collaboration and coordination among them
- There are no national standard data management application forms
- There is no national epidemiological software applied in the country
- HEIs staff is burden by too many different reporting forms on various topics to be filled and sent to numerous and different authorities, at different periods of time
- The Immediate notification form is old and collect not relevant information regarding immediate notification
- Aggregated data on CD at central level (NCIPD) do not include information on TB and STD.
- All laboratories do not collect information for CD surveillance purposes

Supply

- Almost all computers in the HEI CDC departments are not accessible for surveillance purposes; do not have internet/e-mails access and appropriate statistical packages for epidemiological surveillance
- There is lack of PCs and there is no access to the existing ones, absence or low level of internet connection in HEI laboratories
- Insufficient and irregular supply with reagents, diagnostic kits and laboratory consumables and lack of reserve of vaccines for epidemic response at all levels

Training

- There is insufficient specific training on surveillance and computing at all levels
- Insufficient knowledge of understanding and implementation of analytical epidemiology at district level

Equipment needed:

The main focus of the project is to strength the system for CD surveillance and control and to include in the national public health legal framework the Decisions 2119/98/EC, 2000/57/EC, 2000/96/EC, 2002/253/EC, 2003/534/EC and 2003/542/EC.

In order to ensure the effective implementation of above legislation it is necessary to take actions as follows:

Development and enhance the capacity of already existing structures, preparing them for active and effective cooperation in the EU networks through introducing a PC/Internet based epidemiological and laboratory network and respective software for the national CD surveillance network, develop Standard Operating Procedures for the basic components of the surveillance system, coherent with accepted EU standards, elaborate ordinances, instructions and guidelines, equip the national reference laboratories and train all staff in all levels, involved in the CD surveillance.

This equipment and the trained staff will ensure the national commitment for strengthening public health laboratory services

The laboratories foreseen to be supported under this fiche are fully ready to accept the equipment (premises and facilities, staff, funding).

3.2. Sectoral rationale: n/a

3.3. Results:

Programming year 2004:

- National framework for epidemiological CD surveillance system according to all EU Decisions adopted
- Legislation for standards, regulations and guidelines in the field of CD elaborated
- The existing CD epidemiological surveillance system reinforced
- Early warning system as a part of the existing CD surveillance system established
- Working places for the epidemiologists involved in the CD surveillance equipped
- Involved in the CD surveillance epidemiological staff highly trained

Programming year 2005:

- National legislation for the role and responsibilities of the labs in the CD surveillance process developed
- Structures for national laboratory network for the CD surveillance established and reorganized
- Standard Operating Procedures on CD laboratory surveillance developed.
- Laboratories involved in the CD surveillance fully equipped
- Involved in the CD surveillance laboratory staff highly trained

3.4. Activities:

Programming year 2004:

- 1.1. Revision and updating of the existing legislation related to the CD Surveillance system in line with the EU Decisions
- 1.2. Review the ways of involving both public and private health services and other sectors (Defense, Internal Affairs) in the CD surveillance system
- 1.3. Development of regulation a confidentiality issues in surveillance and control of CD as separate part of CD surveillance system
- 1.4. Definition of tasks and description of relationships between authorities and institutions in order to simplify the flow of information in the field of CD surveillance
- 1.5. Development of information system for the early warning and detection of health threats as part of the overall CDS system, including danger of cross-border spread of CD.
- 2.1. Updating and simplifying the immediate notification form in order to collect useful and relevant information
- 2.3. Development of manuals for providing relevant information on CD surveillance at national and district level
- 3.1. Establishment of a PC network with appropriate software at all levels
- 3.2. Development of a national standard protocol and national standard data management application form
- 3.3. Elaboration of guidelines regarding case definitions, outbreak investigation methodology etc.
- 3.4. Implementation of weekly descriptive analysis on daily notification data and monthly analysis based on monthly data at HEI level (following trends over time, mapping of cases, description by age groups etc.)
- 3.5. Elaboration of a new immediate notification form for all diseases to reduce the number of forms to be filled
- 4.1. Establishment of early warning system as a part of the existing CD surveillance system established
- 5.1. Supply of PCs at all levels only for surveillance purposes
- 5.2. Ensuring of appropriate statistical packages for CD surveillance
- 5.3. Supply of fax machines and internet .
- 6.1 Continuous and refresher training of epidemiologists on surveillance and computing at all levels
- 6.2. Training of HEI epidemiologists in advanced epidemiological analysis (modern surveillance, EPI-INFO, EPI map, basic statistics, other statistical packages, computer use and basic computer skills)
- 6.3. Training of HEI epidemiologists in descriptive epidemiology, epidemic investigation, study design, emergency response, data accuracy and communication in PH, evidence based prevention, reports and presentations
- 6.4. Training of all epidemiologists in antimicrobial resistance in order to include them in the surveillance of antimicrobial resistance
- 6.5. Training of trainers and regular short-term courses for the staff involved in the regional CD surveillance and individual training and practical work for all experts (central and regional level) in the NCDSC.

Programming year 2005:

- 1.1. Elaboration of regulation according laboratories participation in data collection for CD purpose
- 1.2. Updating of the existing legislation for Accreditation of labs in collaboration with professional scientific organizations

- 1.3. Development of Standard Operating Procedures on CD laboratory surveillance coherent with accepted international standards and EU norms
- 1.4. Elaboration of regulation for involvement of the private labs in the CD surveillance including antimicrobial resistance
- 1.5. Elaboration of regulation for the supervision and quality control of reference labs to private labs, involved in the CD surveillance including TB, HIV/AIDS surveillance
- 2.1. Establishment of computerized laboratory network to transmit test results rapidly
- 2.2. Establishment of a National Reference Laboratory for Tuberculosis
- 2.3. Reorganizing of TB and STD labs in order to be included in the CD surveillance network
- 3.1. Elaboration of a special lab reporting form for CD surveillance purposes
- 3.2. Development of a national standard protocol on CD laboratory surveillance
- 3.3. Updating of the existing laboratory guideline for specimen collection, packaging and transportation, guide for rapid response etc.
- 3.4. Adaptation of rapid diagnostic tests and other technologies in order to strength the national capacity for laboratory confirmation of priority health events
- 4.1. Supply labs with basic lab equipment
- 4.2. Supply of equipment for high quality serological investigations
- 4.3. Supply of equipment for minimum number of rapid diagnostic techniques
- 4.5. Establishment of central specimen bank
- 4.6. Supply of computers, internet connection for all labs
 - 5.1. Training of lab staff on CD surveillance (basic epidemiology and biostatistics)
- 5.2. Training of lab staff on specific issues concerning sampling techniques, data quality checks, lab safety, transport and storage of biological specimens

3.5. *Linked activities:*

Since 2001 Bulgaria has participated in three meetings under the Stability Pact for South Eastern Europe for Social Cohesion Initiative. Training of two specialists (epidemiologist and biostatistician) from NCIPD has been conducted in Slovenia 10-22 November 2003. At the last meeting in Brussels, December 2003 in the field of CDS the country achieved the following:

- Multinational team assessment missions
- National Action Plans for CDS
- Strategy for strengthening the national CDS system including portfolio of project proposals
- Harmonised definitions and methodologies
- Increased institutional and human capacities
- Integration of national CDS Systems through a regional network in SEE region

Regarding the WHO project for development of information system “Environment. Health. Communicable Diseases” software and hardware problems occurred. It is necessary to assure funds for changing the software in order to meet the requirements on new CD legislation.

3.6. *Lessons learned:*

Two Peer Review missions, commissioned by DG SANCO and DG ENLARG/TAIEX to assess the CD system have been carried out in June 2002 and 2003 in Bulgaria. The technical assistance needs for the implementation and enforcement of the EU accession with respect to CD surveillance system have been evaluated. Additionally, an assessment of the national surveillance system has been conducted by the experts of WHO-EURO office in May 2003. The recommendations of the peer reviews were as follows:

- The list of notifiable diseases should be reviewed to include all diseases in EU decisions

- Training of professional applied epidemiologists is required
- Professional Training in modern laboratory techniques is required
- Laboratory equipment and techniques should be updated to meet minimum EU requirements
- Participation in the EU communicable disease networks should be gradually introduced
- A system for early warning needs to be developed.
- The legislation in relation to communicable disease should be urgently updated
- A regular feedback system allowing dissemination of information in the CD
- Surveillance system should be developed
- Privacy and data protection issues should be addressed

4. Institutional Framework

The NCIPD founded in 1881 is leading national health institution in Bulgaria specialized in the field of CD surveillance and control. The scope of the principle activities of the NCIPD comprises research, postgraduate training, infectious diseases surveillance, development and evaluation of new programs for surveillance, prevention and control of CD.

The national reference laboratories in microbiology, virology and parasitology are responsible for adoption of new lab techniques conducting quality control for HEs labs, as well as participation in lab bases surveillance network.

The Ministry of Health exercises state sanitary control on communicable diseases. The state sanitary control is managed directly by the Deputy-Minister of Health, who is also Chief Sanitary Inspector of the Republic of Bulgaria. At the national level Directorate “Health Prophylactics and State Sanitary Control” (HPSSC) directs, plans, coordinates and controls the activities of the district inspectorates (HEIs) and exercises their methodological guidance in implementing the CD surveillance and control EU legislation.

The 28 District Hygiene and Epidemiological Inspectorates implement the CD surveillance and control measures at local level. The CDC Department and the Laboratory Department of the HEI are structures responsible for and directly involved in carrying out the CD surveillance and control. The CDC Department in MoH controls at national level the activities of the CD surveillance in HEIs.

5. Detailed Budget

Year 1/Phase 1	Phare Support					
	Investment Support	Institution Building	Total Phare (=I+IB)	National Co-financing*	IFI*	TOTAL
Contract 1 Twinning covenant		0.9	0.9	*		0.9
Contract 2 Supply of equipment	0.900		0.900	0.300		1.2
Total	0.900	0.9	1.800	0.300		2.1
Year 2/Phase 2	Indicative	Phare	Support			
Contract 1 Twinning covenant		0.9	0.9	*		0.9
Contract 2 Supply of equipment	0.900		0.900	0.300		1.2
Total	0.900	0.9	1.800	0.300		2.1
TOTAL	1.800	1.8	3.600	0.600		4.2

The Phare contribution for investment costs will be no more than 75% of eligible public expenditure, the balance having to be covered by the national co-financing. The national co-financing will be provided by the National Fund Directorate at the Ministry of Finance. All operational and running costs and the maintenance of the equipment will be provided by the final beneficiaries.

(*) Up to 10% of the Twinning project will be covered from the national budget through the National Fund Directorate at the Ministry of Finance. Phare and national co-financing will be tendered and contracted jointly.

6. Implementation Arrangements

6.1 Implementing Agency

The CFCU will be the Implementing Agency responsible for tendering, contracting and accounting with assisting in good project design and implementation and Phare procurement and payment rules. The CFCU (Ministry of Finance) is in charge of the contracting and financial management of the project. The Secretary General of Ministry of Finance will act as PAO of the project. His contact details are:

Secretary General of Ministry of Finance and PAO
Address: 102 Rakovski Str.
1040 Sofia
Tel: 359 2 9859 2772
Fax: 359 2 9859 2873

6.2 Twinning

The beneficiary Ministry of Health will have the responsibility for technical preparation and control (designing, selecting).

MoH contact point:

Head of Administration and Project Management Department

Address: Ministry of Health

39, Alexander Stamboliyski Blvd

1000 Sofia, Bulgaria

Tel: + 359 2 9301202

Fax: + 359 2 9875583

e-mail: stodorova@mh.government.bg

The PAA should have the following profile:

- experience in epidemiological surveillance of CD
- substantial experience in implementation of the EU legislation in the field of CD surveillance and control
- experience in mutual co-operation with international organizations in the field of public health
- excellent inter-personal communication skills
- initiative and co-operative attitude
- Fluency in English.

Profile of the short and medium term experts

The short- and medium-term experts should have the following profile:

- knowledge of the outbreak investigation and conducting of control measures
- knowledge of early warning and response of health threats in the Member States
- experience in preparing and providing training programs in the field of CD surveillance system
- knowledge of IT (collecting data, analysing data, trends in CD surveillance)
- fluency in English

6.3 Non-standard aspects

The PRAG Procedures strictly will be followed

6.4 Contracts

Programming year 2004:

Contract (1) – Twinning covenant 0.9 M €plus national co-financing up to 10%

Contract (2) – Supply of equipment 1.2 M €plus national co-financing 25%

Programming year 2005

Contract (1) – Twinning covenant 0.9 M €plus national co-financing up to 10%

Contract (2) – Supply of equipment 1.2 M €plus national co-financing 25%

7. Implementation Schedule

Contract 1 - TW

Start of tendering/call for proposals	October 2004
Start of project activity	September 2005
All activities completed	March 2007

Contract 2 – Supply of Equipment

TS prepared and verified by	May 2004
Start of tendering/call for proposals	July 2005
Start of project activity (sign contract)	September 2005
Project Completion	January 2006

8. Equal Opportunity

All participating Bulgarian institutions are equal opportunity employers. No discrimination of whatever nature will be applied.

9. Environment

The supplies will be delivered into existing premise. No environmental impact is expected and the supply of equipment falls does not require any sort of environmental assessment.

10. Rates of return

The equipment will not generate incremental costs related to the current running of the laboratories. Staff and premises exist and are running. It will nevertheless generate additional income thanks to the increased quantity/type of samples per year. Non-tangible benefits will be related to increased human health protection.

11. Investment criteria

11.1 Catalytic effect:

A well functioning surveillance system can facilitate the identification, monitoring and control of communicable diseases. A well developed surveillance system can help Bulgarian Public Health Authorities:

To obtain good information for early detection and rapid response to outbreaks or potential outbreaks

To identify diseases trends and their risk factors

To identify the possible protective measures

To obtain appropriate information for priority setting, planning, implementation and resource allocation for preventive programmes and control measures

To prepare the Bulgarian System for Epidemiological Surveillance to become part of the Community Network for the epidemiological surveillance and control of communicable diseases

PHARE support will enable the Bulgarian Public Health Authorities to realize the wider objectives related to the Surveillance and Control Network of Communicable Diseases in Bulgaria and in the EU.

11.2 Co-financing:

The National Fund will finance at least 25 % of the total contract costs for supply and up to 10% for twinning.

The Phare contribution for investment costs will be no more than 75% of eligible public expenditure, the balance having to be covered by the national co-financing. The national co-financing will be provided by the National Fund Directorate at the Ministry of Finance. All operational and running costs and the maintenance of the equipment will be provided by the Bulgarian authorities.

If the total cost of such investment is less than the amount envisaged in the fiche, the amount of Phare support will be reduced to maintain unchanged the relative proportions of Phare support and national co-financing shown in the fiche. If the total cost is greater than the amount envisaged in the fiche, the extra funding required will be provided by additional national co-financing or the cost reduced, consistent with the respective roles and responsibilities of the concerned Bulgarian agencies laid down in the Memoranda of Understanding setting up the NF and the CFCU.

11.3 Additionality:

Not applicable.

11.4 Project readiness and size:

Technical specifications and tender documentation should be ready at the time of the signature of the Financing Memorandum.

11.5 Sustainability:

Sustainability of project results is assured through the need and commitment by Bulgaria to implement its CD surveillance and control policy.. Staff increased (or decreased) are not expected as a result of the project. The training of the personnel during the implementation of the project will increase the motivation of the staff. The Department of Epidemiological Surveillance and Early Warning in the NCIPD will assure the continuity of the training through elaboration of training programs in CD surveillance, control measures, early warning, etc. All supported investment actions (supplies) are sustainable in the long term beyond the date of Accession. They will comply with the EU norm and standards (accredited), and will be coherent with the sector policies of the EU. Future maintenance and operation costs will be covered by the Bulgarian national budget.

11.6 Compliance with state aids provisions

All investments will respect the state aid provisions of the European Agreement

11.7 Contribution to NDP and/or Structural Funds Development Plan/SPD

Not applicable

12. Conditionality and sequencing

The need assessment for the supply of equipment and the technical specifications for the laboratory equipment will be prepared by independent external contracted expert (PPF) by the end of May 2004.

ANNEXES TO PROJECT FICHE

1. Logical framework matrix in standard format (compulsory)
2. Detailed implementation chart (compulsory for year/phase 1)
3. Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period) (compulsory for year/phase 1)
4. Feasibility study for the laboratory equipment for the two phases will be performed by an independent expert by the end of May. Terms of Reference have been elaborated and submitted for financing from PPF 2002.
5. List of relevant Laws and Regulations (optional)
6. Reference to relevant Government Strategic plans and studies (may include Institution Development Plan, Business plans, Sector studies etc) (optional) not applicable
7. List of the equipment for the NCIPD and 28 HEIs
8. Needs assessment for the laboratory equipment for NCIPD and 28 HEIs (will be revised after the equipment needs analysis of the PPF consultant is elaborated)
9. Organigramme of the Bulgarian Communicable Disease Surveillance System

ABBREVIATIONS

MoH	– Ministry of Health
HPSSC	- Health Prophylactics and State Sanitary Control
NCIPD	- National Center of Infectious and Parasitic Diseases
NCHI	- National Centre for Health Information
HEI	- Hygiene and Epidemiological Inspectorate
RHEI	- Regional Hygiene and Epidemiological Inspectorate
CD	- Communicable diseases
CDC	- Communicable Diseases Control
CDS	- Communicable Diseases Surveillance
SSC	- State Sanitary Control
GP	- General Practitioner
NRL	- National Reference Laboratory
NLN	- National Laboratory Network
SOP	- Standard Operating Procedures
WHO	- World Health Organization
NCDSC	- National Communicable Diseases Surveillance Centre
ESEW	- Epidemiological Surveillance and Early Warning
STD	- Sexual Transmitted Diseases
TB	- Tuberculosis
PPF	- Project Preparation Facilities

ANNEX 2:

DETAILED IMPLEMENTATION CHART

	2005				2006			
	1 q.	2 q.	3q.	4 q.	1 q.	2 q.	3 q.	4 q.
Twinning	T	T	C	I	I	I	I	E
Supply of equipment	T	T	C	I	I	E		
Etc.								
T – Tendering; C – Contracting, I - Implementation; E - End								

ANNEX 3:

CUMULATIVE AND DISBURSEMENT SCHEDULE (MEUR)

	2005				2006				2007	
	1q	2q	3q	4q	1q	2q	3q	4q	1q	2q
Contract 1										
Contracted			1.8							
Disbursed				0.45	0.9	1.35	1.8			
Contract 2										
Contracted			1.8							
Disbursed				1.2	1.8					

List of Relevant Laws and Regulations

1. Draft Health Act
2. Instruction No 6/21.06.2000 of MoH for notification, registration and reporting of communicable diseases
3. Regulation No 4/21.06.2000 of MoH for notification, investigation and registration of food-borne outbreaks
4. Regulation No 13/07.08.1998 of MoH for organization of prophylaxis and control of hospital acquired infections
5. Instruction No 9/25.09.2000 of MoH for control of Influenza and Acute respiratory diseases
6. Instruction No 3/11.02.1997 of MoH for prevention, treatment and control of indigenous parasitic diseases
7. Order No RD-09-111/18.03.2002 of MoH: National standard of clinical microbiology
8. Order No RD-09-181/29.04.2002 of MoH: Medical standard of virology
9. Order No RD-09-211/16.05.2002: National standard of medical Parasitology
10. Regulation No 137/19.07.2000 of MoH for border sanitary control in Republic of Bulgaria
11. Regulation No 4/04.04.1992 for testing and notification of HIV/AIDS
12. Ordinance No 2/06.02.2004 defines the list of CD diseases for compulsory notification
13. Decision 2119/98/EC setting up a network for the epidemiological surveillance and control of communicable diseases in the Community
14. Decision 2000/57/EC on the early warning and response system for the prevention and control of communicable diseases under Decision 2119/98/EC
15. Decision 2000/96/EC on the communicable diseases to be progressively covered by the Community network under Decision 2119/98/EC
16. Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision 2119/98/EC
17. Decision 2003/534/EC amending Decision No 2119/98/EC of the European Parliament and of the Council and Decision 2000/96/EC as regards communicable diseases listed in those decisions and amending Decision 2002/253/EC as regards the case definitions for communicable diseases
18. Decision 2003/542/EC amending Decision 2000/96/EC as regards the operation of dedicated surveillance networks

Project title: Strengthening of the National Surveillance System for Communicable Diseases

Equipment for the central level

National CD Surveillance Center

Sort of equipment	Quantity	Unit price (in Euro)	Total price (in Euro)
PC	8	1 500	12 000
Laptop	5	2 000	10 000
Printer	8	700	5 600
Scanner	4	2 500	10 000
Copier	4	2 500	10 000
Fax	8	300	2 400
Server	2	20 000	40 000
Software product	1	50 000	100 000
Subtotal			190 000

Microbiological reference laboratories (10) - NCIPD

Sort of equipment	Quantity	Unit price (in Euro)	Total Price (in Euro)
Microbiological safety cabinet class III	3	15 000	45 000
Microbiological safety cabinet class II	4	10 000	40 000
Microscopes-fluorescence	3	15 000	45 000
Microscopes-light	10	10 000	100 000
Incubators	10	3 000	30 000
Sterilisators	10	2 000	20 000
Incubators-CO ₂	4	5 000	20 000
Refrigerators-(-20 ⁰)	20	2 000	40 000
Refrigerators-(-70 ⁰)	4	10 000	40 000
Centrifuges	10	3 000	30 000
ELISA readers	5	5 000	25 000
Server	4	20 000	80 000
Diagnostic kits			70 000
Diagnostic media and reagents			65 000
Molecular biology equipment (amplificators, readers, software products)			130 000
Computers	10	1 500	15 000
Printer	10	700	7 000
Copier	10	2 500	25 000
Fax	10	300	3 000
Renovation of the ref labs			120 000
Subtotal			950 000
Total			1 140 000

Equipment for the peripheral level

CD Surveillance Units/Focal Points in HEI

Sort of equipment	Quantity	Unit price (in Euro)	Total price (in Euro)
PC	28	1 500	42 000
Printer	28	700	19 600
Copier	28	2 500	70 000
Fax	28	300	8 400
Scanner	28	2 500	70 000
Subtotal			210 000

Microbiological laboratories – HEI (28)

Sort of equipment	Quantity	Unit price (in Euro)	Total Price (in Euro)
Microbiological safety cabinet class II	8	15 000	120 000
Microscopes-fluorescence	8	15 000	120 000
Microscopes-light	15	10 000	150 000
Sterilisators	20	2 000	40 000
Incubators	8	3 000	24 000
Incubators-CO ₂	5	5 000	25 000
Refrigerators (-20 ⁰)	6	2 000	12 000
Refrigerators (-70 ⁰)	2	10 000	20 000
Centrifuges	25	3 000	75 000
ELISA readers	16	5 000	80 000
Diagnostic kits			194 000
Diagnostic media and reagents			190 000
Subtotal:			1 050 000
Total:			1 260 000
TOTAL ALL YEARS:			2 400 000

NEEDS ANALYSIS FOR THE LABORATORY EQUIPMENT FOR NCIPD AND 28 HEIs

The Ministry of Health exercises state sanitary control on communicable diseases. The state sanitary control is managed directly by the Deputy-Minister of Health, who is also Chief Sanitary Inspector of the Republic of Bulgaria. At the national level Directorate “Health Prophylactics and State Sanitary Control” (HPSSC) directs, plans, coordinates and controls the activities of the regional inspectorates (HEIs) and exercises their methodological guidance in implementing the legislation concerning the CD surveillance.

Due to the budgetary constraints the regional HEI do not have flexibility and spent money mainly on personnel and consumables. Capital investments have not been registered for the last 10 years as top-level decision makers (Ministry of Finance under the supervision of International Monetary Fund) considers a higher priority for the other health sectors.

Other financing sources for HEIs are: the national and international programmes (CINDI, health promotion, environmental health, etc) and the taxes charged for provided services (preliminary sanitary control, food testing, etc).

There is not a special budget allocated for emergency situations and in case of outbreaks Ministry of Health can not release money from a reserve fund.

- CD surveillance data do not reach directly NCIPD but reach first the NCHI that does not have surveillance and response responsibilities.
- The communicable disease surveillance and the specific disease surveillance systems for TB, STI and HIV/AIDS are not adequately integrated.
- District epidemiologists are over burdened with control activities and they lack of time for real CD surveillance.
- The GPs receive limited feedback and are not well informed about the epidemiological situation outside their service areas.

The NCIPD performs annual analyses of infectious and parasitic diseases as well as of antimicrobial resistance. These analyses are published in the NCIPD informational journal every 2 months, but the regional HEI have not funds to pay for it.

The creation of the NCDSC will increase the efficiency and the quality of the CD surveillance system. Definition of the tasks and description of relationships between authorities and institutions, involved in the system, definition of role and function of national referral laboratories will ensure better CD surveillance management at all levels.

The National centre for infectious and parasitic diseases (NCIPD) has been designated as a national reference laboratory and has capacity to carry out all traditional microbiological and parasitological analyses and most traditional virological analyses. Capacity in molecular biology is not up to date. The laboratories do not have computerised archives and there is no biological specimen bank.

The laboratory network in Bulgaria is composed of 28 laboratories (with microbiological, virological and parasitological units) one in each HEI area. The virological and parasitological units can make only serological diagnoses.

The district public health laboratories do most of the routine analyses for the surveillance system. Even the labour costs in PH are guaranteed by the state, the budget for supplies (reagents and diagnostic kits) is insufficient. The prohibition of the Ministry of Finance

to make capital investments in all HEI structures, including laboratories result in a very old laboratory equipment and facilities.

The project wills strength the capacity of the laboratories to perform CD surveillance activities:

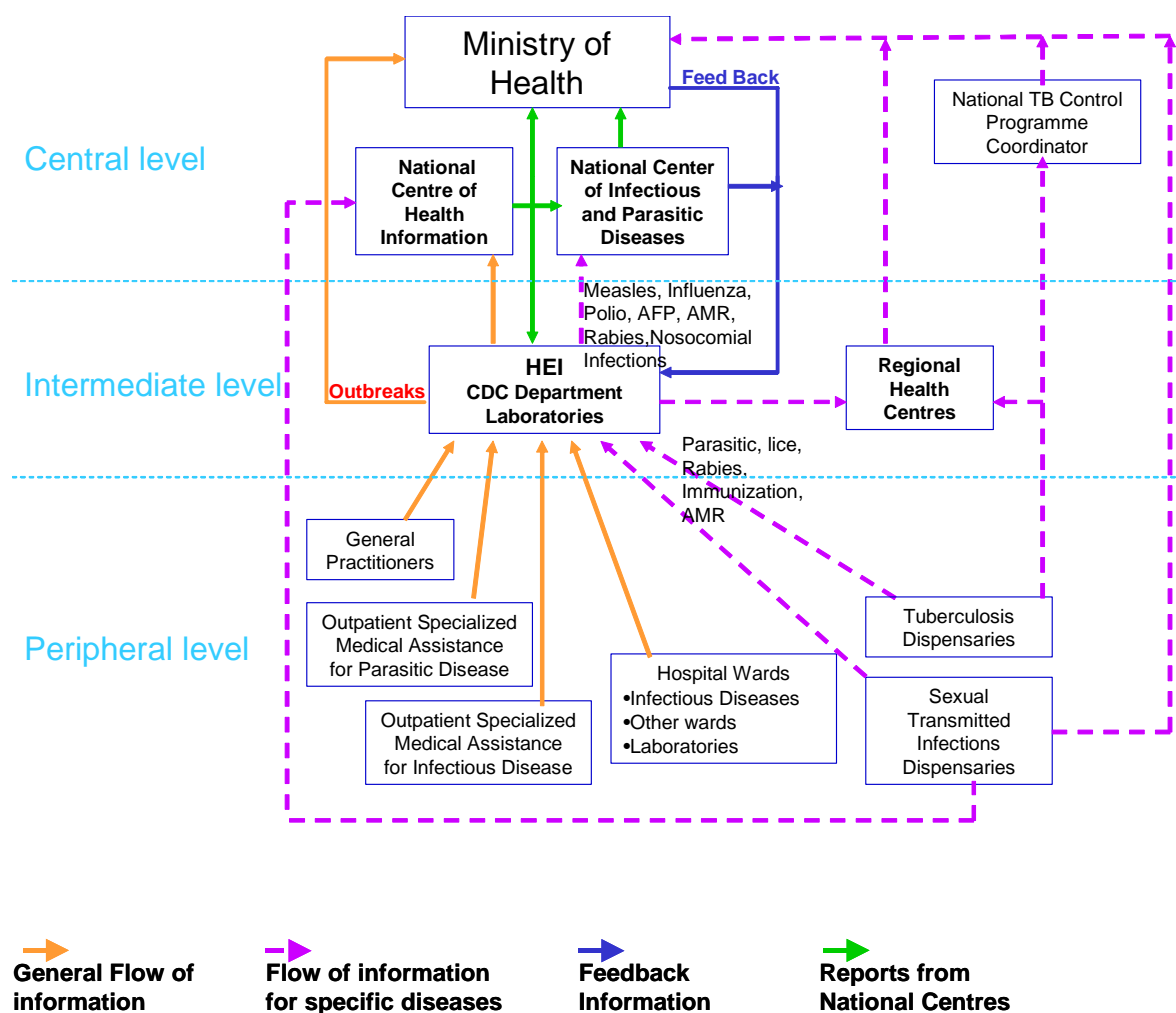
- standardize laboratory procedures for the CD under surveillance (standardization of specimen collection, preservation, shipment and diagnostic techniques)
- implementation of rapid tests for primary diagnosis
- provide laboratories with equipment and supplies appropriate to the procedures performed
- facilitate communication between laboratory, epidemiology and clinical staff

First step will be the training of the staff in the new established NCDSC (7 specialists) and training for the specialists in MoH (3 specialists).

From all 28 HEIs it is foreseen 78specialists to be trained in CD surveillance (both epidemiologists and microbiologists).

After the independent expert analysis a more objective justification for the need of equipment will be presented to all stakeholders.

Organigram of the Bulgarian Communicable Disease Surveillance System.



ANEX 1 Phare log frame

LOGFRAME PLANNING MATRIX FOR Project	Programme name and number	
Strengthening of the National Surveillance System for Communicable Diseases	Contracting period (year 1) expires on 30 November 2006	Disbursement period (Year 1) expires on 30 November 2007
	Total budget year 1: 2.1 MEUR	Phare budget year 1: 1.8 MEUR

Overall objective	Objectively verifiable indicators	Sources of Verification	
To strength the CD surveillance system and to establish national early warning system assuring better control of CD in Bulgaria	<ul style="list-style-type: none"> Updated, synchronized with the EU requirements surveillance system for CD in place in 2006 Favourable trends for morbidity in both Bulgaria and EU region 	<ul style="list-style-type: none"> Reports of the MoH concerning the results of CD Epidemiological bulletins Annual lab reports 	
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
Ensure the integration of the national CD surveillance system into the EU surveillance networks through adopting the EU legislation and strengthening the administrative capacity of the involved institutions.	<ul style="list-style-type: none"> Availability of the adopted by the MoH ordinances, instructions, guidelines, in line with the EU legislation-improved by 2006 Trained at least 65 experts in the field of epidemiology and laboratory diagnostic 	<ul style="list-style-type: none"> Official MoH bulletins MoH, NCIPD, HEIs 	<ul style="list-style-type: none"> The drafted legislation is adopted by the relevant bodies Necessary human resources available
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<p>Programming year 2004</p> <p>3.3.1. National framework for epidemiological CD surveillance system according to all EU Decisions adopted</p> <p>3.3.2. Legislation for standards, regulations and guidelines in the field of CD elaborated</p> <p>3.3.3. The existing CD epidemiological surveillance system reinforced</p>	<ul style="list-style-type: none"> Trained experts for CD surveillance legislation at all levels End of 2006 fully functioning early warning system End of 2005 NSP to be completed End of 2006 the data protection system to be established 	<ul style="list-style-type: none"> MoH, NCIPD, HEIs 	<ul style="list-style-type: none"> Co-operation with other interested parties Technical specifications done on time Needed equipment delivered on time

<p>3.3.4. Early warning system as a part of the existing CD surveillance system established</p> <p>3.3.5. Working places for the epidemiologists involved in the CD surveillance equipped</p> <p>3.3.6. Involved in the CD surveillance epidemiological staff highly trained</p> <p>Programming year 2005</p> <p>3.3.1. National legislation for the role and responsibilities of the labs in the CD surveillance process developed</p> <p>3.3.2. Structures for national laboratory network for the CD surveillance established and reorganized</p> <p>3.3.3. Standard Operating Procedures on CD laboratory surveillance developed.</p> <p>3.3.4. Laboratories involved in the CD surveillance fully equipped</p> <p>3.3.5. Involved in the CD surveillance laboratory staff highly trained</p>	<ul style="list-style-type: none"> • The bulletin for CD surveillance regularly issued since 2005 • Manual for SOP published 	
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Activities	Means	Assumptions
<p>Programming year 2004</p> <p>3.4.1.1. Revision and updating of the existing legislation related to the CD Surveillance system in line with the EU Decisions</p> <p>3.4.1.2. Review the ways of involving both public and private health services and other sectors (Defense, Internal Affairs) in the CD surveillance system</p> <p>3.4.1.3. Development of regulation a confidentiality issues in surveillance and control of CD as separate part of CD surveillance system</p> <p>3.4.1.4. Definition of tasks and description of relationships between authorities and institutions in order to simplify the flow of information in the field of CD surveillance</p> <p>3.4.1.5. Development of information system for the early warning and detection of health threats as part of the overall CDS system, including danger of cross-border spread of CD.</p> <p>3.4.2.1. Updating and simplifying the immediate notification form in order to collect useful and relevant information</p>	<ul style="list-style-type: none"> - Twinning contract - Supply contract 	<ul style="list-style-type: none"> • Requested budget is provided • Technical specification ready and confirmed • Laboratory premises fully ready and staffed to accept the equipment

3.4.2.3. Development of manuals for providing relevant information on CD surveillance at national and district level

3.4.3.1. Establishment of a PC network with appropriate software at all levels

3.4.3.2. Development of a national standard protocol and national standard data management application form

3.4.3.3. Elaboration of guidelines regarding case definitions, outbreak investigation methodology etc.

3.4.3.4. Implementation of weekly descriptive analysis on daily notification data and monthly analysis based on monthly data at HEI level (following trends over time, mapping of cases, description by age groups etc.)

3.4.3.5. Elaboration of a new immediate notification form for all diseases to reduce the number of forms to be filled

3.4.4.1. Establishment of early warning system as a part of the existing CD surveillance system established

3.4.5.1. Supply of PCs at all levels only for surveillance purposes

3.4.5.2. Ensuring of appropriate statistical packages for CD surveillance

3.4.5.3. Supply of fax machines and internet .

3.4.6.1 Continuous and refresher training of epidemiologists on surveillance and computing at all levels

3.4.6.2. Training of HEI epidemiologists in advanced epidemiological analysis (modern surveillance, EPI-INFO, EPI map, basic statistics, other statistical packages, computer use and basic computer skills)

3.4.6.3. Training of HEI epidemiologists in descriptive epidemiology, epidemic investigation, study design, emergency response, data accuracy and communication in PH, evidence based prevention, reports and presentations

3.4.6.4. Training of all epidemiologists in antimicrobial resistance in order to include them in the surveillance of antimicrobial resistance

3.4.6.5. Training of trainers and regular short-term courses for the staff involved in the regional CD surveillance and individual training and practical work for all experts (central and regional level) in the NCDSC.

Programming year 2005

3.4.1.1. Elaboration of regulation according laboratories participation in data collection for CD purpose

3.4.1.2. Updating of the existing legislation for Accreditation of labs in collaboration with professional scientific organizations

3.4.1.3. Development of Standard Operating Procedures on CD laboratory

<p>surveillance coherent with accepted international standards and EU norms</p> <p>3.4.1.4. Elaboration of regulation for involvement of the private labs in the CD surveillance including antimicrobial resistance</p> <p>3.4.1.5. Elaboration of regulation for the supervision and quality control of reference labs to private labs, involved in the CD surveillance including TB, HIV/AIDS surveillance</p> <p>3.4.2.1. Establishment of computerized laboratory network to transmit test results rapidly</p> <p>3.4.2.2. Establishment of a National Reference Laboratory for Tuberculosis</p> <p>3.4.2.3. Reorganizing of TB and STD labs in order to be included in the CD surveillance network</p> <p>3.4.3.1. Elaboration of a special lab reporting form for CD surveillance purposes</p> <p>3.4.3.2. Development of a national standard protocol on CD laboratory surveillance</p> <p>3.4.3.3. Updating of the existing laboratory guideline for specimen collection, packaging and transportation, guide for rapid response etc.</p> <p>3.4.3.4. Adaptation of rapid diagnostic tests and other technologies in order to strengthen the national capacity for laboratory confirmation of priority health events</p> <p>3.4.4.1. Supply labs with basic lab equipment</p> <p>3.4.4.2. Supply of equipment for high quality serological investigations</p> <p>3.4.4.3. Supply of equipment for minimum number of rapid diagnostic techniques</p> <p>3.4.4.5. Establishment of central specimen bank</p> <p>3.4.4.6. Supply of computers, internet connection for all labs</p> <p>3.4.5.1. Training of lab staff on CD surveillance (basic epidemiology and biostatistics)</p> <p>3.4.5.2. Training of lab staff on specific issues concerning sampling techniques, data quality checks, lab safety, transport and storage of biological specimens</p>		
<p>Preconditions</p> <ul style="list-style-type: none"> Existing of the basic national legislation 		