PHARE 2003
STANDARD SUMMARY PROJECT FICHE

1. Basic Information.

1.1. CRIS Number: PHARE 2003/005-551.04.02

1.2. Title: Strengthening the capacity to manage the veterinary acquis. Improvement of capabilities at central and regional and county level to enforce and observe the new harmonized veterinary norms.

Twinning component: RO03/IB/AG/02
- Title: Strengthening the capacity to manage the veterinary acquis. Improvement of capabilities at central and regional and county level to enforce and observe the new harmonized veterinary norms
- Duration: 20 months
- Budget: 1,2 M €

1.3. Sector: Agriculture, Sanitary Veterinary and Zootechnical Fields.

1.4. Location: Romania, Ministry of Agriculture Food and Forests (MAFF); National Sanitary Veterinary Agency (NSVA).

2. Objectives.

2.1. Wider objectives.

Alignment of Romanian administrative and technical capabilities and procedures used for surveillance, prevention of animal disease, and diagnosis and of those necessary for border veterinary control, with those of the European Union.
Enhancement of livestock production and protection of human health in respect of the quality of food of animal origin and transmissible animal diseases and move towards EU standards for veterinary and food quality controls.

2.2. Project purpose:

- Through a twinning programme to strengthen the National Sanitary Veterinary Service through capacity building at specific levels in respect of epidemiology, disease surveillance, prevention and control of diseases with particular reference to List A and zoonotic diseases including strengthening of laboratory services.

2.3. Accession partnership and NPAA priority:

Short term priorities:
- Improving the surveillance system and control of animal diseases, by laboratory examination, at regional and central level;
- Endowing with equipment for harvesting, packing and transport of samples from field to regional and central laboratories for diagnosis;
- Setting up a monitoring system for the transport of samples from field to regional and central laboratories for diagnosis;
- Improvement of import/export procedures, and of procedures and facilities for inspection at the borders and continuing of endowment with equipment and means of communication and control of Border Inspection Posts;
- Continuing of endowment with equipment at the laboratory of 3rd degree biosafety.

Medium term priorities:

- o Organization and implementation of the program of harvesting, packing and transport of organs, pathological products, blood samples and other materials destined for laboratory diagnosis, with the view to align to EU requirements regarding surveillance and control of animal disease by laboratory examination;
- o Strengthening of the capacity of veterinary administration to assume Communitary Acquis, especially concerning:
- o Improvement of the capabilities at central and regional level to enforce and observe the harmonized legislation;
- o Continuous aligning to EU requirements of diagnostic capabilities and laboratory testing.

2.4. Contribution to National Development Plan.

Not applicable

2.5. Cross Border Impact.

Not applicable

3. Description.

3.1. Background and justification.

Background.
The competent central veterinary authority of Romania is the National Sanitary Veterinary Agency (N.S.V.A.) organized as a directorate within the Ministry of Agriculture, Food and Forests. Under the Agency there are the central specialized institutes in Bucharest and county sanitary veterinary offices and the border sanitary veterinary inspectorate. State sanitary veterinary services are organized as a pyramid with central, county and local levels.
The professional staff in the field are supported by animal technicians and those in the institutes by laboratory technicians and ancillary workers.
At central level the N.S.V.A. is organized into 3 specialized sections (Animal Health, Hygiene and Public Health and Veterinary Inspection and Control). At the central level there are also 3 national veterinary institutes subordinated to the N.S.V.A., as follows:

- Institute for Diagnosis and Animal Health;
- Hygiene and Veterinary Public Health Institute;
- Institute for the Control of Biological Products and Veterinary Drugs.

Institute for Diagnosis and Animal Health (IDAH) includes in its structure:

a. Diagnosis and Animal Health
b. Border Sanitary Veterinary Control
c. European Integration, Legislative Transposition, International Programs and Relations
d. Finance and administration

The IDAH serves as the national reference laboratory and service laboratory to those in the counties, with a principal remit for disease diagnosis, reagent supply, and research. It provides sophisticated diagnostic support.
At county level and in Bucharest respectively, the veterinary activity is co-ordinated by the county veterinary section (NVSA). There are services representing the veterinary administration and a county sanitary veterinary laboratory. The laboratories are technically linked to the central institutes but line managed by the county veterinary officers. The border inspection posts are responsible to the central control located in the IDAH.

Justification.

Critical points.
The location of Romania with land borders with Hungary, Moldova, Ukraine, Bulgaria and Serbia with access to the Black Sea will after accession mean that there will be critical borders with non-member States. Strong border controls (BIPs), will keep disease out, and an efficient epidemiological surveillance system will detect early evidence of disease. The Government strategy for integrated border management foresees that veterinary border control will be supported by designated specially equipped Regional laboratories close to the BIP's at Arad, Satu Mare, Suceava, Iasi, Constanta, Braila and Calarasi.
The necessary veterinary diagnostic services and control measures must be in place prior to accession, supported by equivalent national legislation as soon as possible. One of the purpose of this project is to

enhance and complement the progress already made in certain areas as referred to in Section 3. In the veterinary sector all the proposed inputs will strengthen what is essentially a disease diagnosis, prevention and control network in which the epidemiology unit will play a pivotal role.

Epidemiology.
For the period leading to acquis it is necessary for there to be a continuum of improvement in all activities of the NSVA with appropriate EU support targeted in key areas. It must be carefully planned and prioritized. Strengthening of the coordination and collaboration between all sectors of the NSVA is essential. The establishment of an able dedicated Epidemiology Unit will greatly assist in this, in particular linking the diagnostic laboratories with planning and policy makers in MAFF. It is critical to have reliable information on the prevalence and incidence of animal diseases in the country and know if those afforded priority in the past are of importance under changed production systems.
With the emergence of new diseases and changing epidemiological characteristics, often influenced by global climatic change, as in the case of arthropod borne viruses such as Bluetongue, West Nile Virus and African Horse Sickness, countries have to be increasingly vigilant for disease incursion. Romania is in an important geographical location in this respect. The increase in global travel and trade also pose threats, as seen with FMD, Bovine Spongiform Encephalopathy (BSE), Porcine Respiratory and Reproductive Syndrome (PRRS) and many poultry diseases.
Wildlife reservoirs such as wildboar (CSF); bats (Hendra, Nipah virus and rabies), water fowl (avian influenza) must also be subject to epidemiological surveillance. All these tasks must be founded on a sound scientific base, valid diagnostic and statistical techniques and both active and passive surveillance programmes to provide the correct prioritisation of prevention and control measures both nationally and as a component of international programmes.
The epidemiology unit to be established at the Institute for Diagnosis and Animal Health will assess risk, operate an early warning system, liaise with veterinary field services, BIPs, laboratories, meat inspection services, private veterinarians and medical epidemiologists and disseminate epidemiological concepts within the veterinary profession. Therefore support is goind to be provided through this project for the set up of such an epidemiological unit.

The establishment of an epidemiology unit and disease surveillance network to a high standard will enable the Romanian veterinary service to meet EU requirements for this type of specialization and provide support in all its activities. It will provide the means to identify animal disease problems and zoonoses, devise and implement prevention, control and eradication programmes on a sound scientific basis. As Romania will be a key member state as regards animal health control the unit will play a critical part in securing the disease free status of the EU as a whole.

Laboratory services.
Much effort has already been expended in support of the laboratory services, particularly in the supply of equipment but more is needed. As this becomes more specialized it is recognized that the key requirements are for the training of professional and technical operatives, and quality control in all the veterinary laboratories. Acceptance of results, certification for disease freedom, and movement within the EU and internationally rests on specific and sensitive diagnostic methods and veterinary and technical personnel with the knowledge and expertise to carry out the tasks.
Disease security in the laboratories must be tightened and the health and safety procedures, this requires comprehensive written codes of practice and staff training. Satisfactory methods for solid and liquid waste disposal are essential to prevent disease spread from laboratories working with high risk pathogens. These project proposals aim to achieve satisfactory methods for solid and liquid waste disposal at laboratories, in particular at the IDAH working with high risk pathogens.

A strategy has been decided to develop the IDAH as the central national reference laboratory for Romania; to develop equipment at selected Regional laboratories for the routine diagnosis of TSE's at Arad, Satu Mare, Suceava, Iasi, Constanta, Braila and Calarasi and to develop the regional laboratories close to the BIP's which will be at the borders in 2007, and the Regional laboratory at Brasov. Local County laboratories will only carry out basic routine diagnosis not be supplied with sophisticated and costly equipment. They will refer samples to the Regional laboratories of the IDAH for specialized testing. Therefore only same basig equipment to be supplied by the projects will go to the above mentioned regional laboratories.

The construction of a second High Security Facility (Category III) at the IDAH for animal passage work (TSE's) and Transmissible Spongiform Encephalopathies is an essential sound investment although modifications of existing facilities can be fraught with difficulties; the installation of a self contained purpose built module is often the best solution. While the government will finance from national resources

the modification of the existing facilities or the new building, Phare funds will be dedicated for the installation of a self contained module. Good written instruction is planned based on pathogen risk assessments and the laboratory will have the maximum backup from international reference laboratories. Expert advice is necessary in later stages of construction and prior to the laboratory being commissioned and application made for EU approval.This advice will be provided be the twinning project.

With the number of veterinary laboratories in Romania, the emphasis placed a quality assessment and quality control is fully justified and must be ongoing; developing ring testing and membership of international organizations. Sample submission must be satisfactory with the provision of appropriate guidelines, transport media and containers. This project will contribute to this with investments in sampling equipment for all animal health laboratories especially those in Regions and at BIP's. Of crucial importance is the maintenance of a sufficient flow of diagnostic specimens to:

a) justify capital expenditure on facilities and equipment;
b) standardize test methods;
c) enable staff to be familiar with the techniques;
d) provide replicable reliable results.

This can only be achieved in the selected Regional laboratories.
In the past with large farms this has been easier to achieve and it is understood that there is still a requirement for routine periodic testing of livestock. Targeted surveillance based on sound epidemiology will replace some of the routine activities.

It is right to enhance the facilities at selected regional laboratories for residue testing, particularly close to BIPs and introduce more specialized techniques, if these are subject to good quality control. The benefits of introducing rapid molecular diagnostic methods (PCR) to regional laboratories will assist in keeping disease out of the country. A comprehensive review of the diagnostic service to consider the number and location of laboratories, throughput, methodologies, equipment, staffing, abilities and training as EU procedures may be completed within the framework of the proposed twinning project and could serve as a basis for multi-annual investment planning. It has to be devined among the first activities of the twinning in case the current on going strategic planning is not yet achieved. This should be linked to the development of a national strategic plan for the NSVA.

Justification of laboratory equipment to be purchased within the project

1. The IDAH is the chosen facility in which to locate unit for national disease surveillance. The IT equipment supplied will facilitate an effective epidemiology this and link the unit to the HO,BIPs and county laboratories.
2.The IDAH is located on an open site with traffic to the adjacent University of Bucharest Veterinary Faculty. There is no satisfactory system of liquid or solid waste disposal from a laboratory which is working on dangerous pathogens. The proposed facilities will increase disease security.
3.A category 3 unit is being constructed for work on vesicular viruses. However there is no satisfactory facility for work onTSEs, CSF, rabies, Newcastle Disease, Avian Influenza etc. The proposed Cat 3 accomodation will provide a cost effective facility. Modules have been use in the UK during the FMD epidemic for work on FMD serology.
4.Waste disposal at the county laboratories is unsatisfactory. A number of small incinerators would improve disease security.
5. There are significant problems in maintaining a satisfactory service for sampling and dispatch of samples. Tte collection and containment of good specimens is critical for diagnostic purposes and disease surveillance with a Laboratory Manual on sampling requirements.
6. Regional and county laboratories are working with both animal and human pathogens. A supply of safety cabinets is essential to minimise disease risks.
7. TSEs are recognised in many countries and scrapie although not yet BSE has been confirmed in Romania. With the EU demands for the screening of slaughtered animals there is a need for prion testing equipment in designated diagnostic laboratories in the regions.
8. It is recognised that there are proposals to update the residue testing equipment in the Food and Feedingstuffs Institute, however no such equipment is available in the IDAH. Proposals are made for limited resources for the IRADin this important dicipline. It will be important however to coordinate the work and expertise between the two institutes.

Equipment	Quantity	Cost	Total	Location
1. PCs,hardware, software	20	16000	2,000	IDAH & Regional laboratories
Wide area network (if custom built) dial up is unreliable and expensive	1	160,000	160,000	IDAH
Server	1	15,000	15,000	IDAH
2. Incinerator	1	170,000	170,000	IDAH
Liquid waste disposal . system	1	200,000	2000,000	IDAH
3. Cat 3 high security module, equipped.	1	420,000	420,000	IDAH
4. Small incinerators	20	2,500	50,000	Regional lab. BIP's & designated lab.
1. 5. Sampling equipment, vacutainers, containers, for instruments. laboratories	41	4,500	94,5000	All vet. lab.
6. Safety cabinets,class 2	20	15,000	300,000	IDAH, Reg. lab. & designated lab.
7. TSE prion testing equipment and safety cabinets.	8	55,000	440,000	Designated lab.
8. HPLC equipment-with mass Detector(MSD)	1	120,000	120,000	IDAH
-with diode array UV detector	1	60,000	60,000	IDAH
Elisa-plate washer	1	12,000	12,000	IDAH
-plate reader	1	15,000	15,000	IDAH
-associated equipment (incubator,pipes,mixers etc.)	1	16,000	16,000	IDAH
Gas chromatograph for Pesticides. -GC/MSD	1	120,000	120,000	IDAH
Thin layer Chromatograph -Spotter,drier,evaporator,tanks	1	18,000	18,000	IDAH
-Scanner	1	21,000	21,000	IDAH
ICPMS detector(heavy metals)	1	150,000	150,000	IDAH
Mass spectrometer(for confirming Positives)	1	245,00	245,000	IDAH
Associated hardware for residues programme. Freezers	1	55,000	55,000	IDAH
LIMS system and QA network (sample management)	1	45,000	45,000	IDAH
Fume cupboards,safety cabinets, Balances, ph meters,glassware, Washers etc	1	60,000	60,000	IDAH

Strategic planning.
Sound strategic veterinary planning for the short, medium and long term, is an essential discipline for operating an efficient, secure and cost effective service. The Romanian service will have a key role as one of the most important in the EU.

To ensure the allocation and prioritization of resources over the period to acquis both in the field and in the laboratories a national strategic plan is being developed for the NSVA. As always there will be competing demands for limited financial resources which have to be addressed; much will depend on full cooperation, collaboration and coordination within the NSVA. A senior experienced veterinary manager from a member state will support planning and implementation as this is brought forward.

Contingency planning (List A and B diseases).
Contingency planning for any eventuality is highly important, particularly where vaccines are unavailable or vaccination is banned. EU demands are rigid and hinge on well prepared plans with expert epidemiological input which are comprehensive and which can be fully implemented immediately.

A principal concern of EU member states is the prevention and eradication of all List A diseases. The development of written contingency plans and staff instructions to deal with these, based on the EU directives has high priority. Progress on developing such plans with some staff training has been made. It is essential to continue with and broaden these initiatives.
At present Classical Swine fever (CSF) poses a major problem in Romania and it must be eradicated; this will only be possible with an identification and registration system for pigs. This need should be considered in the context of the Cattle Identification and Movement Control Scheme but the preparation of the legal framework would be dealt with in the context of the current twining project. Considerable resources are used for FMD serological surveillance. As contingency plans are elaborated and epidemiological surveillance is strengthened the justification for this programme will be reviewed.
List B diseases will have to be dealt with as necessary to establish country, area and farm status. Fortunately Romania is free from brucellosis in cattle although Brucella ovis is present in small ruminants. BSE surveillance will be extended and targeted to met EU requirements. Bovine tuberculosis remains a problem which will only be contained with adequate cattle identification, movement controls and financial compensation for slaughtered livestock. Again specific, sensitive, standardized and quality controlled test procedures are critical, supported by sound epidemiological planning.

Animal By-products.
The emergence of BSE has illustrated the vulnerability of livestock to the risks from animal derived protein by-products and waste. The control and prohibition of these is a key to the prevention of many List A diseases. Recent EU legislation has had a major impact, not only on the problem, but on the meat industry and import/export. This sector must be subject to an indepth review to ensure the implementation of new national legislation and protect both animal and human health.

Import/Export, BIPs.
Progress is being made in this field with the transposition of EU legislation and improved border control. It is a high priority area which justifies continued investment to develop facilities, communication networks, specific detailed instructions for staff and inter veterinary liaison. Resources are required to implement the ANIMO and SHIFT IT systems with experienced IT support. A main obstacle to progress is the time taken for approval and commencement of new building at BIPs. BIP laboratories are an integral part of the laboratory services and information derived from BIPs is part and parcel of epidemiological surveillance.

3.2. Linked activities.

Taiex and Phare programmes have made a highly significant impact on the capacity and capabilities of the veterinary sector in Romania, including:

RO 9804 03 02 01 – Procurement of equipment for diagnostic laboratories and border points. The overall objectives consist in to aligning with current EU standards animal health control at 5 major border crossing points and diagnostic standards at 6 designated laboratories. The major part of the project is intended to purchase laboratory equipment to fulfill the requirements of the existing sector in the framework of pre-accession strategy. All laboratory methods in the veterinary field must be harmonized and rated in compliance with internationally accepted standards. The specific objectives consist in equip the IDAH and five regional laboratories (Bucharest, Cluj-Napoca, Constanta, Iasi, Timisoara) and provide adequate communication and control facilities at five Border Inspection Points (Constanta, Giurgiu, Halmeu, Albita and Siret).
RO9804.02.03. – The strengthening of the institutional and administrative capacity to manage the sanitary-veterinary acquis. The main objectives of this project consist in strengthening of the administrative capacity of Romanian veterinary for managing the Acquis Communautaire related to the following fields: Border inspection points (BIPs); Health and animal protection; Foodstuffs for animal and animal residues; Quality assurance within those three designed central laboratories with the view of accreditation; Animal identification (bovines).
RO006-09 -"Reinforcement of Agri-food control systems", the objective of which is to reinforce Romanian food administration and to promote effective co-operation between all the institutions. Therefore, the current project on the vet. acquis need to fully take into account the results of the running one (project R00006-09) or be in line with it.

RO006.11. – Improvement and harmonization of veterinary legislation and enforcement capabilities which had as wider objective align with current EU standards animal health and diagnosis controls and observance of food hygiene to contribute to maintenance of confidence in the safety of food and to safeguard the health status of herds and flocks.

RO 0107.08 Developing and implementing the national bovine animal identification and registration system with following objective: Strengthening the institutional structures and their personnel to enable them to operate in compliance with European and international standards and principles; Implementation of EU standards and practices in this field; To develop and implement a national animal I&R (identification and registration) system.
RO 2002/000-586.04.06. Surveillance, prevention, diagnosis and control of animal diseases, and alignment with the acquis inn the field of animal nutrition. The wider objective consist in alignment of Romanian administrative and technical capabilities and procedures used for surveillance, prevention, diagnosis and control of animal diseases and of those necessary for the border veterinary control with those of the European Union. At the same time developing and strengthen the Romanian administrative capacity within the MAFF with a view of taking over and implementing the European Union acquis on animal nutrition.

The major impact of these programmes, of which RO02/1B/AG/01 is still ongoing has been in:

- training veterinary staff, other professionals and laboratory workers;
- improving the quality of laboratory equipment and range of diagnostic procedures;
- improving the sensitivity and specificity of tests, quality control and capacity leading to laboratory accreditation;
- the provision of a high security (Category III facility) especially for FmD, not yet completed;
- strengthening the concept of disease contingency planning;
- adding to the bank of knowledge on the prevention, control and evaluation of Office International des Epizooties (OIE) List A and List B diseases;
- improving border control facilities and procedures;
- improving food safety and the safety of animal feeding stuffs;
- assisting in the transposition of veterinary legislation.

Through these inputs much has been achieved in a short space of time due to the enthusiasm of the NSVA staff and their earnest desire to move forward over the next few years. Some 230 relevant directives and regulations have been transposed into Romanian (approximately 80 per cent), major improvements have been made in the veterinary laboratories and staff training is taking a high priority. This progress must be strongly supported and this project will do so.
It is noted that a project to develop and implement a national bovine animal identification and registration system will commence in 2003.
Overall coordination between the various projects or their respective results is required.

3.3. Results

The foreseen results related to this project will be evident during 2004-2005. The project is be structured as a twinning project with significant investment in equipment including specialist rapid disease diagnostic equipment and focused training input in critical veterinary sectors. In the limited timescale to acquis it is important to avoid too much in-built rigidity in the project and recognize the need for some flexibility as it is certain that the proposed activities and an ongoing gap analysis will identify some areas requiring additional support.
Two project components will focus on twinning and training, respectively investment and follow to:

- ***Creation of an Epidemiology Unit and disease surveillance network to serve the whole of the NSVA.***
- ***Sound strategic veterinary planning.***
- ***Safe animal byproducts and animal waste disposal.***
- ***Comprehensive Border Veterinary Inspection.***
- ***Improved laboratory services primarily at the IDAH national reference laboratory in carefully selected and designated Regional laboratories.***
- ***Sound disease contingency planning (List A and B diseases).***

Creation of an Epidemiology Unit and disease surveillance network:

- a dedicated Epidemiology Unit and disease surveillance network will be established to serve all the territory of Romania;
- the Unit will be within the IDAH and the team leader will have direct access to senior veterinary managers in the NSVA, to assist in strategic planning;
- the Unit will have the facilities, equipment and transport to initiate field epidemiological studies;
- the Unit will be linked to each section of the veterinary service centrally, regionally and at county level by e-mail, fax or telephone;
- the Unit will have established links with the veterinary faculties to obtain and exchange information;

- the Unit will be developed to internationally acceptable standards to carry out epidemiological planning, passive and active disease surveillance, data processing and reporting;
- the Unit will work closely with other national epidemiology units, EU, OIE and FAO.

Strategic veterinary planning:

- the NSVA will have a refined, prioritized, and long term budgeted strategic plan with phased inputs, objectives and targets leading to acquis with a sound epidemiological support base.

Animal by-products and animal waste disposal:

- the disposal of animal carcasses and animal waste will be accomplished to minimize risks to livestock and public health;
- the methods used will meet EU requirements as reflected in national legislation;
- these initiatives will underpin disease prevention and control of both List A and B diseases.

Border Veterinary Inspection and Import/Export:

- the information from border control will be linked into the epidemiological surveillance network;
- BIP laboratories will have the necessary equipment for sample submission and basic veterinary laboratory work.

Laboratory services:

- the High Security Laboratories at the IDAH will be secure and operational; security for BSE work will be developed (High Security Facility -Category III), and means for waste disposal installed. Investment from the project will be made in equipment. Reagents for sampling and testing in all the veterinary diagnostic laboratories is part of the laboratory services running cost. Veterinary technical support training in their use will be provided;
- the veterinary designated regional diagnostic laboratories will be in a position to meet their responsibilities for acquis and be more efficient and cost effective.

Disease contingency planning (List A and B diseases):

- disease contingency plans for the major List A diseases will be completed and publicized; they will be based on sound epidemiological principles;
- all veterinary and support staff will have completed a training course/seminars on disease contingency planning with a crucial epidemiological input.

3.4. Activities

Creation of an Epidemiology Unit and disease surveillance network:

- provision of suitable dedicated accommodation for this at the IDAH;
- provision of data processing equipment and IT networked to senior veterinary management in Head Office, Veterinary Institutes, regional laboratories and BIPs;
- overseas study training in epidemiological methodology for 10 veterinary officers, each for 2 months;
- development of national passive and active surveillance programmes with required inputs and outputs for national and international requirements;
- epidemiological support for disease contingency planning and prevention, control and eradication schemes;
- transfer of knowledge on epidemiological principles and methodology to national veterinary staff;
- provision by the twinning partner of expert epidemiological and IT support;
- investment in the IT network.

Training courses on a modular basis are being developed at the Regional Veterinary College London specifically for overseas students. Opportunities for practical experience could be available at the Veterinary Laboratory Agency Weybridge and the Communicable Disease Unit Colindale, London. Other opportunities will be identified and proposed in the expression of interests for twinning submitted by the Member States.

Strategic veterinary planning:

- veterinary support and advice on the development of strategic veterinary planning over the period to acquis based on sound epidemiological advice;
- provision of support by a senior experienced state veterinary manager.

Animal by-products and animal waste disposal:

- provision of veterinary support and advice on the EU demands regarding the animal by-products industry and the disposal of animal waste to complement the national disease control policies;
- support by a veterinarian experienced in animal byproducts disposal.

Border Veterinary Inspection and Import/Export:

- linking the BIP laboratories to designated regional laboratories the epidemiological surveillance network;
- linking epidemiological surveillance with the BIP information system;
- input by the epidemiological and IT experts.

Laboratory services:

- the assessment of the structure, equipment, procedures and methodology adopted in the new high security facility at the IDAH;
- preparation for approval by the EU of the facility as a Cat. III High Security Laboratory;
- provision for the containment of BSE;
- provision for safe laboratory waste disposal at the IDAH (Regional laboratories);
- veterinary technical training to maximize the use of equipment;
- provision of advice from a specialist in List A disease containment;
- implementation of an indepth review of veterinary diagnostic laboratory services by a veterinary laboratory expert and senior veterinary technical officer, as soon as possible;
- investment in waste disposal facilities, laboratory equipment and specimen sampling equipment.

The gap analysis in preparation by the Project Preparation Facility will also identify a need for a review of to diagnostic laboratories but, irrespective of the outcome, the strategy for selective improvement and support has already been determined by veterinary management. This is a sound decision compatible with EU policy demands and the future importance of Romania as an outlying member state.

Disease contingency planning (List A and B diseases):

- provision of epidemiological support and advice to the NSVA on disease contingency planning to meet EU demands;
- training in sound epidemiological principles;
- input by the epidemiological expert.

3.5. Learned lessons

In 2002 Regular Reports towards the progress made by Romania for Accession it was started that the Community Acquis on veterinary aspects was transposed but not implemented. So, it is necessary to continue harmonization of the Romanian sanitary-veterinary sector with the EU directives and regulations.

4. Institutional framework.

The project implementation agency is the CFCU, and the implementing authority is the National Sanitary Veterinary Agency within MAFF. The General Directorate for European Integration is responsible for the general coordination and implementation of PHARE assistance at the level of MAFF. The National Sanitary Veterinary Agency will be the principle responsible for the technical implementation of the project.

5. Detailed budget

	PHARE SUPORT					
	Investment support	Institution building	Total Phare (= I + IB)	National co-financing	IFI	Total
Twinning		1.2	1.2			1.2
IT and Laboratories equipment to include high security for work on TSEs, waste disposal, incineration and diagnostic equipment for IDAH.	2.8		2.8	0.93		3.73
TOTAL	2.8	1.2	4.0	0.93		4.93

6. Implementation Arrangements.

6.1. Implementing Agency.

CFCU – Ministry of Finance
36-38, Mendeleev Street, 4th Floor, Sector 1, Bucharest
Mrs. Jeana BUZDUGA
General Director

Implementing Authority
National Sanitary Veterinary Agency within the Ministry of Agriculture, Food and Forestry 24, Carol I Boulevard, Sector 3, Bucharest.
Ministry of Agriculture Food and Forests, Phare Program Implementing Unit (PIU) No. 17, Carol I Blvd., Sector 3, Bucharest.

6.2. Twinning

Procedures will follow those specified in the Twinning manual. The Romanian Project Coordinator is the Undesecretary of State in charge with the veterinary serviceswithin MAFF. The PAA Counterpart is the General Director of NSVA, MAFF.

Profile of the PAA.
The PAA will be a public officer. He/She must have experience in law enforcing systems, in the field of state veterinary medicine, preferably in epidemiology and EU requirements. One of the requirements refers to the ability to co-ordinate a team of experts as well as multi-functional activities.
He/She must be able to establish contacts with EU experts, with other sector organizations in the field and with the EU institutions in general. The Twinning project will have a duration of 20 months. The twinning is foreseen to start in July 2004 at the latest.
The Romanian partner will provide:

- adequate human resources to implement the twinning project together with the twinning partner;
- all the facilities that are necessary for the smooth implementation of the twinning (office, computer, printer, telephone, access to internet, etc.);
- funds to cover any travel costs of the Romanian authorities in the context of training seminars or study visits.

6.3. Non-standardised Aspects
Not applicable

6.4. Contracts

Within this Project, the following contracts will be signed:
Contract 1: Twinning Convention, with a value of 1.2 Meuro.
Contract 2: Acquisition of IT and laboratory equipment, with a total value of 2.8 MEuro at IDAH
The contracts will be concluded in compliance with the provisions of the Twinning Manual (for the twinning component) and with the Practical Guide Provisions (for the investment component).

7. Implementation Schedule.

7.1. Start of tendering/call for proposals
Februay 2004 or the date of signing of Financing Memorandum whichever is the first.

7.2. Start of project activity
August 2004.

7.3. Project completion
April 2006.

8. Equal opportunity.

The selection of the personnel who work in the project shall be based on the objective of his/her qualifications no matter the sex.

9. Environment.

Controls introduced in the disposal of animal waste will improve the environment and minimize the risk of transfer of pathogens from livestock and companion animals to wildlife.

10. Rate of return.

Not applicable

11. Investment criteria.

11.1. Co-financing.
Romanian authorities commit themselves from signing of the Financing Memorandum, to provide for the necessary co-financing funds in view of this project operation. Co-fiancing will consist of financing inparralel the necessary civil enageineering works to build up the facilities for TSE high containment unit, the work for installation of waste disposal. The works will start early enough as to allow the timely implementation of the Phare supply contract. By implementing the new veterinary legislation that transposes into Romanian legislation the specific Community legislation that has been already transposed (Directive 85/73/CEE with amendments), additional sums from taxes and tariffs from veterinary activities will be collected, which can be used for carrying out the specific activities of the project. Co-financing of IDAH for works will be 1.0 Meuro.

11.3. Additionality.
Not applicable.

11.4. Project readiness and size.
The National Sanitary Veterinary Agency as national authority and project beneficiary will elaborate all the technical analysis necessary for the support of the project contracting in correlation to the requirements related to the size of the project.

11.5. Sustainability.
The investments that are to be carried out as a result of the project have a long feasibility term, implicitly beyond the date of accession. Whereas these investments shall be carried out according with EU norms and standards, they shall ensure the adequate implementation of the Community acquis in direct correlation to the sector policies within the common agricultural policy. The investments that are to be carried out have no negative effects on the environment.
The results obtained by the implementation of this project will be continued and consolidated by supporting from the state budget some specific actions that ensure the maintenance and the operation of the implemented systems for a long period of time.

11.6. Compliance with the state aids provisions.
Not applicable.

11.7. Contribution to National Development Plan.
Not applicable.

12. Conditionality and sequencing.

12.1. Equipment acquisition is possible provided the provisions concerning the national co-financing are met.

12.2. Training activity is possible provided the personnel named for carrying out these activities are available.

Annexes to Project Fiche
1. Logical framework matrix in standard format.
2. Detailed implementation chart.
3. Contracting and disbursement schedule by quarter for full duration of programme.

Surveillance, prevention, diagnosis and control of animal diseases		**Contracting period expires: 30 November 2005**	**Disbursement period expiree: 30 November 2006**
		Total budget: 4.93 MEURO	**Phare budget: 4.0 MEURO**
Overall objective	**Indicators of Achievement**	**Sources of Information**	
? Alignment of Romanian technical capabilities and procedures used for surveillance, prevention, diagnosis and control of animal diseases with those of the EU. ? Enhancement at livestock production and protect human health in respect of the quality of food of animal origin and transmissible animal disease. ? Improved economic returns from livestock. ? Protection of EU member states from disease introduced into Romania.	? Establishment of the necessary measures to protect the health of livestock and human health in respect of zoonotic diseases. ? Improved methods of veterinary diagnosis, epidemiological surveillance and animal disease prevention, control and eradication in line with EU regulations. ? Internationally accepted standards results from diagnostic testing.	? National Program Adopting the Community Acquis. ? Accession Partnership. ? White Paper regarding the preparation of the Central and Eastern European countries for accession to EU ? Snagov Declaration. ? The Treaty establishing an association between the EU on the one hand and Romania on the other hand (The European Treaty). ? The Commission country reports from 1998, 1999, 2000, 2001, 2002. ? The European Commission Monitoring Report regarding the registered progress by associated third countries applied to accession to EU. ? National Strategic Programme for animal diseases surveillance, control and prophylaxis. ? Official Journal of Romania.	
Project purpose and activities	**Indicators of Achievements**	**Sources of Information**	**Assumptions**
<u>Epidemiology</u> ? To strengthen the National Sanitary Veterinary Service through capacity building in respect of epidemiology, disease surveillance, prevention and control of diseases with particular reference to List A and zoonotic diseases.	? A dedicated Epidemiology Unit and disease surveillance network will be established to serve all the territory of Romania.	? Bilateral screening activities. ?Instruction actions realized by TAIEX-European Commission with the veterinary staff of associated countries. ? EU and OIE Standard Operations Procedures and GLP practices introduced in Romanian legislation. ? NSVA reports regarding achievements in implementation of EU procedures in veterinary laboratory.	? Availability of governmental resources to establish the epidemiology unit and national surveillance network. ? The availability of staff for training and the retention of the trained staff in the areas to match their abilities.

Veterinary strategy ? To establish a dedicated epidemiology unit for epidemiological planning, and passive and active disease surveillance to serve all divisions in the NSVA. ? To support the development of disease contingency planning and training. ? Support for the development of a national veterinary strategy for Romania with specific goals, targets and priorities.	? The NSVA will have a refined, prioritized, and long term budgeted strategic plan with phased inputs, objectives and targets leading to acquis. ? Programmes will be in place to deal successfully with the most important List B diseases. ? Disease contingency plans for the major List A diseases will be completed and publicized, with appropriate epidemiological support.		
Animal waste disposal ? To review and advise on the measures necessary to meet the EU requirements for animal by-products and animal waste disposal. ? To provide the necessary investment to improve laboratory waste disposal.	? The disposal of animal carcasses and animal waste will be accomplished to minimize risks to livestock and public health.		
Disease security ? To provide secure containment of pathogens and diagnostic equipment.	? The High Security Laboratory at the NDAH Institute will be secure and operational; security for BSE work will be developed.		
Laboratory equipment ? To provide additional laboratory equipment.	? The veterinary laboratory diagnostic services will be more efficient, more cost effective and better able to meet the onerous demands placed on it by acquis.		

Results	Indicator of Achievements	Sources of Information	Assumptions
<u>Epidemiology</u> ? A dedicated epidemiology unit for epidemiological planning, and passive and active disease surveillance to serve all divisions in the NSVA will be established at the IDAH and epidemiological expertise increase in regions. ? The National Sanitary Veterinary Service through capacity building at all levels in respect of epidemiology, disease surveillance, prevention and control of diseases with particular reference to List A and zoonotic diseases will be strengthened.	? Suitable dedicated accommodation for the Unit, provided at the IDAH. ? Data processing equipment and IT networked to senior veterinary management in Head Office, Veterinary Institutes, regional laboratories and BIPs established. ? Overseas study training in epidemiological methodology for 10 veterinary officers completed. ? National passive and active surveillance programmes with required inputs and outputs for national and international requirements established. ? Epidemiological support for disease contingency planning and prevention, control and eradication schemes available and properly utilized. ? Transfer of knowledge on epidemiological principles and methodology to national veterinary staff accomplished. ? Epidemiological information will added to the data base.	? Training reports on staff involved in the project. ? Verified passive and active surveillance systems in operation. ? Quarterly reports by the Veterinary Epidemiological TA and IT experts. ? Partial and final reception notes for the acquisition of equipment. ? Quarterly reports and progress reports. ? Government/NSVA records of implementation and compliance. ? Industry returns and records. ? NSVA reports. ? Follow up inspections to establish progress in rectifying deficiencies. ? Monitoring of training of veterinary and support staff. ? Results of quality control exercises. ? Documentation on new facilities equipment and methodologies. ? Satisfactory intake of diagnostic specimens. ? Satisfactory reports from customers.	?Full support by the General Director of NSVA, Director of IDAH and other institutions. ? Appropriate placement of staff for overseas training. ? Identification of young receptive and ambitious trainees. Cooperation with international training centres and Community laboratories. Acceptance of the need for epidemiological surveillance by institutions and stakeholders in Romania. ? Full support by senior veterinary management. ? Adequate secretarial/translator support. ? Acceptance of the cost to government and the industry. ? Acceptance of the requirements by livestock owners. ? Provision of alternative safe methods for disposal. ? Establishment of the necessary cooperation between responsible sectors in the NSVA. ? Staff adequately trained in their responsibilities with clear job descriptions and written instructions. ? No defects in construction, operation or utilization. ? Full cooperation by IDAH staff. ? Development of proposals with are adequate, justifiable and cost effective. ? Prompt bidding procedures and allocation of contracts. ? Good cooperation by the NSVA senior management. ? Good cooperation by laboratory personnel. ? Provision of recent documentation on methodology and all other matters relating to laboratory activities.
<u>Veterinary strategy</u> ? The NVSA will have a refined, prioritized, and long term budgeted strategic plan with phased inputs, objectives and targets leading to acquis based on sound epidemiological principles.	? Good cooperation within the NSVA and with twinning input resulting in a fully satisfactory veterinary strategic plan and contingency plans for the service to achieve national targets and meet EU criteria.		
<u>Animal waste disposal</u> ? Animal and human health will be safeguarded by vigorous application of EU demands for the safe disposal of animal carcasses and animal waste.	? The methods eventually used will meet EU requirements. ? Such sources of risk for disease transmission will be eliminated. ? The safe disposal of laboratory waste materials.		

<u>Disease security</u> ? The security of the High Security Laboratory at the IDAH will be assured. Security for work on the animal. Transmissible Spongiform Encephalopathies (TSES) will be provided.	? High Security Laboratories safe, approved by the EU and commissioned for operation. ? Plans and facilities made for the maintenance of secure and safe working procedures on the animal TSES.		

Annex 2

Detailed TIME Implementation Chart for Project No.

	2004												2005												2006											
Calendar months	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Activities																																				
Twinning	D	D	D	C	C	C	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I	I										
Equipment Supply			D	D	D	C	C	C	C	I	I	I	I	I	I	I	I	I	I	I	I															
	D = Design C = Contracting I = Implementation																																			

ANNEX 3

CUMULATIVE CONTRACTING AND DISBURSEMENT SCHEDULE (MEURO).

Title: Strengthening the capacity to manage the veterinary acquis. Improvement of capabilities at central, regional and county level to enforce and observe the new harmonized norms.

	31/03/04	30/06/04	30/09/04	31/12/04	31/03/05	30/06/05	30/09/05	31/12/05	31/03/06	30/06/06	30/09/06	31/12/06
CONTRACTED	1.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
Twinning	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Laboratory equipment		2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8	2.8
DISBURSEMENT												
Twinning		0.1	0.2	0.3	0.5	0.7	0.8	0.9	1.1	1.2		
Laboratory equipment			1.7	2.8	2.8							