Standard Summary Project Fiche for the Transition Facility

Strengthening the institutional capacity of National Sanitary Veterinary and Food Safety Authority

1. Basic Information

1.1. CRIS Number: 2007/19343.02.01

RO /2007-IB/AG /01
RO /2007-IB/ AG /02

1.2. Title: **Strengthening the institutional capacity of National Sanitary Veterinary and Food Safety Authority**

1.3. Sector:

1.4. Location: Romania

2. Objectives

2.1. Overall Objective:

Strengthening the state veterinary control in the field of animal health, animal welfare, rendering and laboratory diagnostic system in accordance with the EU acquis

2.2. Project purpose:

The project purpose is to further strengthen the Romanian veterinary and food safety administration.

2.3. Justification

The current Facility Project aims to improve the implementation of the veterinary and food safety acquis taking into consideration the following FVO and European Commission recommendations.

In accordance with the veterinary and food safety acquis and the documents issued by the European Commission (Comprehensive Monitoring Report on the Romania 16th of May 2006 and Monitoring report on the state of preparedness for EU membership of Bulgaria and Romania from 26th of September 2006, peer review reports, **DG(SANCO)/8305/2006 Mission Report**) much remains to be done to ensure that Romania is in a position to operate Common Agricultural Policy and rural development support mechanisms, especially in sanitary veterinary field.

In the Romanian Government strategy for 2005 – 2008 it is clearly stipulated that, in the framework of improvement of the institutional capacities, the NSVFSA must be strengthened. In this context, the Government approved, at the beginning of 2006, the supplementation of the number of staff by the Government Emergency Ordinance no. 1/2006 regarding some measures for strengthening of the administrative capacities of Romania in the view of European Integration. Also, the Government post accession strategy for 2007-2013 stipulates as priorities on short term the necessity for increasing of the implementation process of the EU acquis in veterinary and food safety field. All gaps in the field are included in the

Priority Measures Plan, assumed by the Government, and monthly the stage is reported to the European Affairs Department.

3. Description

3.1. Background and justification:

For an efficient application of animal diseases surveillance and monitoring, the Romanian veterinary services act within their own organizational structure and in correlation with other existing structures in order to transpose and implement the EU legislative requirements on animal diseases into the Romanian legislation in a similar way as in EU. This continuous activity takes into consideration the concordance with the Community legislation laying down animal diseases surveillance and prevention rules, the specific measures aiming to protect animal and public health, as well as the aspects regarding import, export and transit of live animals, animal origin products, other products (cosmetics, drugs, raw materials used for the production of above mentioned products and certain medical instruments), medicated feeds, feedstuffs.

The application of control measures is achieved through the implementation of the National Contingency Plans for animal diseases. These programs enforces control measures in accordance with the Community provisions, enforces the endowment of Local Centres for Disease Control, increases the safety and protection level for the operators involved in applying of control measures, supports the Romanian authorities in the acquisition of necessary equipments and consumable materials used for eradication of disease outbreaks.

The present project is a continuation of the previous Phare projects, the objective being complementary, no overlap and duplication will occur due to the fact that under TF project new veterinary and food safety issues will be addressed like monitoring of animal by-products and implementation of rendering system, implementation of the "new hygiene package" legislation and elaboration and implementation of the national surveillance and monitoring plan of feed chain in the field of animal nutrition.

The stress will be laid on training of veterinary officers employed at the lowest administrative level and on drawing up and, where necessary improving, the strategies, programs and procedures need to be implemented in the field of veterinary and food safety sector.

Particular efforts are needed to improve the veterinary control system in the Internal Market and to strengthen the administrative structures for controls at the site of origin and non-discriminatory spot checks during transport and at destination, in accordance with the last last DG(SANCO)/8024/2006 Mission Report "*Country profile of Romania on food and feed safety, animal health, animal welfare and plant health*".

The new legislation on trade in live animals and animal products as well as on animal welfare needs to be further implemented. The DG(SANCO)/7746/2005 Mission Report mentions that further efforts are necessary in order to ensure effective inspections in the field of animal welfare.

The DG(SANCO)/8093/2006 mission report concludes that compliance with the requirements of the animal by products Regulation could not be ensured given deficiencies in the current hygiene, structural and operational conditions of the animal by products plants, and gaps in official controls along the animal by products chain.

The report makes a number of recommendations addressed to the Romanian competent authorities, aimed at rectifying the shortcomings identified and further enhancing the implementing and control measures in place.

The FVO report on rendering makes a number of recommendations addressed to the Romanian competent authorities, aimed at rectifying the shortcomings identified and further enhancing the implementing and control measures in place. In accordance with FVO recommendations "*At county and local level: The instructions and guidelines should be fully known by the inspectors and furthermore the documents. The Official Veterinarians at local and county level on their knowledge should know about the relevance of the controls of different animal by products when used for different purposes (they could not explain the purpose of such controls).The level of implementation of different issues (legislations, procedures, instructions, records) differed by counties and establishments and should be harmonized at the national level. The official controls should be carried out in a consistent manner as described in the Art.6 of Reg. (EC) No 882/2004. The CCA should be in the position to provide an overview of the animal by products chain and to ensure that all animal by products are collected, transported and identified as required in Art.3(1) of the animal by products Regulation. The procedure for certification should be correctly followed as required in Art 30 of Reg. (EC) No 882/2004 and therefore should avoid the diversion of animal by products into the food and feed chain. The Official controls on traceability should be carried out and the records should be used to verify the correct channeling of the different categories of animal by products and processed materials as required in Art.7 of the animal by products Regulation.*" Although some progresses have been done by the NSVFSA, this project aims to improve all these deficiencies in order to fulfill its task as new Member State.

In the field of animal identification, relations between the operator and the National Sanitary Veterinary and Food Safety Authority (NSVFSA) are not sufficiently streamlined to guarantee that the NSVFSA, as the competent authority, ensures effective management of the system. The system of identification of animals and registration of their movements had been set up.The bovine database is operational. The management of the database (IT system for animal registration) must be substantially improved which implies the reinforcement of the administrative capacity of the veterinary authorities. Correction of the errors is crucial for an operational database and also improvement of validation filters within the IT system for animal registration.The administrative capacity of the animal identification department must therefore be considerably strengthened, being a system that is accessible to all parts of the Agricultural Payments and Intervention Agency.

As regards animal disease control, a functional chain of command and rapid response of different structures to crises situation is still an issue to be addressed. Some steps forward were made by setting up National and Regional Crisis Centers according to European Union Rules but efforts are still necessary to make this structures functional.

As regards trade in live animals and animal products and animal disease control, Romania has submitted a global plan for monitoring, control and eradication of classical swine fever. However the overall monitoring and control capacities of the veterinary services should be considerably strengthened.

A number of controls on exports of equines have been performed in trade in live animals and animal products. However, preparations in this area still need to be stepped up. As regards public health, the implementation of the upgrading programme for the agri-food establishments is on-going. The number of "non-compliant establishments without an upgrading plan" has been considerably reduced. This is a sign of good progress and the current pace of upgrading should be maintained. Preparations should be stepped up to improve the management of the collection and treatment of non-compliant raw milk. The legislation on direct sales remains to be completed and further implemented.

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Taking into account that veterinary system is the support of the food safety, it was considered that the proposed twinnings are suitable for aligning the veterinary and food safety administration at EU rules and for technical assistance could be used private consultancy in order to develop some implementation procedures at national level.

According with the present form of Operational Programs of Structural and Cohesion Funds, as well as the Agriculture Funds for Romania the proposed project cannot be financed under the above mentioned funds.

3.2. Linked Activities

The activities in this project are linked and represent a continuation/strengthening of PHARE supported activities that have been performed in the past years, as follows:

The first project for Romanian veterinary and animal health was completed in 1996 (plans for reorganization and privatization of state veterinarians). More substantial allocations have been made from the 1998 Programme, comprising 0,55 MEuro for twinning on disease detection and control and a further allocation of 2,5 MEuro for essential investment in procurement of equipment to improve laboratory facilities, BIPs, TB diagnostic services and an animal identification system.

- Phare Programme RO 0006.11 –"Improvement and harmonisation of legislation and enforcement capabilities", that included: a Twinning Project RO2000/IB/AG-03-Improvement of capabilities at national and central level to enforce and observe the new and harmonised veterinary norms"; investment components for supply of equipment for veterinary laboratories and BIPs; a training project for the Romanian veterinary services.

- Phare Programme RO 0107.08 – Developing and implementing the nation-wide animal identification and registration systems that includes a TA component and Investments components for supply of eartags and IT equipment

-Phare Programme RO2002/000-586.04.06 – Surveillance, prevention, diagnosis and control of animal diseases and alignment with the acquis in the field of animal nutrition, that includes: a twinning component RO 02/IB/AG/01 and investment component for supply of ETS and molecular biology equipment

-Phare Programme 2003/005.551.04.02 – Strengthening the capacity to manage the veterinary acquis, including a Twinning component and investment components for supply of veterinary equipment

- Phare Programme RO 2004/IB/AG/14-"Support for strengthening the National Sanitary Veterinary and Food Safety Agency" – Twinning - This program is ongoing and the activities are:

- NSVFSA structure reinforced and able to fulfill its mandate as regards risk assessment/management/communication
- NSVFSA Scientific Council strengthened to provide the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission
- Authority's Risk Communication capacity strengthened
- Authority's capacity for risk analysis upgraded
- Permanent crisis team operational
- Implementation of TRACES and global IT strategy

- Phare Programme RO 2004/016-772.03.02 – "Strengthening the administrative capacity of the National Sanitary Veterinary and Food Safety Authority for the surveillance, prevention, diagnosis and control of avian influenza"

Supply component with the following results:

- Increasing the safety and protection level for the operators involved in applying the control measures for avian influenza
- Setting up a **stock of consumable materials and useful and prime necessity equipment** in order to apply the control measures for avian influenza

- Phare Programme RO 2005/17-553.03.02 – "Supply of IT and communication equipment for development and strengthening the Romanian NSVFSA for RASFF, TRACES" – Supply component that will provide specific IT equipments (computers, faxes, copy-machines, scanners) for NSVFSA, Institute for Hygiene and Veterinary Public Health and Institute for Veterinary Drugs and Biological Products

- Phare Programme RO 2005/017-553.03.02.16 – "Supply of equipment for the veterinary services - Border Inspection Posts" – Supply component - Functioning border inspection facilities (BIPs) to support import/export, for the 8 selected BIPs, through equipment purchasing (office furniture, incinerators, palets trucks, laboratory equipments, autolaboratories)

- Phare Programme RO 2005/017-553.03.02.18 - "Further supply of Kits (BioRad, TSE and Prionics Western)" – Supply component - The results of this program are:

- TSE surveillance fully in line with the EU acquis. The current surveillance network extended in the whole Romanian territory and for all the concerned species.
- Fast tests carried over in order to achieve an early, specific and fast TSE diagnosis
- Traceability assured for live animals in relation to their products, as regarding TSE
- Specific measures implemented on animal health protection against TSE, concerning the ruminants feeding, rendering and processing of the carcasses, collecting and processing of animals waste;
- Measures regarding public health protection implemented by setting up a labelling system for beef and veal meat, by eliminating specific risk materials, by eliminating the risk bovine offal, by prohibiting the mechanic recovery of bovine meat

Other donors:

The National Sanitary Veterinary and Foof Safety Authority received assistance from:

- World Bank through MAKIS Project for building a new facility for Institute for Hygiene and Veterinary Public Health and for three Border Inspection Posts and some small supplies. Some study visits and training of trainees will be performed in animal welfare field. *The Transition Facility Program will be a continuation of the these trainings and will be focused in principal on applying the Regulation 2005/1/EC.*

- World Bank through the project "*Avian influenza control and human pandemic preparedness and response project*" – Project ID P100470 - will receive technical assistance and some small supplies. The objective of the project is to increase preparedness to prevent and control the spread of bird flu among animals and humans and to prepare for, control, and respond to influenza pandemics and other infectious disease emergencies in humans. Beneficiaries of the project – Ministry of Health and NSVFSA. At this moment the Law for approval of this project is at the Parliament of Romania for comments and approval. The main results will focus on:

- Enhancing HPAI Prevention and Preparedness Capability
- Strengthening Disease Surveillance, Diagnostic Capacity and Virus Research

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❖ Strengthening HPAI Control Programs and Outbreak Containment Plans

❖ Improving Bio-security in Poultry Production and Trade

- FAO Program OSRO/ROM/501/GER – In line with the FAO/OIE Global strategy for the Progressive Control of HPAI, this project has been developed to provide additional support to Romania besides the one that is going to be provided under the Technical Cooperation Programme (TCP) "*Emergency Assistance for Early Detection and Prevention of Avian Influenza in the Region of Eastern Europe and Caucasus region*". The objective of the project is to enhance diagnostic ability fo the country to early detect and early respond to occurance of HPAI outbreaks so as to prevent mortality in poultry due to HPAI and the maintenance of the virus in the domestic poultry population. The project will contribute to this by improving National Veterinary Services capabilities to gain a better understanding of the impact and risks of AI and to plan and implement appropriate control and preventive measures. The project will also provide for technical input into contingency planning, emegency preparedness and laboratory diagnostic activity. Two trainings on avian influenza epidemiology in wild birds have been carried out (one in Tulcea and one in Bucharest) and some supplies for the county Sanitary Veterinary and Food Safety Laboratory in Tulcea have been provided (kits, pipettes, tips, a.s.o)

As regards the last two programs on avian influenza, the Transition Facility Program will be a completion by including aspects related with crisis management and problems occurred in slaughterhouses.

3.3. Results

Result 1: Further improving of the implementation and official control measures concerning animal by-products (ABP) and animal welfare rules

Result 2: The veterinary services capable to monitor, eradicate and control animal diseases

Result 3: TA for further improving the animal identification and registration system in Romania

Result 4: Supply of the equipment (laboratory equipment) for residues control

The project is expected to deliver the following sub results:

- Sub results for result 1:
  - 1.1 Compliance with the requirements of the animal by-products Regulation and developing the existing rendering, collection and treatment system for high-risk and low risk material from veterinary point of view, standardizing the veterinary system and not modifying the national strategy in this field
  - 1.2 Control procedures and methodology for the rendering system worked out, approved and disseminated to all veterinary officials in the territory;
  - 1.3 Control system in the animal welfare field fully operational;
- Sub results for result 2:
  - 2.1. The administrative structure able to manage the crisis produced by the new outbreaks.
  - 2.2. Training courses on control and eradication of infectious animal diseases. The participants, mainly veterinary officers, fully trained and ready to apply contingency plans, as well as EU and Romanian legislation in the field;

- Sub results for result 3:
  - 3.1.The animal identification database fully operational, able to serve the need of the veterinary services in surveillance and controlling of animal diseases,
- Sub results for result 4:
  - 4.1. Further supply of laboratory equipments for detection of residues of most of the unauthorized and authorized substances in accordance with the European Union legislation in the field, for effectively survey of residues in animal and non animal origin products and also live animals

3.4. Activities (including Means)

The project will be implemented through two Twinning Components, one Technical Assistance Component and one Supply Components as follows:

Result 1- *Twinning* - Further improving of the implementation and official control measures concerning animal by-products (ABP) and animal welfare rules

The purpose of this twinning project is to ensure a further support of veterinary administration in the field of rendering and animal welfare through completion of the measures for the achievement of control system in the animal welfare field, trainings for improving the existing control fiches, training of the veterinarians involved in the accomplishment of inspections. For rendering point of view, the purpose of the project is to assure that the measures put in place by NSVFSA for the handling of *animal by products,* give effect to EU rules on *animal by products non intended for human consumption* as laid down in Regulation 1774/2002 and additional EU legislation.

Activities for sub result 1.1.

1. Provision of support for developing procedures for manipulation, marking, storage, certification and destination of byproducts, alternative rendering methods, monitoring and reporting (42,925.00 Euro)

2. Provision of support for training the staff at central level in charge with the enforcement of the legislation in the field of rendering (82,025.00 Euro)

3. Provision of support for elaboration of guidelines for implementation of the Regulations amending the Reg. (EC) 1774/2002 (like Reg. 79/2005) and increasing of NSVFSA capacity to control the rendering system based on provisions of Reg. (EC) No 882/2004 (73,175.00 Euro)

Activities for sub result 1.2.

1. Organization of staff training at national and regional level in order to enable them to undertake their duties competently and to carry out official controls in an effective and consistent manner, as referred to in Art. 6 of Regulation (EC) No 882/2004 (74,875.00 Euro)

2. Training of regional and local veterinary administration regarding matters not developed satisfactorily in the field of animal by-products Regulation and developing the existing strategy for rendering, collection and treatment of high-risk and low risk material (80,925.00 Euro)

Activities for sub results 1.3.

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1. Provision of support for implementation of legislation, including the newly issued EU acquis in the field of animal welfare (like Regulation 1/2005) by improving the existing guidelines (18,625.00 Euro)

2. Provision of support for implementation of EU legislation for farm animals, especially for broilers (EC Directive no.2007/43/CE) (41,874.00 Euro)

3. Training courses for veterinary inspectors in the field of animal welfare (31,437.00 Euro)

The project will be implemented as a TW project with the duration of 12 months.

RTA Profile:

- The Resident Twinning Adviser should be a senior civil servant or having equivalent proven experience in EU in one of the Member States administration competent in rendering field.
- Confirmed communication capabilities and ability to work in a difficult environment are required.
- He/She should also have ability to manage a team of experts and co-ordinate highly complex and politically sensitive activities and to liaise with EU institutions and other donors.
- Fluent English is required.
- He/she will be responsible for all activities of the project.
- Familiarity with the Veterinary legislation in the EU Member States and its implementation practices will be an asset.
- Minimum 5 years of experience in veterinary field

A Medium Term Expert specialized in animal welfare and a pool of short-term experts will support the RTAs in performing daily activities. MTA and STEs Profile (as it is stipulated in the budget annex, there are forseen 33 STEs, but some different activities could be performed by the same expert):

- Knowledge and experience in veterinary field;
- Experience in preparing and delivering of training programmes for staff;
- Fluency in English (written and spoken);
- Computer literacy

Result 2 – *Twinning* - The veterinary services capable to monitor, eradicate and control animal diseases

The purpose of this twinning project is to improve the management of crises linked by evolution of infectious diseases like classical swine fever, bluetongue, foot and mouth disease, TSE.

Activities for sub results 2.1.

1. Provision of support for further implementing the EU legislation on animal diseases and EU Guidance in the field. (10,250.00 Euro)
2. Training on crisis management and methods of killing the animals in crisis situations (especially in classical swine fever, bluetongue, foot and mouth disease and TSE) (29,950.00 Euro)
3. Developing of strategy and guidelines for public awareness in crisis situations (18,100.00 Euro)

The project will be implemented as a TW project with the duration of 9 months.

RTA Profile:

- The Resident Twinning Adviser should be a senior civil servant or having equivalent proven experience in EU in one of the Member States administration competent in veterinary field.
- Confirmed communication capabilities and ability to work in a difficult environment are required.
- He/She should also have ability to manage a team of experts and co-ordinate highly complex and politically sensitive activities and to liaise with EU institutions and other donors.
- Fluent English is required.
- He/she will be responsible for all activities of the project.
- Familiarity with the Veterinary legislation in the EU Member States and its implementation practices will be an asset.
- Minimum 5 years of experience in veterinary field

STEs Profile (as it is stipulated in the budget annex, there are forseen 8 STEs, but some different activities could be performed by the same expert)

- Knowledge and experience in veterinary field;
- Experience in preparing and delivering of training programmes for staff;
- Fluency in English (written and spoken);
- Computer literacy.

Result 3 - *Technical Assistance* for further improving the animal identification and registration system in Romania.

The purpose of the contract will be technical assistance for the veterinary administration in the field of animal identification.

Activities for result 3 – 225,000 Euro:

- Elaboration of guidelines, procedures and reports for improving the I&R system through:
  - Improving of the Manual of procedures for correction of errors generated by the National System for Identification and Registration of Animals
  - Auditing and improvement of the National IT system for identification and registration of animals
  - Elaboration of the Manual regarding the quality of data and Guide for assuring the quality of IT system for identification and registration of animals

The project will be implemented as a Technical Assistance project with the duration of 6 months.

Key experts:

- 1 Expert in Veterinary field (identification and registration of animals) – 6 months, 18,750 Euro/month
- 1 Expert in IT field (identification and registration of animals) – 6 months, 18,750 Euro/month
- Lump sum + translation services – 11,000 Euro

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Total – 0.236 Mil. Euro

Key expert 1: Team Leader
Qualifications and skills

- University degree in veterinary field
- Fluency in English
- Knowledge of the relevant aquis

General professional experience

- Minimum 5 years of experience in veterinary field
- Proven ability to communicate with seniors decision-makers in the public sector and to get the cooperation of other institutions involved;
- Ability to communicate with in order to ensure interconnectivity with other projects related to this;
- Proven ability to transfer know-how;
- Proven abilities of manager in forming an appropriate team of short-term experts.

Specific professional experience

- Experience in implementation of EU acquis in the field of veterinary and food safety sector
- Expertise in identification and registration of animals

Key expert 2: Senior expert
Qualifications and skills

- University degree in IT
- Fluency in English
- Knowledge of the relevant aquis

General professional experience

- Minimum 5 years of experience as IT specialist in veterinary field
- Proven ability to communicate with seniors decision-makers in the public sector and to get the cooperation of other institutions involved;
- Ability to communicate with in order to ensure interconnectivity with other projects related to this;
- Proven ability to transfer know-how;

Specific professional experience

- Experience in developing/managing an IT structure for identification and registration of animals in accordance with EU legislation

Result 4: Supply of the equipment (laboratory equipment) for residue controls

Activities for result 4: Acquisition of laboratory equipments for sanitary veterinary system

The need comes directly from the recommendations of the *DG SANCO - FVO mission reports 7511/2005 and 8009/2006* the *„NSVFSA has to ensure, as a priority, that national laboratories are equipped with analytical instruments which are able to meet Community requirements and provide a timetable for the upgrading of these institutes. The NSVFSA has to develop and implement also appropriate screening and confirmation methods for all relevant analytes and to undertake full validation of existing and new methods in accordance with Commission Decision 2002/657/EC.The National Reference Laboratory for National Residue Control Plans should implement the confirmation methods for residues, especially*

group A substances. A lack of analytical instruments hinders the development of mandatory methods". (See annex 6)
The requested equipments will be delivered to Institute for Hygiene and Veterinary Public Health, Institute for Control of Biological Products and Veterinary Medicines and County Sanitary Veterinary and Food Safety Directorate in Bucharest (National Reference Laboratory for non-animal origin products). All premises have sufficient space to accommodate the equipments at their delivery. All possible arrangements and modifications required will be completed before delivery of the equipments in order not to delay the project implementation.

3.5. Lessons learned:

"See annex5"

4. Institutional Framework

In August 2003 the Romanian Agency for Food Safety was established according to the Government Ordinance No.90 (Aug. 28, 2003). In January 2004, the Government Ordinance No. 42/29.01.2004 reorganized the veterinary services with a unitary conception in the Veterinarian and Food Safety Agency which is set-up by the reorganization of the Food Safety Romanian Agency and Sanitary Veterinary National Agency. For its proper operation, the Veterinary and Food Safety Agency initiated a legislative document which determined the adoption by the Romanian Government of the Government Decision no. 308/11.03.2004, concerning the organization and the functioning of the Veterinary and Food Safety Agency (AVSA) and the subordinated units. The Agency is led by a President with the rank of State Secretary appointed through a decision of the Prime Minister.

Romanian Parliament, supporting the Government initiative to regulate and to align this field to the European Union requirements, has adopted the Law 215/2004 which provides that the Sanitary Veterinary and Food Safety Agency becomes the National Sanitary Veterinary and Food Safety Authority (NSVFSA), as the authority for settling in the sanitary veterinary and food safety fields, specialized organism of central public administration, with juridical personality, under Government subordination and the Minister of Agriculture coordination.

The Parliament authorized NSVFSA to be the contact structure with the European Food Safety Authority and to act based on functional and decisional autonomy according to the commitments assumed by Romania in international relations.

The entire structure of the National Sanitary Veterinary and Food Safety Authority coordinates the process of the specific institutional construction done in order to achieve the veterinary and food safety objectives, from the production of raw materials to the food distribution towards consumer.

Presently, the NSVFSA functions in accordance with the Government Decision no. 130/2006 concerning the organization and the functioning of the National Sanitary Veterinary and Food Safety Authority (NSVFSA) and the subordinated units.

NSVFSA is the regulatory authority in the veterinary and food safety field, public central administration specialised institution, with legal personality, under Government subordination, in Agriculture Minister's coordination. NSVFSA has responsabilities for the functioning of the whole single veterinary and food safety system (from technical point of view).

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Three national reference institutes are under subordination of National Sanitary Veterinary and Food Safety Authority: Institute for Diagnosis and animal Health, Institute for Hygiene and Veterinary Public Health and Institute for Control of Biological Products and Veterinary Medicinal Use Products.

For investment in laboratory equipments the beneficiaries will be the National Reference laboratories in Romania in veterinary and food safety field - Institute for Hygiene and Veterinary Public Health, Institute for Control of Biological Products and Veterinary Medicines and Bucharest Sanitary Veterinary and Food Safety Directorate

For the day-to-day implementation of the respective activities, close collaboration will be established with the directly concerned departments or institutes. The harmonisation of the national legislation with EU Regulations will be coordinated with the Director for the relevant Department and/or Institution and their legal adviser(s). Close co-operation will also be established with the Phare Implementation Unit (PIU) of the NSVFSA.

5. Detailed Budget

MEuro	Transition Facility Support			Co-financing			Total cost
	Investment	Institution Building	Total Transition Facility (=I+IB)	National Public Funds (*)	Other Sources (**)	Total cofinancing of the project	TF plus cofinancing
Project 01- Twinning	0.00	0.70	0.70	0.00	0.00	0.00	0.70
Project 01 *parallel confinanci ng*	0.00	0.00	0.00	0.03*	0.00	0.03*	0.03*
Project 02 - Twinning	0.00	0.306	0.306	0.00	0.00	0.00	0.306
Project 02 *parallel confinanci ng*	0.00	0.00	0.00	0.01*	0.00	0.01*	0.01*
Project 03 - Technical Assistance	0.00	0.236	0.236	0.00	0.00	0.00	0.236
Project 04 -Supply	1.8	0.00	1.8	0.6**	0.00	0.6**	2.4
Total	**1.8**	**1.242**	**3.042**	**0.64**	**0.00**	**0.64**	**3.682**

* *–parallel confinancing*
** *– joint cofinancing*

(*) contributions from National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises. All the co-financing is joint co-financing and will be provided from the state budget. The requested sum will be earmarked for the beneficiary institution in its budgetary appropriations for the year 2008-2009. In the case where the final overall cost is lower than foreseen in the project fiche, the national public and Transition Facility co-financing shall be reduced proportionally so as to maintain the agreed rate of co-financing.
(**) private funds, FIs loans to private entities

Contributions from the <country> administration for effective implementation of the twinning/twinning light/TA may be further detailed in the twinning contract/terms of references.

To ensure smooth implementation of the project, the beneficiary will provide adequately equipped office space with telephone, PC (Internet) and fax. Photocopier and access to the necessary information as well as secretarial support will be ensured during the project life-time. In addition the beneficiary will provide space and facilitites for workshops (training), consultations and seminars. The national co-financing will be specified in the twinning contract.

VAT is not an eligible expenditure under both the Transition Facility and national cofinancing funds indicated in the above budget table. Where contracts are subject to VAT due to provisions of national legislation, these funds have to be provided from national resource outside and in addition to the amounts indicated in the budget table.

6. Implementation Arrangements

6.1. Implementing Agency

The Implementing Agency is Central Finance and Contracts Unit (CFCU)/Ministry of Public Finance Mircea Voda blvd, no. 44, sector 3, Bucharest, Romania.
Contact person: Carmen Rosu, PAO
Phone: +40 21 326.55.55
Fax: +40 21 326.87.30
Email : carmenrosu@cfcu.ro

The CFCU will be the tendering and contracting authority and supervise the financial implementation of the entire project.

National Sanitary Veterinary and Food Safety Authority will be the principal responsible for the technical implementation of project. The beneficiaries of the projects will be National Sanitary Veterinary and Food Safety Authority, as well as the subordinated units.

The Implementing Authority for the project is the National Sanitary Veterinary and Food Safety Authority through the Phare Implementing Unit (PIU)/NSVFSA.

SPO: Mr. Razvan Tiru, Secretary General
Negustori, 1B, sector 2
Bucharest, Romania
Phone: +40 21 315 7875/107
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The PIU/NSVFSA will co-ordinate and administer the implementation of the proposed Transition Facility projects in Romania.

Steering Committee
A joint Steering Committee (SC) for each Twinning project will be established to oversee the project implementation and make the key strategic decisions concerning the project. Steering Committee will oversee the results of the projects, assure co-ordination between different projects and give comments to the project reports. The SC will meet once in a quarter. Twinning MS project leader will be involved to the Steering Committee proceedings.

6.2. Twinning

Twinning 1- Further improving of the implementation and official control measures concerning animal by-products (ABP) and animal welfare rules	1 contract
Twinning 2 - Further strengthening of the veterinary services capacity in order to monitor, eradicate and control animal diseases	1 contract

6.3. Non-standard aspects

The new Twinning manual will be strictly followed for twinning and for supply and technical assistance contracts National Procurement Rules will be applied.

6.4. Contracts

Twinning 1	1 contract	IB (TF 0.70 ME + cofinancing 0.03 ME)	0.73 Mil €
Twinning 2	1 contract	IB (TF 0.306 ME + cofinancing 0.01 ME)	0.316 Mil €
Technical Assistance	1 contract	IB	0.236 Mil €
Supply	1 tender	Supply	2.4 Mil €

7. Implementation Schedule

7.1. Start of tendering/call for proposals

January 2008

7.2. Start of project activity

March 2008

7.3. Project completion

November 2009

8. Sustainability

The National Sanitary Veterinary and Food Safety Authority and all subordinated units which benefit from the project have foreseen adequate staff and financial resources to maintain administrative function. Training of staff must be continued and experts must be encouraged to remain in the sector through provision of adequate financial packages and motivated working conditions.
Romanian Government will make available sufficient national resources in order to ensure the sustainability of the project's results. Sufficient funding has to be provided to national disease control and vaccination programmes and in case of epidemics to outbreak control.
User manuals and guidelines will enable to carry out further training, if needed. This will ensure the continuity of users: it w ill be easy to involve new users.

9. Conditionality and sequencing

The project will be sequenced as shown in the Detailed Implementation Chart for the project in Annex 2.
Any special preparatory work for the twinning components is not needed until the stage of selection of the twinning partners.

The key milestones in this project are:

- In case of twinnings
  - The appointment of Twinning Member State;
  - Commencement of Twinning;
  - Training programmes and materials prepared, training to the relevant staff delivered;

- In case of technical assistance

  - The appointment of experts for Technical Assistance;
  - Training programmes and materials prepared, training to the relevant staff delivered;
  - Operational monitoring programmes and working instructions available;

- In case of supply
  - Tender documentation for supply component prepared and approved;
  - Supply tender launched and contracts signed in time;
  - The equipment foreseen under supply tender delivered as planned

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 project (including disbursement period)
4. List of relevant Laws and Regulations
5. Lessons learnt from previous years
6. List of equipments
7. Detailed budgets
8. Needs assessment report

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Log frame
Transition Facility programme for Romania

LOGFRAME PLANNING MATRIX FOR Project Fiche		Programme name and number 2007/19343.02.01	
Title of the project **Strengthening the institutional capacity of National Sanitary Veterinary and Food Safety Authority**		Contracting period expires: 15.12 2009	Disbursement period expires: 15.12.2010
		Total budget : 3.682 mil Euro	TF budget : 3.042 mil Euro
Overall objective	**Relates to Copehagen criterion and acquis chapter**[1]	**List of other projects with same objective**	
Strengthening the state veterinary control in the field of animal health, animal welfare, rendering and laboratory diagnostic system in accordance with the EU acquis.	• In accordance with the documents issued by the European Commission (Comprehensive Monitoring Report on the Romania 16th of May and 26th of September 2006, peer review reports, DG SANCO - FVO mission reports), and also the last Interim Evaluation Report R/RO/AGR/0610, much remains to be done to ensure that Romania is in a position to operate Common Agricultural Policy and rural development support mechanisms, especially in sanitary veterinary field.	RO 0006.11 – "Strengthening the Romanian veterinarian administration capacity at central and regional level for harmonisation of the veterinary norms with the EU ones" RO 0107.08 – "Developing and implementing the nation-wide bovine animals identification and registration systems" RO 2002/000-586.04.06 – "Surveillance, diagnosis and control of animal diseases and alignment with the acquis in the animal nutrition field" RO2003/IB/AG/02 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 RO -2003/005- 551.04.02 - IT and laboratories equipment to include high security for works on TSEs, waste disposal, incineration and diagnostic equipment for IDAH RO 2004/IB/AG/14-"Support for strengthening the National Sanitary Veterinary and Food Safety Agency" RO 2004/016-772.03.02 – "Strengthening the administrative capacity of the National Sanitary Veterinary and Food Safety Authority for the surveillance, prevention, diagnosis and control of avian influenza" RO 2005/17-553.03.02 – "Supply of IT and communication equipment for development and strengthening the Romanian NSVFSA for RASFF, TRACES"	

[1] Please specify here the recommendation made in Comprehensive Monitoring Report or other relevant documents (SIGMA (financial control, procurement, Peer Reviews, Evaluation reports, Final reports of TW projects)

		RO 2005/017-553.03.02.16 – "Supply of equipment for the veterinary services - Border Inspection Posts" RO 2005/017-553.03.02.18 - "Further supply of Kits (BioRad, TSE and Prionics Western)"	
Project purpose **Purpose:** • Further strengthening the Romanian veterinary and food safety administration.	**Objectively verifiable indicators** • Institutional capacity of the Romanian veterinary administration improved by the end of the project; • Competency of the veterinary officers to implement EU regulations improved by the end of the project.	**Sources of Verification** Project progress reports, reports on special investigative research, project evaluation reports (intermediate and final). EC veterinary authorities' reports and regulations. Laboratory tests performed.	**Assumptions** Romanian Government continues to comply with the commitments taken during the negotiation process, by timely implementation of policies in the veterinary sector. Provision of adequate activities to ensure project sustainability after expiry of contract period Trained staff can be retained.
Results	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
Results fulfilling the overall purpose **Result 1**: Further improving of the implementation and official control measures concerning animal by-products (ABP) and animal welfare rules	- Competency of the veterinary services to implement and control the measures concerning animal by-pruducts and animal welfare	Project progress reports, reports on special investigative research, project evaluation reports (intermediate and final). EC veterinary authorities reports and regulations. Bulletins of analyse for laboratory tests performed.	Sufficient absorption capacity in the beneficiary institutions to effectively use project resources. Smooth process of

• **Sub results for result 1:** - 1.1.Compliance with the requirements of the animal by-products Regulation and developing the existing rendering, collection and treatment system for high-risk and low risk material from veterinary point of view, standardizing the veterinary system and not modifying the national strategy in this field - 1.2. Control procedures and methodology for the rendering system worked out, approved and disseminated to all veterinary officials in the territory - 1.3 Control system in the animal welfare field fully operational	OVI purpose - An appropriate veterinary rendering, collection and treatment system for high-risk and low risk material fully operational at the end of the project. - All animal by-products rendered, collected and treated in accordance with the EU legislation on high-risk material. - 100% veterinary inspectors in the field of rendering trained by the end of the project on the following subjects: applying of control procedures manuals, collection, manipulation, marking, storage, certification and destination of by-products alternative rendering methods of the territory, monitoring and reporting in the field of animal by-products - 100% veterinary inspectors in the field of animal welfare trained by the end of the project on the following subjects: farm animal welfare (all species), killing methods for control of diseases (all species), ways of stunning and blooding of animals for farm and backyard animals (all species).	Tests at the end of each training course and certificates for participation and graduation Reports after each simulation exercise	procedures concerning the tendering, contracting and implementation.
Result 2: The veterinary services capable to monitor, eradicate and control animal diseases	- Capacity of veterinary services to draw up programs of monitoring, eradication and control of animal diseases, including capacity of stamping out in case of outbreaks of classical swine fever, bluetongue, foot and mouth disease and TSE		
• **Sub results for result 2:** - 2.1. The administrative structure able to manage the crisis produced by the new outbreaks. - 2.2. Training courses on control and eradication of infectious animal diseases. The participants, mainly veterinary officers, fully trained and ready to apply contingency plans, as well as EU and Romanian legislation in the field;	- 100% veterinarians involved in crisis management trained in methods of animal killing in crisis situation and public awareness for classical swine fever, foot and mouth disease, bluetongue, TSE; - 4 trainings provided by the end of the project for the following diseases: classical swine fever, foot and mouth disease, bluetongue, TSE;		

Result 3: Further improving of veterinary services in the field of animal identification and registration system in Romania	- Operationality of animal identification and registration system		
Sub results for result 3: The animal identification database fully operational, able to serve the need of the veterinary services in surveillance and controlling of animal diseases	- An animal identification and registration database fully operational at the end of the project		
Result 4: Supply of the equipment (laboratory equipment) for residue controls	Laboratory analyses performed at EU standards		
• **Sub results for result 4:** Further supply of laboratory equipments for veterinary and food safety system	- 11 equipments purchased for detection of residues of most of the unauthorized and authorized substances in accordance with the European Union legislation in the field for effectively survey of residues in animal and non-animal origin products and also live animals		
Activities	**Means**		**Assumptions**
• **Activities for Result** 1: Activities for sub result 1.1. 1. Provision of support for developing procedures for manipulation, marking, storage, certification and destination of byproducts, alternative rendering methods and monitoring and reporting 2. Provision of support training the staff at central level in charge with the enforcement of the legislation in the field of rendering 3. Provision of support for elaboration of guidelines for implementation of the Regulations amending the Reg. (EC) 1774/2002 (like Reg. 79/2005) and increasing of capacity of NSVFSA to control the rendering system based on provisions of Reg. (EC) No 882/2004	Twinning		-TW partner adequately selected -Availability of RO staff to participate in project activities and in training -Commitment of NSVFSA staff -Trained staff kept within the organisation following training -Co-financing money assured in time

Activities for sub result 1.2. 1. Organization of staff training at national and regional level in order to enable them to undertake their duties competently and to carry out official controls in an effective and consistent manner, as referred to in Art. 6 of Regulation (EC) No 882/2004 2. Training of regional and local veterinary administration regarding matters not developed satisfactorily in the field of animal by-products Regulation and developing the existing strategy for rendering, collection and treatment of high-risk and low risk material Activities for sub results 1.3. 1. Provision of support for implementation of legislation, including the newly issued EU acquis in the field of animal welfare (like Regulation 1/2005) by improving the existing guidelines. 2. Provision of support for implementation of EU legislation for farm animals, especially for broilers (EC Directive no.2007/43/CE). 3. Training courses for veterinary inspectors in the field of animal welfare			
• **Activities for Result 2:** 1. Provision of support for further implementing the EU legislation on animal diseases and EU Guidance in the field. 2. Training on crisis management and	Twinning		

methods of killing the animals in crisis situations (especially in classical swine fever, bluetongue, foot and mouth disease and TSE) 3. Developing of strategy and guidelines for public awareness in crisis situations			
• **Activities for Result 3**: - Elaboration of guidelines, procedures and reports for improving the I&R system through: ➢ Improving of the Manual of procedures for correction of errors generated by the National System for Identification and Registration of Animals ➢ Auditing and improvement of the National IT system for identification and registration of animals ➢ Elaboration of the Manual regarding the quality of data and Guide for assuring the quality of IT system for identification and registration of animals	Technical Assistance		
• **Activities for Result 4**: Acquisition of laboratory equipments for sanitary veterinary system	Supply		

Annex 2 - Detailed time implementation chart

Adoption of the new statistical acquis communautaire provisions

	2007							2008												2009												2010											
calendar months	**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**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
activities																																										
Technical assistance				D	D	D	D	C	C	I	I	I	I	I	I																											
TW 1				D	D	D	D	D	D	C	C	C	C	C	I	I	I	I	I	I	I	I	I	I	I	I																	
TW 2						D	D	D	D	D	D	C	C	C	C	C	C	I	I	I	I	I	I	I	I																			
Supply				D	D	D	D	D	C	C	C	I	I	I	I	I	I	I																									
	D = Design **C = Contracting** **I = Implementation**																																									

Annex 3

Annex 3a - Cumulative contracting schedule

	31/03/07	30/06/07	30/09/07	31/12/07	31/03/08	30/06/08	30/09/08	31/12/08	31/03/09	30/06/09	30/09/09	31/12/09
CONTRACTED Twinning							0.70					
NB: *All contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of the FA.*												

Result 1 - Twinning - Further improving of the implementation and official control measures concerning animal by-products (ABP) and animal welfare rules

Annex 3b - Cumulative disbursement schedule

	31/03/07	30/06/07	30/09/07	31/12/07	31/03/08	30/06/08	30/09/08	31/12/08	31/03/09	30/06/09	30/09/09	31/12/09
DISBURSEMENT Twinning							**0.3**	**0.5**	**0.6**	**0.70**		
NB: *All disbursements must be completed within 36 months of signature of the FA.*												

Result 2 – *Twinning* - Further improving of the veterinary services capacity in order to monitor, eradicate and control animal diseases

Annex 3a - Cumulative contracting schedule

	31/03/07	30/06/07	30/09/07	31/12/07	31/03/08	30/06/08	30/09/08	31/12/08	31/03/09	30/06/09	30/09/09	31/12/09
CONTRACTED Twinning								0.306				
NB: *All contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of the FA.*												

Annex 3b - Cumulative disbursement schedule

	31/03/07	30/06/07	30/09/07	31/12/07	31/03/08	30/06/08	30/09/08	31/12/08	31/03/09	30/06/09	30/09/09	31/12/09
DISBURSEMENT Twinning								0.1	0.2	0.3	0.306	
NB: *All disbursements must be completed within 36 months of signature of the FA.*												

Result 3: *Technical Assistance* for further improving of veterinary services in the field of animal identification and registration system.

Annex 3a - Cumulative contracting schedule

	31/03/07	30/06/07	30/09/07	31/12/07	31/03/08	30/06/08	30/09/08	31/12/08	31/03/09	30/06/09	30/09/09	31/12/09
CONTRACTED TA					0.236							
NB: *All contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of the FA.*												

Annex 3b - Cumulative disbursement schedule

	31/03/07	30/06/07	30/09/07	31/12/07	31/03/08	30/06/08	30/09/08	31/12/08	31/03/09	30/06/09	30/09/09	31/12/09
DISBURSEMENT TA					0.1	0.236						
NB: *All disbursements must be completed within 36 months of signature of the FA.*												

Result 4: *Supply* of the equipment (laboratory equipment) for residue controls

Annex 3a - Cumulative contracting schedule

	31/03/07	30/06/07	30/09/07	31/12/07	31/03/08	30/06/08	30/09/08	31/12/08	31/03/09	30/06/09	30/09/09	31/12/09
CONTRACTED Supply						1.8						
NB: *All contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of the FA.*												

Annex 3b - Cumulative disbursement schedule

	31/03/07	30/06/07	30/09/07	31/12/07	31/03/08	30/06/08	30/09/08	31/12/08	31/03/09	30/06/09	30/09/09	31/12/09
DISBURSEMENT Supply						1.08	1.08	1.08				
NB: *All disbursements must be completed within 36 months of signature of the FA.*												

Annex 4 - Reference list of relevant laws and regulations

- ✓ Regulation (EC) No. 178/2002 of the European Parliament and of the Council dated 28 January 2002 laying down general principles and requirements of food law.
- ✓ Regulation (EC) no 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
- ✓ Regulation (EC) no 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs.
- ✓ Regulation (EC) no 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.
- ✓ Regulation (EC) no 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- ✓ Commission Decision 98/179/EC of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products.
- ✓ COUNCIL DIRECTIVE 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes
- ✓ COUNCIL DIRECTIVE 88/166/EEC of 7 March 1988 complying with the judgment of the Court of Justice in Case 131/86 (annulment of Council Directive 86/113/EEC of 25 March 1986 laying down minimum standards for the protection of laying hens kept in battery cages)
- ✓ COUNCIL DIRECTIVE 91/629/EEC of 19 November 1991 laying down minimum standards for the protection of calves
- ✓ COUNCIL DIRECTIVE 91/630/EEC of 19 November 1991 laying down minimum standards for the protection of pigs
- ✓ COUNCIL DIRECTIVE 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes
- ✓ COUNCIL DIRECTIVE 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing
- ✓ COUNCIL REGULATION (EC) No 1255/97 of 25 June 1997 concerning Community criteria for staging points and amending the route plan referred to in the Annex to Directive 91/628/EEC
- ✓ COUNCIL REGULATION (EC) No 411/98 of 16 February 1998 on additional animal protection standards applicable to road vehicles used for the carriage of livestock on journeys exceeding eight hours
- ✓ COUNCIL REGULATION (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97
- ✓ COUNCIL DECISION 88/306/EEC of 16 May 1988 on the conclusion of the European Convention for the Protection of Animals for Slaughter
- ✓ COMMISSION DECISION 2000/50/EC of 17 December 1999 concerning minimum requirements for the inspection of holdings on which animals are kept for farming purposes
- ✓ COUNCIL DIRECTIVE 80/1095/EEC of 11 November 1980 laying down conditions designed to render and keep the territory of the Community free from classical swine fever

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- ✓ Commission Decision 96/553/EC of 6 September 1996 laying down the rules for technical and scientific measures concerning the control of classical swine fever and the financial contribution from the Community
- ✓ Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever
- ✓ REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 October2002 laying down health rules concerning animal by-products not intended for human consumption (EC) No 1774/2002
- ✓ Commission Decision 92/562/EEC of 17 November 1992 on the approval of alternative heat treatment systems for processing high-risk material
- ✓ Regulation 999/2001/EC of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
- ✓ Commission Regulation of 12 May 2003 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council 81/2003/EC as regards the intra-species recycling ban for fish, the burial and burning of animal by-products and certain transitional measures
- ✓ Commission Regulation 813/2003/EC of 12 May 2003 on transitional measures Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards the collection, transport and disposal of former foodstuffs
- ✓ Commission Regulation 878/2004/EC of 29 April 2004 laying down transitional measures in accordance with Regulation (EC) No 1774/2002 for certain animal by-products classified as Category 1 and 2 materials and intended for technical purposes
- ✓ Commission Regulation 92/2005/EC of 19 January 2005 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards means of disposal or uses of animal by-products and amending its Annex VI as regards biogas transformation and processing of rendered fats
- ✓ Commission Regulation 197/2006/EC of 3 February 2006 on transitional measures under Regulation (EC) No 1774/2002 as regards the collection, transport, treatment, use and disposal of former foodstuffs
- ✓ Commission Directive of 3 September 1998 98/64/EC establishing Community methods of analysis for the determination of amino acids, crude oils and fats, and olaquindox in feedingstuffs and amending Directive 71/393/EEC
- ✓ COMMISSION DECISION of 10 July 1985 85/382/EEC prohibiting the use in feedingstuffs of protein products obtained from Candida yeasts cultivated on n-alkanes
- ✓ COUNCIL DIRECTIVE 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs
- ✓ COMMISSION DIRECTIVE 2000/45/EC of 6 July 2000 establishing Community methods of analysis for the determination of vitamin A, vitamin E and tryptophan in feedingstuffs
- ✓ COMMISSION DIRECTIVE 2002/27/EC of 13 March 2002 amending Directive 98/53/EC laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs
- ✓ Commission Directive 2003/121/EC of 15 December 2003 amending Directive 98/53/EC laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs
- ✓ COMMISSION DIRECTIVE 2003/126/EC of 23 December 2003 on the analytical method for the determination of constituents of animal origin for the official control of feedingstuffs
- ✓ COMMISSION DIRECTIVE 2004/43/EC of 13 April 2004 amending Directive 98/53/EC and Directive 2002/26/EC as regards sampling methods and methods of analysis for the

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official control of the levels of aflatoxin and ochratoxin A in food for infants and young children

- ✓ COMMISSION REGULATION (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
- ✓ COMMISSION DIRECTIVE 76/372/EEC of 1 March 1976 establishing Community methods of analysis for the official control of feedingstuffs
- ✓ EIGHT COMMISSION DIRECTIVE 78/633/EEC of 15 June 1978 Establishing Community methods of analysis for the official control of feedingstuffs
- ✓ COUNCIL DIRECTIVE 92/59/EEC of 29 June 1992 on general product safety
- ✓ TWELFTH COMMISSION DIRECTIVE 93/117/EC of 17 December 1993 establishing Community analysis methods for official control of feedingstuffs
- ✓ ELEVENTH COMMISSION DIRECTIVE 93/70/EEC of 28 July 1993 establishing Community analysis methods for official control of feedingstuffs
- ✓ COMMISSION DIRECTIVE 98/88/EC of 13 November 1998 establishing 'guidelines for the microscopic identification and estimation of constituents of animal origin for the official control of feedingstuffs
- ✓ COMMISSION DIRECTIVE 98/68/EC of 10 September 1998 laying down the standard document referred to in Article 9(1) of Council Directive 95/53/EC and certain rules for checks at the introduction into the Community of feedingstuffs from third countries
- ✓ COMMISSION DIRECTIVE 1999/27/EC of 20 April 1999 establishing Community methods of analysis for the determination of amprolium, diclazuril and carbadox in feedingstuffs and amending Directives 71/250/EEC, 73/46/EEC and repealing Directive 74/203/EEC
- ✓ COMMISSION DIRECTIVE 1999/76/EC of 23 July 1999 establishing a Community method of analysis for the determination of lasalocid sodium in feedingstuffs
- ✓ REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EC) No 183/2005 of 12 January 2005 laying down requirements for feed hygiene
- ✓ COUNCIL DIRECTIVE 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition
- ✓ COUNCIL DIRECTIVE 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermedi aries operating in the animal feed sector and amending Directives 70/524/EEC, 74/63/EEC, 79/373/EEC and 82/471/EEC
- ✓ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed
- ✓ Council Directive 90/167/EECof 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
- ✓ Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as amended.
- ✓ Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, as amended.
- ✓ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC, as amended.
- ✓ Commission Decision 89/153/EEC of 13 February 1989 concerning the correlation of samples taken for residue examination with animals and their farms of origin.

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- ✓ Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products.
- ✓ Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances as amended.
- ✓ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, as amended.
- ✓ Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC
- ✓ Regulation 2003/2169/EC of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents
- ✓ Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries, as amended.
- ✓ Council Directive 97/79/EC of 18 December 1997 amending Directives 71/118/EEC, 72/462/EEC, 85/73/EEC, 91/67/EEC, 91/492/EEC, 91/493/EEC, 92/45/EEC and 92/118/EEC as regards the organisation of veterinary checks on products entering the Community from third countries.
- ✓ Council directive 77/98/EEC of 21 December 1976 amending Directives 64/432/EEC, 72/461/EEC and 72/462/EEC on health and veterinary problems, as amended.
- ✓ Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption.
- ✓ 2001/471/EC: Commission Decision of 8 June 2001 laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultry meat, as amended.
- ✓ Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC, as amended.
- ✓ Council Directive 97/78/EC application of the EC procedure concerning the veterinary checks on products entering the Community from Third Countries;
- ✓ Commission Regulation (EC) No 136/2004 of 22 January 2004 laying down procedures for veterinary checks at Community border inspection posts on products imported from third countries;
- ✓ Commission Regulation (EC) No 745/2004 of 16 April 2004 laying down measures with regard to imports of products of animal origin for personal consumption;
- ✓ Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals;
- ✓ Commission Decision 2002/134 laying down the list of products to be examined at border inspection posts under Council Directive 97/78/EC
- ✓ Commission Decision 2003/279 amending Commission Decision 93/13/EEC in respect of the certificate of veterinary checks on products from third countries
- ✓ Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods of sampling for the official control of feedingstuffs

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- ✓ Council Directive 96/25 on the circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC
- ✓ Council Directive 2005/94/CE of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC
- ✓ Regulation 1760/2000/CE of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97 Regulation of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97
- ✓ Commission Regulation 1082/2003/CE of 23 June 2003 laying down detailed rules for the implementation of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the minimum level of controls to be carried out in the framework of the system for the identification and registration of bovine animals
- ✓ Commission Regulation 911/2004/EC of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards eartags, passports and holding registers
- ✓ Commission Regulation 494/1998/EC of 27 February 1998 laying down detailed rules for the implementation of Council Regulation (EC) No 820/97/EC as regards the application of minimum administrative sanctions in the framework of the system for the identification and registration of bovine animals
- ✓ Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals
- ✓ Council Regulation 21/2004/EC of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC
- ✓ Commission Decision 2000/678/EC of 23 October 2000 laying down detailed rules for registration of holdings in national databases for porcine animals as foreseen by Council Directive 64/432/EEC
- ✓ Commission Decision 2006/80/EC of 1 February 2006 granting certain Member States the derogation provided for in Article 3(2) of Council Directive 92/102/EEC on the identification and registration of animals
- ✓ Council Decision 90/424/CEE of 26 June 1990 on expenditure in the veterinary field
- ✓ Commission Decision 450/2004/CE of 29 April 2004 laying down standard requirements for the content of applications for Community financing for programmes for the eradication, monitoring and control of animal diseases

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Annex 5 - Lessons learnt from previous years

Note to the attention of the Head of PIU

Identified Gaps or Recommended courses of intervention	*Action for covering the Gap or implement the recommended intervention*	*Phare Programming (Project Reference) 2004-2006*		*Transition Facility*[4]
- Limited developments in the field of TSE (transmissible spongiform encephalopathies) and **animal by-products**[21] - Further efforts are necessary in order to ensure effective inspections in the field of **animal welfare** (transport inspections)[1]	- Training of veterinary administration regarding matters not developed satisfactorily in the field of animal by-products Regulation and developing the appropriate strategy for rendering, collection and treatment of high-risk material - Training of veterinary officers in control systems in the animal welfare field		RO 2005/017-553.03.02.18 – "Further supply of Kits (BioRad, TSE and Prionics Western" – Supply RO/05/IB/AG/01 –"Twinning for further strengthening and development of the veterinary services in compliance with the EU requirements" – *component for establishment of a Rendering Board and some connected activities*	**"Twinning** *for further improving the implementation and official control measures concerning animal by-products (ABP) and animal welfare rules"* *"Further* ***supply*** *of kits for TSE"*
- NSVFSA has to commit all the efforts in order to improve the surveillance plans of **avian influenza** by a better clarification of poultry monitoring and testing methods used[1]	- Training courses and simulation exercises concerning control and eradication of avian influenza.	RO 2004/016-772.03.02 – "Strengthening the administrative capacity of the National Sanitary Veterinary and Food Safety Authority for the surveillance,		**"Twinning light** *for further strengthening of the veterinary services capacity in order to control Avian Influenza"*

[2] Source: Comprehensive Monitoring Reports on the Romania 16th of May and 26th of September, Interim Evaluation Report R/Ro/AGR/0610, DG(SANCO)/7746/2005 Mission Report, DG(SANCO)/8093/2006 Mission Report, DG(SANCO)/8305/2006 Mission Report, RO2003/IB/AG/02 Twinning Program Report, DG(SANCO)/8075/2006 Mission Report, DG(SANCO)/8024/2006 Mission Report "*Country profile of Romania on food and feed safety, animal health, animal welfare and plant health*"

		prevention, diagnosis and control of avian influenza" - *Supply*		
- The administrative capacity of the **animal identification** department must be considerably strengthened and there are no sufficiently guarantees that the NSVFSA, as competent authority, ensures effective management of the system[1]	- Supplementing Authorithy's organizational scheme.[2] - Elaboration of guidelines, procedures and reports for improving the I&R (identification and registration) system	-	-	**"Technical assistance** *for further strengthening of the animal identification and registration system in Romania"*
- The new legislation on trade in live animals and animal products as well as on **animal welfare** needs to be further implemented.[1]	- Elaboration of a national strategy in order to reduce the delays in animal transport and creation of facilities for animals during transport		RO/05/IB/AG/01 –"Twinning for further strengthening and development of the veterinary services in compliance with the EU requirements" – *component for welfare at slaughter and of laboratory animals and establishing licensing system for transporters*	**"Technical assistance** *for developing the strategy for strengthening the animal welfare system during transport"*
- NSVFSA, as central authority for surveillance of **animal health status**, has to be able to cooperate with the National Agency for Protected Areas in the area of **nature protection** establishing a network for surveillance and monitoring of ecotoxicological risk factors in relation with animal health[1].	- Training of staff for performing analysis and establishing animal health status in polluted areas analysing the link between the health status of animals and the safety of animal origin products in these specific areas	-	-	**"Twinning light** *for strengthening the institutional capacity regarding surveillance and monitoring of ecotoxicological risk factors in relation with animal health"*
- As regards **animal disease control**, a functional chain of command and rapid response of different structures to crises	- Training veterinary officers in organizing simulation exercises and also drawing up programs and procedures for monitoring and	-	-	**"*Twinning light*** *for strengthening the capacity of the Veterinary Task Force*

[2] The action will be financed from the state budget.

situation is still an issue to be addressed. - NSVFSA has to be able to submit to the European Commission applications for financial contribution from the Community Veterinary Fund for **programmes for the eradication, monitoring and control of animal diseases** in accordance with the Council Decision 90/424/CE and Commission Decision 2004/450/CE provisions[1]	controlling of diseases			*Group in order to draw up of programs of monitoring, eradication and control of animal diseases, including zoonosis, and organize simulation exercises for controling of epidemics"*
- Preparations should be stepped up to improve the management of the collection and treatment of **non-compliant raw milk**. The legislation on **direct sales** remains to be completed and further implemented[1].	- Elaborating procedures and guidelines for implementation of the legislation stipulated in the "new hygiene package"		RO/05/IB/AG/01 –"Twinning for further strengthening and development of the veterinary services in compliance with the EU requirements" – *component for explanation of some aspects of the new Hygiene Package and discussion of implementation in Romania*	***"Technical Assistance** for improving of legislation and elaboration of the procedures for implementation of the EU "new hygiene package" in the field of direct sales and wild and farmed game sector"*
- Regarding the **residues** in animals and animal origin products it is necessary to elaborate a risk analysis in order to draw up the National Residue Control Plan (NRCP) and to implement the measures of this Program (the measures of surveillance and control of certain substances and their residues in live animals and their products, the veterinary drugs residues in animal origin products) taking into consideration the future position of Romania as Member State.	- Elaborating of risk analysis and the National Residue Control Plan (NRCP) with implementation procedures		RO/05/IB/AG/01 –"Twinning for further strengthening and development of the veterinary services in compliance with the EU requirements" – *component for training staff in some laboratory methods on residues*	***"Technical Assistance** for elaborating of a risk analysis in order to draw up the National Residue Control Plan (NRCP) and implementation procedures"*
- The control system for **animal**	- Training for improving the	-	RO/05/IB/AG/01 –"Twinning	***"TA** for elaboration and*

nutrition needs further improvement in order to meet food and feed safety requirements. Preparations need to be accelerated in this field.[1]	know-how concerning feedingstuff safety		for further strengthening and development of the veterinary services in compliance with the EU requirements" – *component for explanation of animal control plan and training of staff in analytical and sampling methods*	*implementation of the procedures for the national control plan of feed chain in the field of animal nutrition*"
- **Laboratory equipments** are not sufficient in residue fields. A lack of analytical instruments hinders the development of mandatory methods.[1] - Lack of adequate and sufficient working space at NSVFSA, due to the recent increase of the staff number that imply the acquisition of a new building from the state budget and **office equipments** through Phare budget	- Acquisition of office and laboratory equipments for sanitary veterinary system - Acquisition of new building for NSVFSA[2]	-	-	"***Supply*** *of the equipment (office and laboratory equipment) for further strenghtening of NSVFSA*"

Annex 6

Item	Quantity	Indicative cost (Euro)	Beneficiary
Gas Chromatograph/Mass Spectrometer (GC-MS)	2	400,000	1 - Institute for Hygiene and Veterinary Public Health 1- County Sanitary Veterinary and Food Safety Directorate in Bucharest
Liquid Cromatograph/Mass Spectrometer with UV/APCI detectors (LC-UV-APCI-MS)	2	400,000	1 - Institute for Hygiene and Veterinary Public Health 1- County Sanitary Veterinary and Food Safety Directorate in Bucharest
Gas Chromatograph/Mass Spectrometer (GC-MS)/EI	2	400,000	1 - Institute for Hygiene and Veterinary Public Health 1- County Sanitary Veterinary and Food Safety Directorate in Bucharest
Liquid Cromatograph/Mass Spectrometer/MSD	2	400,000	1 - Institute for Hygiene and Veterinary Public Health 1- County Sanitary Veterinary and Food Safety Directorate in Bucharest
Liquid Cromatograph/Mass Spectrometer	2	400,000	1 - Institute for Hygiene and Veterinary Public Health 1- County Sanitary Veterinary and Food Safety Directorate in Bucharest
HPLC/MS-MS System	1	400,000	Institute for Control of Biological Products and Veterinary Medicines
Total		**2,400,000**	

The above mentioned equipments will be used for the following laboratory methods:

Gas Chromatograph/Mass Spectrometer (GC-MS):

- Determination of 3-monochloro-1,2 propanediol from soy sauce
- Confirmation of 17 β-estradiol from bovine serum
- Analysis of zearenol and metabolites from urine, bile, meat, liver and kidney
- Determination of leucomalachit green from fishes
- Confirmation of pesticides residues from fruits and vegetables

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- Residues of stilbenes and derivates – A1 Group (Directive 96/23/CEE and Regulation 2377/1990)

Liquid Cromatograph/Mass Spectrometer with UV/APCI detectors (LC-UV-APCI-MS)

- Quantitative determination of dexamethasone in bovine milk
- Determination of zearelone in milk
- Residues of thyreostatic substances – A2 Group (Directive 96/23/CEE and Regulation 2377/1990)

Gas Chromatograph/Mass Spectrometer (GC-MS)/EI

- Confirmation of hormone residues
- Determination of dioxins in animal origin products
- Determination of residues of steroids - A3 Group Gas Chromatograph/Mass Spectrometer (GC-MS)/EI

Liquid Cromatograph/Mass Spectrometer/MSD

- Determination of residues of mercaptobenzimidazol and other thyreostatic residues from meat and thyroidal tissues
- Determination of NSAIDS – Non steroidal anti inflammatory drugs (B2e Group) in liver, kidney and muscles in bovines and pigs
- Confirmation of nitrofurans in animal origin products
- Determination of residues of trembolon – A3 Group (Directive 96/23/CEE and Regulation 2377/1990)

Liquid Cromatograph/Mass Spectrometer

- Determination of malachit green in muscles (colorants)
- Determination of residues of B2e Group substances

HPLC/MS-MS System

- Control of veterinary medicines and products quality as well as performing the time stability studies of these, establishing of the metabolization routes, pharmacokinetics and elimination of residues from tissues. The microclimatiozation system will ensure an uniform microclimate in microbiology laboratories.

TECHNICAL SPECIFICATIONS

GAS CHROMATOGRAPH - MASS SPECTROMETER GC/MS

Specifications:

1.Gas chromatograph

a). Gas chromatograph

- Local control and by software;
- Column oven
- Temperature hold precision: +/- 0,1 °C;

b). Injector split/splitless.

- Able to work in split or splitless mode;
- Electronic flow /pressure control;

2. Mass Spectrometer MS/MS Detector

- Triple quadrupole detection assembly;
- Collision cell: 180° curved path with pre- and post-filter region; long path ensures high dissociation efficiency;
- Ionization modes: Electron Ionization (EI) and Positive/Negative Chemical Ionization (PCI, NCI) (selected by the user);
- Capable of working in SIM System and full scan;
- Capable of working to MS/MS;
- **Scan speed :**
- **20 scans/second from m/z 100-3000**
- **40 scans/second from m/z 100-1000**
- Resolution: greater than 13000 measured at m/z 2722
- Ionization source by electron impact with a filament and adjustable current between 50 and 950 µA
- Ion detector: positive or negative ions
- Sensibility:

Greater than 10:1 signal-to-noise (peak to peak) at the (M+H) ion at m/z 609.2807 for injection of reserpine

3. Autosampler

- Adjustable injection volume: 0,1 - 10 µl;
- Capacity: minimum 100 vials of 2 ml;
- Programmable injection volume and injection number/vial;

4. CONTROL, ACQUISITION AND DATA PROCESSING SYSTEM

- PC: Pentium IV 3GHz, HDD 80 GB, 512 MB RM, CD-RW, DVD, display LCD 19", mouse, keyboard, 3.5 "floppy;
- Operation system: Windows XP Profesional (licenced);
- A4 printer;
- Spectra library: final NIST version (licenced);

Spectra library final version
Installation kit
Capillary columns (2 pieces)

GAS CHROMATOGRAPH - MASS SPECTROMETER GC/MS/EI

1. Specifications: Gas chromatograph

a). Gas chromatograph

- Local control and by software;
- Column oven:
  - temperature-programmed ramps: 7 ramps with 8 isothermal holds;

b). Injector split/splitless.

- Able to work in split or splitless mode;
- Electronic flow /pressure control;

2. Mass Spectrometer MS/MS Detector

- Triple quadrupole detection assembly;
- Collision cell: 180° curved path with pre- and post-filter region; long path ensures high dissociation efficiency;
- Ionization modes: Electron Ionization (EI) and Positive/Negative Chemical Ionization (PCI, NCI) (selected by the user);
- Capable of working in SIM System and full scan;

- Capable of working to MS/MS;
- Sensibility:
- EI mode full scan: 1 pg octafluoronaphtalene to a signal noise ratio (S/N) of minimum 20;
- EI SIM : 50 fg octafluoronaphtalene to a signal noise ratio (S/N) of minimum 10: 1;
- EI MS/MS: 100 fg octafluoronaphtalene to a signal noise ratio (S/N) of minimum 10: 1
- PCI mode FULL SCAN: 20 pg benzofphenona to a signal noise ratio (S/N) of minimum 10:1
- NCI SIM mode: 5 fg octafluoronaphtalene to a signal noise ratio (S/N) of minimum 10:1;
- PCI mode, MS/MS mode: 100 fg Benzophenone to a signal noise ratio (S/M) of minimum 10:1 RSM

3. Autosampler

- Adjustable injection volume: 0,1 - 10 µl;
- Capacity: minimum 100 vials of 2 ml;
- Programmable injection volume and injection number/vial;

4. CONTROL, ACQUISITION AND DATA PROCESSING SYSTEM

- PC: Pentium IV 3GHz, HDD 80 GB, 512 MB RM, CD-RW, DVD, display LCD 19", mouse, keyboard, 3.5 "floppy;
- Operation system: Windows XP Profesional (licenced);
- A4 printer;
- Software for complete control of the system.
- Spectra library: final NIST version (licenced);

Spectra library final version
Installation kit
Capillary columns (2 pieces)

HPLC/MS/MS SYSTEM

The MS/MS shall be a compact, benchtop, triple quadrupole MS/MS mass spectrometer configured for API LC-MS/MS. Its dimensions are only 880mm x 390mmx 550mm and shall comprises of the following components:

Z-Flow API SOURCE

-Dual orthogonal off-axis source geometry.
Atmospheric pressure ionisation (API) HPLC interface that includes the source and spraying elements. These are visible through the windowed source enclosure and the source elements may be easily removed for cleaning, without breaking vacuum. The nebulized spray is positioned vertically, with the sprayer orientated orthogonally and positioned off axis for maximum source longevity and analyser protection against 'dirty' samples. Positive and negative capability is included. All source voltages are under data system control.
4-Way Mux Option
Cleaning without braking vacuum. Isolation valve shall provide short term MS system stabilization (less then 1h).

QUADRUPOLE ANALYSER

High performance tandem quadrupole analyser of QHQ (Quadrupole-Hexapole-Quadrupole) geometry with inter-element beam focusing and a mass range of 2-2000 amu. The analyser includes the following:
-two high resolution, quadrupole analysers (MS1/MS2).
-pre-filters to maximise resolution and transmission especially at high mass and also to eliminate main filter cleaning.
-two solid state RF generators with 3KV peak-to-peak maximum output.

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COLLISION CELL
High efficiency, hexapole collision cell with beam focusing at cell entry/exit. The collision cell gas pressure is directly monitored in the range 1x10-4 to 1 mbar. Collision gas introduction and pumpout are computer controlled.

DETECTOR
An off-axis photomultiplier tube detector positioned after the second mass analyser. A 5 kV conversion dynode and a 10kV phosphor are positioned at 90° to the analyser for the elimination of neutral noise. The photomultiplier is enclosed in its own vacuum envelope for long life. The detector operates in both positive and negative ion modes and can switch rapidly under software digital control.

VACUUM SYSTEM
Clean, differentially pumped, automated vacuum system comprising:
-an air-cooled turbomolecular pump evacuating both the source & analyser, eliminating the need for water chillers.
-an rotary pump for backing of the turbo pump.
Vacuum read backs and system vent/pump cycles are digitally monitored and controlled, to provide total software control and ensure fail-safe operation in the event of power failure. The source turbo pump is fitted with an electromagnetic vent valve and a Pirani gauge is fitted to the collision cell for gas pressure monitoring.

ADDITIONAL FEATURES
Additional items comprising the MS/MS are:
-electronic mass flow meters for the desolvation gas and cone gas under software control.
-electronic injector valve controllable from the instrument software or the front panel. The injector valve can be also be programmed from software to function as a divert valve.
-an integral syringe pump controlled from software with a flow rate of 1-1000 microlitres/ minute, capable of accepting a wide variety of syringe sizes.
-scan speed 5000amu/sec.
-mass drift 0.2Da in 24hrs.

INSTRUMENT CONTROL AND DATA PROCESSING ARCHITECTURE

All functions relating to instrument control, data acquisition and diagnostic system surveillance are performed by an embedded PC. Post acquisition processing, general data manipulation and networking are carried out by a computer workstation.

a) Scan functions
MS scanning.
MS selected ion recording.
MS-MS precursors (parents).
MS-MS products (daughters).
MS-MS neutral loss/gain.
MS-MS multiple reaction monitoring.

b) Acquisition functions.
Profile data acquisition.
Multi Channel Analysis (MCA) data acquisition.
Centroided data acquisition.
Noise rejection.

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MS to MS-MS scan function switching.
Data Dependent Switching
The instrument has the facility for data dependent acquisitions whereby the instrument automatically switches into MS/MS mode during an acquisition based upon data acquired in MS mode in the previous scan. If any ion is found above a user-defined threshold in an MS survey scan, the instrument immediately switches to acquire a product ion spectrum for that ion. Specific target masses or mass ranges may be selected for switching, or unwanted masses may be excluded. The duration of MS/MS acquisition may be determined by either the signal intensity or by a user-defined switching time. This function allows product ion data to be acquired without prior knowledge of the sample composition or constituent retention times.
Ionisation mode switching.
Digital dynamic range of 4 e6
Multiplet separation.
Total ion current monitoring.
Base peak monitoring.
HPLC control
HPLC Autosampler control
Analogue input: Interfacing of up to 4 ancillary LC detectors (UV, RI, etc.) to datasystem.

- External contact start/stop/events.

Multitasking suite of analytical applications and instrument management software. Includes:
Licence for second Data processing terminal
Microsoft Windows NT operating system, featuring graphical user interface with multiple windows, pull down menus and toolbars.
3-D contour plotting.
Spectral library search facilities (user defined or commercial libraries).
Quantitation software for HPLC analysis

d) Tuning Utilities.
Fully software supported instrument tuning via interactive graphics display window allowing control of:

MS and MS/MS switching.
Ionisation mode and polarity.
MS and MS/MS acquisition.
All ion source parameters.
All lens voltages.
MS1 resolution.
MS2 resolution.
MS1 ion energy.
MS2 ion energy.
Dynamic scanning of collision cell energy and key lens voltages.

Fully software supported autotuning facilities including:.

Autotuning for Electrospray & APcI (in positive and negative ion modes).
Automatic calibration routines.

Data System
The data system shall be a true 32-bit software package designed for Windows NT systems in freestanding or network environments.
The data system shall be Year 2000 compliant.

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The software shall allow the setting of security levels so that only certain operations can be performed by a given user i.e. chemist vs. technician etc. Task level customization by menu selections shall control edit, delete, process, report and acquire functions as well as instrument access, project access and system configurations.
No macros shall be required to set up files, etc. No third party software shall be required. The software shall contain its own spreadsheet complete with custom field and calculation capability.
The software shall allow the formatting of custom reports to meet the users requirements. No importing and exporting from Access, Excel etc. the PDA software shall allow the diode array to be used as either a UV/VIS or a PDA without any loss in sensitivity and save data storage space when routine UV analysis is required.

SENSITIVITY PERFORMANCE SPECIFICATIONS

- Sensitivity, Positive Ion

Measured signal/noise ratio obtained from the chromatogram monitoring the transition m/z 609 - m/z 195 on injection of 10pg (16fmol) of Reserpine will be ≥ 20:1, using 10ul injection of a 1pg/µl Reserpine solution, in 50/50 acetonitrile/water (no additives) at a flow rate of 200µl/min, in MRM mode, 1 second dwell, 0Da Span. The resolution of the ion at m/z 609 will be <1Da peak width at half height (MS1 and MS2)

- Sensitivity, Negative Ion

The signal/noise ratio measured on the [M-H]- peak at m/z 503 from a sample consumption of 10ng Raffinose will be ≥ 100:1. A solution of 5ng/µl Raffinose in 50/50 acetonitrile/water (no additives) will be introduced at a flow rate of 10µl/min and the summation of two 6 second scans over the mass range m/z 100-600 will represents a total sample consumption of 10ng.

- Resolution

Demonstrated using a 1µg/µl solution of PPG 2000 in 50/50 acetonitrile/water containing 1mMolar ammonium acetate. The peaks at m/z 2009.5 and 2010.5 should be resolved with a valley between them which is no more than 15% of the height of the 2010.5 peak. It is recommended that 15 one second scans are summed and the resulting spectrum smoothed (2 passes, 0.5Da SG).

- Mass Measurement Accuracy

Measured from the mean of five repeat analyses of the $[M+NH_4]^+$ peak at m/z 1004.622 from PEG 1000 in 50/50 acetonitrile/water containing 2mMolar ammonium acetate The mean measured mass will be 1004.622±0.05Da. The Standard Deviation of the Mean will be ≤ 0.05Da.
A mass calibration will be performed using the $[M+H]^+$ peaks from a separate analysis over the mass range m/z 700-1300 and the resolution on the $[M+H]^+$ peak at m/z 1031.62 must be between 0.3 and 0.4Da wide at half height after smoothing.

APcI SPECIFICATIONS

- **Sensitivity, Positive Ion**

Measured signal/noise ratio obtained from the mass chromatogram of m/z 609 in SIR mode on direct injection of 10pg (16fmol) Reserpine (10µl injection of a 1pg/µl solution) at a flow a rate of 1ml/min will be ≥ 10:1.

LIQUID CHOMATOGRAPH WITH MASS SPECTROMETER LC/MS

1. Solvent delivery system

Quaternary pump, gradient programmable;
Local control and through LCGCMS software

Max. operating pressure: min. 410 atm.;

Automatic sample introduction system - Autosampler

Programmable injection volume: 1 - 5000 µl;
Injection precision:
< 0,3 % RSD for volumes > 100 µl;
< 0,5 % RSD for volumes 10 - 100 µl;
< 1,0 % RSD for volumes < 10 µl;
Capacity: at least 50 1.5 mL vials,
Injection volume and injection number programmable/vial;

Column oven

Temperature range between 5°C above ambiant to 90°C;
Temperature precision +/- 1 °C;

MASS SPECTROMETER DETECTOR

Triple quadrupole with MS/MS possibilities;
180 ° curved collision cell with pre- and post-filters
Electrospray interface (ESI) for LCMS;
Positive and negative atmospheric pressure chemical ionization interface for LCMS;
Mass range: at **least 50-12000 m/z**
Resolution: grater than 13000 measured at m/z 2722
Maximum scan rate: at least 5000 AMU/sec.
Stability: +/- 0,1 Da over at least 24 hours
Possibilities of working with positive and negative polarities for the same run

electrospray interface (ESI)

pump flow rate: 1 – 1000 µl/min;
needle voltage: 6 kV;

Vacuum system: two stages turbomolecular 330/245 L/sec pump; air-cooled and two fore-pumps.

With syringe pump and drive valve

Seringe volum 100 µL – 10 mL;
Flow rate: 0.5 – 10 mL/min;
Performance:
in ESI SIM mode a signal/noise ration > 10:1 for 500 fg Reserpine;
in ESI MS/MS mode a signal/noise ratio > 20:1 for 500 fg Reserpine;
up gradable to GC/MS/MS.

Data acquisition, control and processing system

PC originally configured (Brand name) with the following configuration:
software for the LC/MS system control, data acquisition and processing, world-wide recognized, licensed and validated:

Nitrogen generator

Nitrogen purity: at least 99,5 % (or the purity requested by the MS system)
Oxygen content: maximum 0,5 % (or the content requested by the MS system)

Accessories:

columns;
connection and tubing for the system installation and putting into operation.

LIQUID CHOMATOGRAPH WITH MASS SPECTROMETER LC/MS/MSD

Solvent delivery system

Quaternary pump, gradient programmable;
Local control and through LCGCMS software

Flow rate range: min. 0,01 - 10 ml/minut;

Automatic sample introduction system - Autosampler

Programmable injection volume: 1 - 5000 µl;
Injection precision:
< 0,3 % RSD for volumes > 100 µl;
< 0,5 % RSD for volumes 10 - 100 µl;
< 1,0 % RSD for volumes < 10 µl;

Column oven

Temperature range between 5°C above ambiant to 90°C;
The oven must be compatible with 25 cm lenght columns;

MASS SPECTROMETER DETECTOR

Triple quadrupole with MS/MS possibilities;
180 ° curved collision cell with pre- and post-filters
Electrospray interface (ESI) for LCMS;
Positive and negative atmospheric pressure chemical ionization interface (APCI) for LCMS;
Capable of working: Selective Ion Monitoring (SIM) mode and full scan mode, , Precurson scan, Poduct scan, Neutral loss scan, Selective reactive Monitoring;
Capable of working to MS/MS;
Ion detector: positive or negative ions, constant 5 kV post acceleration voltage
High Efficiency Electron Multiplier – 300 ms Pos/Neg Switching time

Electrospray interface (ESI)

pump flow rate: 1 – 1000 µl/min;
needle voltage: 6 kV;
nebulising gas flow rate: up to 2 L/min;
capillary voltage: at least until 800 V;

Negative and positive atmospheric pressure chemical ionization (APCI):

Flow rate: 100 – 2000 µl/min;
Nebulising gas flow: up to 2 L/min;

Vacuum system: two stages turbomolecular 330/245 L/sec pump; air-cooled and two fore-pumps.

With syringe pump and drive valve

Seringe volum 100 µL – 10 mL;
Flow rate: 0.5 – 10 mL/min;
Performance:
in ESI SIM mode a signal/noise ration > 10:1 for 500 fg Reserpine;
in ESI MS/MS mode a signal/noise ratio > 20:1 for 500 fg Reserpine;
up gradable to GC/MS/MS.

Data acquisition, control and processing system

PC originally configured (Brand name) with the following configuration:
Windows XP Professional operation system (licensed);
A4 deskjet color printer;
software for the LC/MS system control, data acquisition and processing, world-wide recognized, licensed and validated:

Nitrogen generator

Nitrogen purity: at least 99,5 % (or the purity requested by the MS system)
Oxygen content: maximum 0,5 % (or the content requested by the MS system)
Nitrogen flow: minimum flow request by the MS system

Accessories:

columns;
connection and tubing for the system installation and putting into operation.

LIQUID CHOMATOGRAPH WITH MASS SPECTROMETER LC/MS/UV/APCI

Solvent delivery system
Quaternary pump, gradient programmable;
Local control and through LCGCMS software
Flow rate range: min. 0,01 - 10 ml/minut;
Automatic sample introduction system - Autosampler
Programmable injection volume: 1 - 5000 µl;
Injection precision:
< 0,3 % RSD for volumes > 100 µl;
< 0,5 % RSD for volumes 10 - 100 µl;
< 1,0 % RSD for volumes < 10 µl;
Column oven
Temperature range between 5°C above ambiant to 90°C;
The oven must be compatible with 25 cm lenght columns;
MASS SPECTROMETER DETECTOR
Triple quadrupole with MS/MS possibilities;
180 ° curved collision cell with pre- and post-filters
Electrospray interface (ESI) for LCMS;
Positive and negative atmospheric pressure chemical ionization interface (APCI) for LCMS;
Capable of working: Selective Ion Monitoring (SIM) mode and full scan mode, , Precurson scan, Poduct scan, Neutral loss scan, Selective reactive Monitoring;
Capable of working to MS/MS;
Ion detector: positive or negative ions, constant 5 kV post acceleration voltage
High Efficiency Electron Multiplier – 300 ms Pos/Neg Switching time
Electrospray interface (ESI)
pump flow rate: 1 – 1000 µl/min;
needle voltage: 6 kV;
nebulising gas flow rate: up to 2 L/min;
capillary voltage: at least until 800 V;
Negative and positive atmospheric pressure chemical ionization (APCI):
Flow rate: 100 – 2000 µl/min;
Nebulising gas flow: up to 2 L/min;
Vacuum system: two stages turbomolecular 330/245 L/sec pump; air-cooled and two fore-pumps.
With syringe pump and drive valve
Seringe volum 100 µL – 10 mL;
Flow rate: 0.5 – 10 mL/min;
Performance:
in ESI SIM mode a signal/noise ration > 10:1 for 500 fg Reserpine;
in ESI MS/MS mode a signal/noise ratio > 20:1 for 500 fg Reserpine;
up gradable to GC/MS/MS.
Data acquisition, control and processing system
PC originally configured (Brand name) with the following configuration:
Windows XP Professional operation system (licensed);
A4 deskjet color printer;
software for the LC/MS system control, data acquisition and processing, world-wide recognized, licensed and validated:
Nitrogen generator
Nitrogen purity: at least 99,5 % (or the purity requested by the MS system)
Oxygen content: maximum 0,5 % (or the content requested by the MS system)

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Nitrogen flow: minimum flow request by the MS system

Accessories:

columns;

connection and tubing for the system installation and putting into operation.

Twinning 1

N°	Actions to be undetrtaken under the twinning project	Responsibility		COST			
		RO	MS	Unit Cost	No of Units	Total MS Cost	BC cofinancing
1.	RTA Remuneration						
	Total RTA Remuneration					93.979	
2.	RTA Allowances						
	Total RTA Allowances					79.935	
3.	RTA Training						
	Total RTA Training					1.002	
4.	RTA Assistant						
	Total RTA Assistant costs					24.000	
5.	Project Preparation						
	Total Project Preparation costs					3.750	
6.	Project coordination costs						
	Total project coordination costs					34.400	
7.	Logistic						
	Total logistics						21.000
8.	Project Activities						
	Component 1 - Compliance with the requirements of the animal by-products Regulation and developing the appropriate rendering, collection and treatment system for high-risk material						
1.1	Provision of support for further implementation of legislation, including the newly issued EU acquis in the field of rendering by developing procedures for manipulation, marking, storage, certification and destination of byproducts, alternative rendering methods, monitoring and reporting						
	Total Activity 1.1			W/D	31,0	42.925	
1.2	Provision of support training the staff at central level in charge with the enforcement of the legislation in the field of rendering						
	Total Activity 1.2			W/D	55,0	82.025	3.000,0
1.3	Provision of support for elaboration of guidelines for implementation the Regulations amending the Reg. (EC) 1774/2002 (like Reg 79/2005) and increasing of NSVFSA capacity to control the rendering system based on provisions of Reg. (EC) No 882/2004						
	Total Activity 1.3			W/D	55,0	73.175	
1.4	Organization of staff training at national and regional level in order to enable them to undertake their duties competently and to carry out official controls in an effective and consistent manner, as referred to in Art. 6 of Regulation (EC) No 882/2004						
	Total Activity 1.4			W/D	45,0	74.875	3.000,0
1.5	Training of regional and local veterinary administration regarding matters not developed satisfactorily in the field of animal by-products Regulation and developing the existing strategy for rendering, collection and treatment of high-risk and low risk material						
	Total Activity 1.5			W/D	65,0	80.925	
	Component 2 – An efficient control system in the animal welfare field						
2.1	Provision of support for implementation of legislation, including the newly issued EU acquis in the field of animal welfare (like Reg. 1/2005) by improving the existing guidelines						
	Total Activity 2.1			W/D	15,0	18.625	
2.2	Provision of support for elaboration of national legislation for farm animals not covered by the existing EU legislation (for example: bovine, sheep, rabbits, ducks, turkeys, ostrich and so on)						

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	Total Activity 2.2			W/D	30,0	41.874	
2.3	**Training courses for veterinary inspectors in the field of animal welfare**						
	Total Activity 2.3			W/D	30,0	31.437	3.000,0
	TOTAL COMPONENT 2					**91.936**	**3.000,0**
	Project Sub-Total					**682.927**	
	Provision for changes in prices (2,5% of total budget)					**17.073**	
	PROJECT TOTAL					**700.000**	**30.000**

Twinning 2

ANNEX 4

BUDGET TEMPLATE: BREAKDOWN OF COSTS

N°	Actions to be undetrtaken under the twinning project	Responsibility		COST			
		RO	MS	Unit Cost	No of Units	Total MS Cost	BC cofinancing
1.	**RTA Remuneration**						
	Total RTA Remuneration					**70.484**	
2.	**RTA Allowances**						
	Total RTA Allowances					**102.315**	
3.	**RTA Training**						
	Total RTA Training					**802**	
4.	**RTA Assistant**						
	Total RTA Assistant costs					**18.000**	
5.	**Project Preparation**						
	Total Project Preparation costs					**3.150**	
6.	**Project coordination costs**						
	Total project coordination costs					**45.525**	
7.	**Logistic**						
	Total logistic						**9.000**
8.	**Project Activities**						
	Component 1 - Strengthening the administrative capacity in order to manage the crisis produced by the new outbreaks!						
1.1	**Provision of support for further implementing the EU legislation on animal diseases and EU Guidance in the field**						
	Total Activity 1.1			W/D	10,0	10.250	
1.2	**Training on crisis management and methods of killing the animals in crisis situations (especially in classical swine fever, bluetongue, foot and mouth diseases and TSE)**						
	Total Activity 1.2			W/D	30,0	29.950	1.000,0
1.3	**Developing of strategy and guidelines for public awareness in crisis situations**						
	Total Activity 1.3			W/D	20,0	18.100	
	Project Sub-Total					**298.576**	
	Provision for changes in prices (2,5% of total budget)					**7.464**	
	PROJECT TOTAL					**306.040**	**10.000**

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Technical Assistance

TECHNICAL ASSISTANCE BUDGET - DRAFT

1. TEAM COMPOSITION					
Name of the expert	**Position**	**Availability**	**Costs/month (Euro)** *(including accomodation, salary and all other payments)*	**Number of months**	**TOTAL PRICE (Euro)**
1. Expert 1	Expert in Veterinary field (identification and registration of animals)	80%	18,750.00*	6	112,500.00
3. Expert 1	Expert in IT field (identification and registration of animals)	80%	18,750.00	6	112,500.00
TOTAL OF FEES					**225.000**

2. REIMBURSABLE COSTS IN € (3)			
	Quantity	**Unit Price**	**TOTAL PRICE**
Services (translation, interpretation etc)	1x6 months	1000	6,000.00
Lump sum			5,000.00
TOTAL OF REIMBURSABLE COSTS (2)			**11,000.00**
GRAND TOTAL (3)			**236.000**

*** 750 Eurox21days=15,750 Euro - salary**
1500 Euro/month - accommodation
1500 Euro/month - other payments like health and accident insurance, per diem during local travel, local travel, travel to and from place of duty by plane

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