Standard Summary Project Fiche

1. Basic Information

1.1 CRIS Number: 2004/016-925-01-02

Twinning: LT/2004/AG/02

1.2.Title: Food safety (phase II) — Official control of veterinary medicinal products and feedingstuffs

1.3.Sector: Agriculture

1.4. Location: State Food and Veterinary Service and related institutions.

2. Objectives

2.1. Overall objective:

The overall objective of this **0.969 MEUR** project, of which **0.089 MEUR** is provided as national co-financing, is to ensure safety of food through control of the safety and quality of feed products and veterinary medicinal products in accordance with the EU *acquis.*

2.2. Project purposes:

With a view to ensuring consumer safety through the safety of food, to warrant safety, quality and efficacy of veterinary medicinal products in the Republic of Lithuania and safety and quality of feedingstuffs used in the feeding of animals, the project purposes are the following.

- To strengthen administrative and technical capacities of Lithuanian State Inspection on Veterinary Preparations.
- To enhance professional capacity of the staff in laboratory and statistical survey of data.
- To enhance professional capacity of the responsible staff in the field of control of feed products and veterinary medicinal products.

2.3. Justification

Draft monitoring report on the implementation of commitments made in the accession negotiations stressed that:
Lithuanian State Inspection on Veterinary Preparations (LSIVP) should be strengthened for control of veterinary medicinal products (according to CONF-LT 59/00, p. 15). Its activity is also related to ensure implementation of Good Manufacturing Practice (according to CONF-LT 14/01) and *Acquis* for authorisation of veterinary medicinal products in the Republic of Lithuania (CONF-LT 14/01, p. 5). Marketing authorisations of veterinary medicinal products to be renewed and dossiers for registration to be supplemented by 1 January 2007. Review of dossiers for registration to be performed from 1 January 2004. Further improvement of control of veterinary medicinal products to continue in 2003. The State Inspection on Veterinary Preparation is being strengthened. An improvement of the control of feed ban related to the TSEs and animal by-products (according to CONF-LT 5/02 add6) is foreseen.

Comprehensive monitoring report on Lithuania's preparations for membership underlined:
Transposition of pharmaceuticals legislation has been completed with the exception of the *acquis* on good manufacturing practice. Further improvement is needed in the area of inspection, post-marketing control, pharmacovigilance and supervision of advertising of medicinal products. In the course of the accession negotiations, Lithuania has been granted a transitional period relating to the renewal of marketing authorisations for pharmaceutical products until the end of 2006.
The establishment of the veterinary control system in the internal market is not completed.
The *Acquis* for animal nutrition has been transposed but further work is required for the practical implementation of the legislation. Further efforts will be needed in this field to build up the capacity of the inspection and control bodies. In particular, co-operation and agreement between these bodies in the implementation of feed legislation should be further developed and enhanced.

3. Description

3.1. Background and justification:

The State Food and Veterinary Service of the Republic of Lithuania is an independent budgetary institution under the Government of the Republic of Lithuania. The main tasks of the State Food and Veterinary Service are to ensure consumer safety through the safety of food, to warrant safety, quality and efficacy of veterinary medicinal products in the Republic of Lithuania and safety and quality of feedingstuffs used in the feeding of animals.

The State Food and Veterinary Service of the Republic of Lithuania introduces and implements strict requirements on animal health and on quality, effectiveness and safety of veterinary medicinal products and feedingstuffs according the EU legislation. Main manufacturing, distribution and use of veterinary medicinal products and feedingstuffs control executor in Lithuania is Lithuanian State Inspection on Veterinary Preparations. LSIVP is a subdivision of the State Food and Veterinary Service.

LSIVP is responsible for the control of manufacturing, distribution and use of veterinary medicinal products and feedingstuffs. The main task of LSIVP is to warrant safety, quality and efficacy of veterinary medicinal products in the Republic of Lithuania and safety and quality of feedingstuffs used in the feeding of animals. Certain range of persons in charge from regional State Food and Veterinary Services are involved in performing of some tasks of LSIVP. LSIVP is going to perform control of the quality of veterinary medicinal products both produced in Lithuania and imported from third countries. For that purpose it is a great need to strengthen the Centre for quality control of biological and other veterinary medicinal products. For the proper work of laboratory it is necessary to install an appropriate filtration system to ensure clean flow of air.

For valuable and purposive realisation of functions and in order to ensure irreproachable activity of LSIVP it is necessary to provide all indispensable equipment and appropriately train the staff.

The legislation on official feed controls is based on Council Directive 95/53/EC. Article 2(1) of this Directive requires Member States to check compliance with the:
— Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs,

— Council Directive 1999/29/EC of 22 April 1999 on undesirable substances and products in animal nutrition,
— Council Directive 96/25/EC of 29 April 1996 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 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs,
— Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition,
— Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes — any other rules in the field of animal nutrition.

To comply with these provisions, it is obligatory to take samples of feedingstuffs and analyse them for checking compliance with the above mentioned legislation. Different types of analyses are possible, by selecting the feedingstuffs and the substances, on the basis of risk analysis among those in the following list, which are considered as a priority at a given moment:

- Undesirable substances: heavy metals, dioxins, pesticides, mycotoxins, seeds and fruits of some plants, other elements and ions (fluorine, nitrites).
- Composition of feedingstuffs (feed materials, compound feedingstuffs, pre-mixtures, feed additives and bioproteins): several macro and micronutrients.
- Authorised feed additives: antimicrobial agents, technological additives (preservatives, antioxidants, emulsifiers, stabilisers, thickeners, gelling agents, binders, substances for the control of radionuclide contamination, anticaking agents, acidity regulators, silage additives, denaturants); sensory additives (colourants, flavouring compounds); nutritional additives (vitamins, trace elements, aminoacids); zootechnical additives (digestibility enhancers, gut flora stabilisers / micro-organisms, etc.).

In addition, it is recommended that every year Member States implement a recommendation for a co-ordinated inspection programme in the field of animal nutrition, where some other types of checks may be requested, such as:

- Constituents of animal origin.
- Unauthorised feed additives.

The activities of LSIVP are planned in connection with MRLs monitoring, control and inspection of manufactures, distributors and veterinary medicinal products and feedingstuffs users, pharmacovigilance plans and in cooperation with regional State Food and Veterinary Services in order to provide actions in case of claims.

The staff of LSIVP was given training on different subjects. The EMEA and TAIEX organized these trainings. However, such trainings should be permanent and annually repeated to increase the level of knowledge.

The Mission of Quality Management (Quality Management Benchmarking Visit, 25-26 August, 2003) initiated by the EMEA indicated to improve quality management system of the institution by planning of training on internal quality audit, reconsideration of fee payment system, improving the documentation system according to good documentation practice and consideration about destruction of physical samples.

Until now there were Phare projects for other veterinary fields: strengthening of border veterinary control, upgrading of food control and animal health diagnostic laboratories, etc. This project is exclusively dedicated for strengthening of state control of feed products and veterinary medicinal products.

3.2. Linked activities:

Bilateral assistance

There were no any bilateral projects to strengthen LSIVP.

Phare

There were no any Phare projects dedicated for strengthening of state control of feed products and veterinary medicinal products.

3.3. Results

- Training programmes prepared, staff adequately trained and re-trained on control of feed products and veterinary medicinal products and the competence of the staff increased;
- Evaluation and analysis of the current control system done and recommendations prepared;
- Analysis of working documents completed and detailed working instructions prepared;
- Programmes on control of feed products and veterinary medicinal products developed;
- Study visits conducted;
- Equipment purchased.

3.4. Activities:

The project will be implemented through one Twinning Component and one Supply Component.

3.4.1. Twinning and Training package

Scope of Twinning

The activities which are expected to be implemented under the Twinning are as follows:

- To evaluate the current control system of veterinary medicinal products and feed products and assist in developing the new one;
- To develop veterinary medicinal products and feed products control programmes;
- To analyse the existing working documents and to prepare detailed working instructions;
- To develop training programs and conduct training;
- To organize study visits in the EU member states;
- To procure the equipment for LSIVP.

Required Inputs:

For the Twining component one PAA (18 p/m) providing general management, consultations and assistance to the LSIVP in the development and implementation of control programs of veterinary medicinal products and feedingstuffs, development of working instructions and training of staff.

General profile of the Pre-Accession Adviser (PAA)

- A civil servant from the EU Member State Governmental institution experienced in control of veterinary medicinal products and desirable in feedingstuffs;
- Familiarity with the relevant legislation in the EU Member States;
- Good knowledge of its practical implementation;
- Familiarity with Member State Ministry and associated bodies' structures and procedures;
- Some training experience would be necessary;
- Good communication and management skills;
- Fluency in English (written and spoken);
- Computer literacy.

Short-term experts
Short-term experts (16 p/m) providing training and assistance on:

- Authorisation of veterinary medicinal products;
- Inspection of veterinary medicinal products;
- Administration of state inspection of feedingstuffs (drawing up the annual control plan, criteria used, risk based approach, evaluation of the results of previous years, etc.);
- Inspection of feedingstuffs (inspection of establishments and intermediaries, farms, labelling; sampling, reporting, etc.);
- Authorisation of feed additives;
- Authorisation and inspection of biocidal products used for veterinary purposes;
- Preparation of specifications for databases for inspection of veterinary medicinal products and feedingstuffs;
- Introduction of European databases: Eudravigilance, Europharm and Eudrasafe;
- Preparation of the Centre for quality control of biological and other veterinary medicinal products for accreditation;
- Quality management.

The experts should have:

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

3.4.2. Supply Component

- A Supply Tender will be organised for procurement of the equipment for the Centre for quality control of biological and other veterinary medicinal products.

3.5. Lessons learned

There have been no previous projects and evaluations in this field before. However, during the recently completed bilateral Dutch-Lithuanian project on the *Institutional strengthening of the National Veterinary Services in Lithuania* it was learned that for the successful implementation of the project it is necessary to include implementation at all levels, especially at the work floor (by technical people for technical people).

4. Institutional Framework

The Project will support strengthening of Lithuanian State Inspection on Veterinary Preparations in the sectors of control of veterinary medicinal products and feedingstuffs in Lithuania.

- The counterpart and one of the beneficiaries for this project is LSIVP in the field of animal health, which is responsible for the official control of feed products and veterinary medicinal products in Lithuania.
- Another direct beneficiary involved in this project is the regional State Food and Veterinary Services (SFVS), which are responsible for the official control of feed products and veterinary medicinal products on local level.

The State Food and Veterinary Service (SFVS), which reports directly to the Government of Lithuania is responsible for the legislation and control of feedingstuffs, animal health and welfare, veterinary medicines, to hygiene and safety of food, etc. The SFVS has in its subordination Lithuanian State Inspection on Veterinary Preparations and delegated it official control of feed products and veterinary medicinal products. The SFVS subordinates regional SFVS's: 10 County, 34 District, 4 City State Food and Veterinary Services. Regional SFVS's have persons in charge for the official control of feed products and veterinary medicinal products on local level.

In total, in the official control of feed products and veterinary medicinal products about 90 employers will be involved.

A Steering Committee will be set up to oversee the project implementation. The Steering Committee will meet once in a quarter and it will include the representatives of SFVS, LSIVP, Ministry of Agriculture, the EC Delegation in Vilnius and the National Aid Co-ordinator.

5. Detailed Budget

Project Components	**Transition Facility Support**			**National Co-financing**	**Total**
	Investment Support	**Institution Building**	**Total Transition Facility (I+IB)**		
Twinning and Training package		0.614	0.614		0.614
Supply Component	0.266		0.266	0.089	0.355
Total	**0.266**	**0.614**	**0.88**	**0.089**	**0.969**

6. Implementation Arrangements

6.1. Implementing Agency

The Implementing Agency is the CPMA. The CPMA will be responsible for tendering and contracting:

Mr. Aloyzas Vitkauskas
Central Project Management Agency
J. Tumo Vaizganto str. 8A /2,
LT-2600, Vilnius, Lithuania
Tel.: +370 5 2514400
Fax: +370 5 2514401

The responsibility for Project preparation, implementation and control will be given to the beneficiary institution.

The following persons will act as the contact persons from the State Food and Veterinary Service and Lithuanian State Inspection on Veterinary Preparations:

Dr. Petras Mačiulskis
Deputy Director
State Food and Veterinary Service
Siesikų st. 19
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Dr. Juozas Jokimas
Director of the Inspection
Lithuanian State Inspection on Veterinary Preparations
J. Naujalio g. 21b
LT-3022 Kaunas
Lithuania
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Fax +370 37 36 12 41
jokimas@vet.lt

6.2 Twinning

The Twinning Team will be located at Lithuanian State Inspection on Veterinary Preparations. The counterparts of the PAA will be:

Mr. Laimis Jodkonis
Head of Department of Expertise
Lithuanian State Inspection on Veterinary Preparations
J. Naujalio g. 21b
LT-3022 Kaunas
Lithuania
Tel + 370 37 26 81 29
Fax +370 37 36 12 41
laijod@vet.lt

The PAA will be working at Lithuanian State Inspection on Veterinary Preparations.

6.3. Non-standard aspects

No no-standard aspects are foreseen. The project will be implemented strictly following EDIS rules.

6.4. Contracts

There are two tenders foreseen:

Value of the Twinning Covenant:	0.614 MEU*R*
Value of the Supply Tender:	0.355 MEUR, including 0.089 MEUR of national co-financing

7. Implementation Schedule

Component	Start of Tendering	Start of Project Activity	Project completion
Twinning	2Q/04	4Q/04	2Q/06
Supply	2Q/04	4Q/04	3Q/05

8. Equal Opportunity

The Constitution of Lithuania, the Law on Equal Opportunity between Men and Women, and other legal acts explicitly forbid the discrimination on the basis of sex, nationality, and religion. A Controller on equal opportunities between men and women is appointed by the Seimas (the Parliament).

The institution involved in the project execution will observe equal opportunity of men and women in its recruitment and human resources development. Vacancies are equally open to both genders. The beneficiary will also ensure equal access of men and women to the project activities and results.

9. Sustainability

State Food and Veterinary Service has adequate staff and financial resources to maintain the administrative function of the project. Coverage of costs for maintenance and up-date where necessary is foreseen in the budget of State Food and Veterinary Service.

10. Conditionality and sequencing

The project is conditional upon the availability of national co-financing. The project will be sequenced as shown in the Detailed Implementation Chart for the Project.

Annexes to the Project Fiche

1. Logframe Planning Matrix.
2. Detailed Implementation Chart.
3. Cumulative Contracting and Disbursement Schedule for the Project (MEUR).
4. List of Relevant Laws and Regulations.
5. Investment Part Substantiation (Indicative List of Investment Components of the Project).

Annex 1

LOGFRAME PLANNING MATRIX FOR PROJECT **Food safety (phase II) – Official control of veterinary medicinal products and feedingstuffs**		Project name and number	Food safety (phase II) – Official control of veterinary medicinal products and feedingstuffs LT 2003-X-XX
		Contracting Period Expires: 3Q/06	Disbursement Period Expires: 3Q/07
		Total Budget: 0.969 MEUR	TF Contribution: 0.88 MEUR
Overall Objective	**Objectively Verifiable Indicators**	**Source of Verification**	**Assumptions**
To ensure safety of food through control of the safety and quality of feed products and veterinary medicinal products in accordance with the EU *acquis*	Control system based on the requirements of the directives 2001/82/EC for veterinary medicinal products and 95/53/EEC for feedstuffs and other EU A*cquis* on animal feed products and veterinary medicinal products	EU: Regular Reports. Annual Reports of Lithuanian State Inspection on Veterinary Preparations.	
Project Purpose	**Objectively Verifiable Indicators**	**Source of Verification**	**Assumptions**
To strengthen administrative and technical capacities of Lithuanian State Inspection on Veterinary Preparations. To enhance professional capacity of the staff in laboratory and statistical survey of data. To enhance professional capacity of the responsible staff in the field of control of feed products and veterinary medicinal products.	Administrative and control authorities under operation at a proper level Fully operational control system as in comparable EU member states.	EU: Regular Reports. Annual Reports of Lithuanian State Inspection on Veterinary Preparations.	Full co-operation between staff in LSIVP and SFVS as well experts carrying out the project. Trained staff can be retained.
Results	**Objectively Verifiable Indicators**	**Source of Verification**	**Assumptions**
- Training programmes prepared, staff adequately trained and re-trained on control of feed products and veterinary medicinal products and the competence of the staff increased; - Evaluation and analysis of the current control system done and recommendations prepared; - Analysis of working documents completed and detailed working instructions prepared; - Programmes on control of feed products and veterinary medicinal products developed; - Study visits conducted; - Equipment purchased and installed.	Staff (90 officials) trained and re-trained on control of feed products and veterinary medicinal products and quality of the work increased; Review of working documents done, detailed working instructions developed and put into force; Recommendations on feed product and veterinary medicinal product control system documented in a working paper; The implementation of programmes on control of feed products and veterinary medicinal products introduced; Supplies delivered in time and of the proper level of quality, as planned.	Annual Commission report and Lithuanian progress report. Project reports and independent assessments.	Sufficient absorption capacity in the beneficiary institutions to effectively utilise project resources. Sufficient budget funds for staffing and operational costs. Trained staff can be retained.

Activities	Means	Assumptions
- To evaluate the current control system of veterinary medicinal products and feed products and assist in developing the new one; - To develop veterinary medicinal products and feed products control programmes; - To analyse the existing working documents and to prepare detailed working instructions; - To develop training programs and conduct training; - To organize study visits in the EU member states; - To procure the equipment for LSIVP.	Twinning package for strengthening of control of veterinary medicinal products and feed products. One PAA (18 p/m). Short-term experts (16 p/m). A Supply Tender will be organised for the supply of equipment for the Centre for quality control of biological and other veterinary medicinal products.	Sufficient absorption capacity in the beneficiary institutions to effectively utilise project resources. Sufficient budget funds for staffing and operational costs. Smooth process of procedures concerning the tendering, contracting and implementation.
	Preconditions	
	Suitable Twinning Partner can be found. Continuing sector policy including maintenance responsibilities. National co-financing available.	

Annex 2

Detailed Implementation Chart for the Project

Food safety (phase II) – Official control of veterinary medicinal products and feedingstuffs

Year	2004												2005												2006								
Month	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9
Twinning																																	
Supply																																	

Design

Tendering

Implementation

Annex 3

Cumulative Contracting and Disbursement Schedule (Transition facility Contribution only – 0.88 MEUR)

Food safety (phase II) – Official control of veterinary medicinal products and feedingstuffs

	2004	2005				2006	
	31/12	31/03	30/06	30/09	31/12	31/03	30/06
Contracting							
• Twinning	0.614						
• Supply	0.266						
Total contracting (cumulative)	**0.88**						
Disbursement							
• Twinning	0.204	0.273	0.341	0.409	0.478	0.546	0.614
• Supply	0.159	0.239	0.239	0.266	0.266	0.266	0.266
Total disbursement (cumulative)	**0.363**	**0.512**	**0.580**	**0.675**	**0.744**	**0.812**	**0.88**

Annex 4

List of Relevant Laws and Regulations

1. "Law on Veterinary Activities" adopted by the Parliament of the Republic of Lithuania on 17 December 1991.
2. "Law on Pharmaceutical Activity" adopted by the Parliament of the Republic of Lithuania on 31 January 1991.
3. "Law on Feedingstuffs" adopted by the Parliament of the Republic of Lithuania on 6 April 2000.
4. "Requirements for Manufacturing, Registration and distribution of Veterinary Medicinal products in the republic of Lithuania" adopted by the order No. 584 of Director of State Food and Veterinary Service on 29 December 2001.
5. "Requirements for Good Manufacturing Practice for Veterinary Medicines" adopted by the order No. 451 of Director of State Food and Veterinary Service on 2 October 2002.
6. "Requirements for Manufacture, Use and Trade of Feed Additives" adopted by the order No. 332/395 of Director of State Food and Veterinary Service and Minister of Agriculture on 21 September 2001.
7. "Requirements for official control of products intended for animal nutrition" adopted by the order No. 3D-252 of Minister of Agriculture on 27 June 2003.
8. "Requirements for Manufacture, Distribution and Use of Medicated Feedstuffs" adopted by the order No. 4-168 of Director of State Food and Veterinary Service on 28 June 1999.

Annex 5

Investment Part Substantiation

Indicative List of Investment Components of the Project

	Indicative TF Budget	Indicative national Co-financing	Total Budget (EUR)
HEPA filtration system	266 000	89 000	355 000
TOTAL:	**266 000**	**89 000**	**355 000**

Lithuanian State Inspection on Veterinary Preparations (LSIVP) is responsible for the control of manufacturing, distribution and use of veterinary medicinal products and feedingstuffs. Upon the accession to EU Lithuania obligates to put only high quality and safe food products on common market. State Food and Veterinary Service is responsible for the safety of food products. High quality and safe food products may be produced only from healthy animals. To ensure healthy state of animals, high quality, effective and safe veterinary medicinal products and feedingstuffs have to be used.

The work of LSIVP is based on such EU legal acts: 2001/82/EC (the Community code relating to veterinary medicinal products), 91/412/EEC (the principles and guidelines of good manufacturing practice for veterinary medicinal products), 95/53/EC (the principles governing the organization of official inspections in the field of animal nutrition), 90/167/EEC (the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community), 70/524/EEC (additives in feedingstuffs), 98/8/EC (the placing of biocide products on the market).

Until now there were Phare projects for other veterinary fields: strengthening of border veterinary control, upgrading of food control and animal health diagnostic laboratories, etc. This project is exclusively dedicated for strengthening of state control of feed products and veterinary medicinal products.

To implement entire *acquis* and all relevant directives overtaking veterinary medicinal products and feedingstuffs in the Republic of Lithuania further steps should be taken.

Part of the State budget was used to build a Centre for quality control of biological and other veterinary medicinal products at the LSIVP. These funds (Litas 3,068 mln. or 0.88854 MEUR) covered Phase I, which was began in 2002. This centre still requires appropriate supplying with necessary laboratory and other equipment. However, first of all it is necessary to install appropriate filtration system to ensure proper conditions for the laboratory work of the Centre for quality control of biological and other veterinary medicinal products. Further financial strengthening of LSIVP in this matter would be significant.