1. Basic Information
1.1. CRIS number: 2003/005-710.04.03 Twinning number: 2003/IB/AG/03TL
1.2. Title: TSE control in Poland Part II
1.3. Sector: Agriculture
1.4. Location: Poland

2. Objectives
2.1. Overall Objective(s):
The completion of effective adoption of the EU disease control acquis.

2.2. Immediate objectives:
• TSE screening in Poland upgraded, so as to better enforce standards defined in the Regulation 999/2001/EC.
• Technical harmonisation implemented.
• Network of central units and laboratories meets required qualitative and quantitative levels of operations.

2.3. Accession Partnership and NPAA priority
The project components are in line with the following AP and NPAA priorities:
Accession Partnership
The AP has listed under the short and medium-term priorities a number of areas for action involving the adoption of the Community acquis (notably the veterinary and plant-health fields), upgrading the control arrangements and improvement of diagnostic and testing facilities.
The Accession Partnership 2001 chapter 7.2 includes the following priority under Agriculture:

“Complete transposition of legislation in the veterinary and phytosanitary field (legislation on transmissible spongiform encephalopathies, plant passports, maximum residue levels, animal nutrition) and ensure implementation and enforcement.” And “

National Programme for the Adoption of the Acquis
The NPAA indicates as a priority a number of measures to be taken in the area of “Epidemic protection”, including specific actions on BSE control. The current project will be implemented within the overall context of the NPAA priority of introducing improvements in control arrangements guaranteeing sanitary standards and health protection against TSEs within the meat production and animal waste neutralising sectors.

NPPC PRIORITY 7.2: harmonisation of veterinary law and veterinary administration structures in line with the eu requirements and their implementation. 1. final objective.
Full harmonisation of the Polish veterinary legislation with Community legislation, together with the provisions on public health protection, system of identification and registration of animals and their movement control, animal nutrition, animal protection and veterinary medicines, veterinary border control, organisation of veterinary diagnostic laboratories, control of animal infectious diseases and control over neutralisation of animal origin waste.

3. Description
3.1. Background and justification:
Upgrading the TSE control arrangements forms an important component of actions aimed at the modernisation of the meat producing and animal waste neutralisation sectors. A key element of the control environment involves the introduction of an appropriate level (numbers of conducted tests) and quality standards of testing, through a network of regionally available laboratories. In order to assure consumers - both inside and outside the country – on the safety of Polish meat and products of animal origin, Poland needs to introduce control standards which will allow to continually prove and verify the national BSE status. The EU Scientific Advisory Commission placed Poland in the third category...
(which means probable BSE cases) concerning BSE risk classification of the countries. Through that date four BSE cases had been found in Poland, recently such cases has been identified in laboratory.

In order to effectively control Poland’s BSE status it is necessary to fully introduce the EU conformity examination methodology as described in Regulation (EC) No 999/2001 of the European Parliament and of the Council of May 22, 2001 (and its amendments) laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

Since April 1, 2001 within the framework of animal and public health protection against TSEs in Poland, regulations of the Minister of Agriculture have entered into force excluding products from dead animals from the animal feed chain. Moreover, the use of animal proteins for the production of ruminant feed was banned, while the dying of parts of slaughter animals regarded as SRM was introduced.


If Poland is to meet compliance requirements in the area of TSE testing by 1-st of May 2004 it is urgently required to upgrade the nationally available testing facilities in terms of their capacity and scale of operations. By the end of July of 2002 more then 160 000 samples were tested in Poland, with the first BSE positive result recorded in May 2002. In order fully to comply with the EC Regulation Poland should apply rapid (prion) tests on approximately 300 000 ruminants per annum. It is therefore necessary to acquire the required numbers of prion (rapid) tests from one of the Member States and to develop a special “background” laboratory for the histopathology examination, immunocytochemistry, immunoblotting or demonstration of characteristic fibrils by electron microscopy, which examinations are requested as control measures.

Since Poland applies for financial assistance to cover the costs of testing kits from PHARE funds until the end of 2005, it will not be entitled for relevant Community’s financial assistance as a Member State in 2004 and 2005. Therefore Poland will not apply for Community’s financial assistance to cover the relevant test kits as a Member State in the years 2004 and 2005.

Laboratory staff and veterinarians must be trained and better prepared for operations under the EU compliant regime. Currently laboratories conducting the tests are located in Warszawa, Wroclaw, Kraków, Gdansk and Pulawy. In order to achieve a better geographic coverage the next three laboratories will be prepared by the Phare 2002 project in Poznan, Krosno and Bialystok. This will increase the effectiveness of TSE control and upgrade the Warszawa unit.

As a result of the project Poland will meet EU compliance requirements in the area of TSE control and will have reached the necessary testing capacities by January 2004. However, the Phare 2003
support in delivering the required quality and quantity of tests will extend till the end of 2005, so as to
guarantee a next 17 month period of testing. The Phare 2003 project will upgrade laboratory
equipment in Wroclaw, Kraków and Gdansk. At the present time these laboratories use rapid tests
accepted in the EU Member States and are equipped with the relevant laboratory equipment. The
project will finance procurement of the necessary missing and outdated equipment. The Reference
Laboratory in Pulawy will use one of the following tests: Prionics Check (Prionics), Platelia R BSE or
Enfer Tests (Enfer).

The Technical Specification comprises the list of equipment necessary to the proper operation of a
standard TSE diagnostic laboratory. Technical Specification for the equipment is based on experience
drawn in previous Phare programmes and analysis of destination, quantity as well as costs of the
equipment procured in the framework of the “TSE control in Poland part I” project. List of equipment
will be finally adjusted to the changes of conditions by the Twinning-light experts. In case, for
example, of the new generation ULTRALUX apparatus used for conducting quick BIO-RAD tests, the
market price for the hardware is still unknown. Moreover, the type of equipment should be compatible
with the type of test kits as the system of testing should work together.

3.2. Linked activities:
Previous and on-going Phare funded actions impacting directly on the current project include
foremost:
- PL98.05.02. Reform and Strengthening of the Veterinary Administration, which included a
twinning arrangement and training in the areas of BSE control;
- PL01.04.05. Feeding-stuff Control, which involves a twinning arrangement looking into control
actions in the “from stable to table” paradigm.
- Project Phare 2002 “TSE (Transmissible Encephalophaty Spongiform) control in Poland”

3.3. Results:
- 300 000 prion tests conducted annually (totally 425 000 prion tests during the project
implementation) in this 35 000 samples from fallen stock over 24 months, witch have to be tested
(as amendment of Regulation 999/2001 to Commission Regulation 1494/2002)
- quality of tests meets EU conformity standards
- capacities and network of laboratories conducting BSE testing upgraded in quantitative and
qualitative terms.

3.4. Activities
The project will provide advisory and training support in implementing EU standards in TSE control,
and investment support for the modernisation of the equipment of the existing Laboratory of
Veterinary Hygiene in Gdansk, Wroclaw i Kraków Phare 2003 will upgrade laboratory equipment.
Phare 2003 also will renew the number of TSE tests for period of 2004-2005 and will meet EU
compliance requirements in the area of TSE control.

Project activities therefore will include one twinning light arrangement on TSE control, one training
component and two supply contracts (laboratory equipment and prion tests).

3.4.1 Twinning light
A twinning light project will assist the General Veterinary Inspectorate (GVI) in adopting and
implementing the EU veterinary control system in Poland, with respect to TSE control arrangements
and improvement of diagnostic and testing facilities.
The twinning experts will work together with the expert staff of GVI and the Department of Animal
Production and Veterinary Control of the Ministry of Agriculture and Rural Development.

Under the twinning arrangement work on the harmonisation of the TSE control system will cover:
- a review of the current Polish regulations and developing any necessary and recommended
modifications in the field of TSE control, related to changes of regulations in EU ;
3.4.1. Profile of the medium -term experts:
Two medium – term experts will be needed. They should have the following professional profile and experience:

First mid-term expert:
- trained veterinarian with significant practical experience in the field of control of TSE, involving laboratory testing;
- hands on experience in the work of laboratories and in procuring equipment necessary under investment projects designed to guarantee higher capacity and quality levels of testing;
- experience in conducting institutional (technical and human resources) capacity research, based on surveys in existing facilities;
- excellent inter-personal and communication skills;
- fluency in English.

Second mid-term expert:
- regulatory and policy level experience in introducing solutions for TSE control;
- proven expertise in dealing with the technical issues involved in TSE control;
- experience in managing international projects with training, regulatory and institution building components;
- excellent inter-personal and communication skills;
- fluency in English.

3.4.1.2. Short term experts
The short term experts will be responsible for providing the practical technical support for the personnel of the laboratories benefiting from the investment support and using new tests. This support will be tailored to the specific solutions and equipment adopted in the laboratories, and will be targeted at meeting qualitative and quantitative targets set for each laboratory and process. The requested short term experts will therefore involve a small team of technicians and practitioners specialised in:
- testing procedures;
- quality control;
- technical operations;
- equipment management and logistics of laboratory operations;
- human resources development and training.
Furthermore the short term experts must have fluency in English.

3.4.2. Training for the staff of the TSE laboratories and key veterinarian staff.
The training component will include a series of seminar-type training actions in Poland for 30 TSE laboratory experts and 34 veterinarians. Training topics will concentrate on new TSE control developments, specific methodologies/tests/techniques used in EU countries and examples of best practise and emergency operations.

About 30 laboratory staff and 34 veterinarians will thus be expected to be fully trained and ready to conduct testing operations at qualitative and quantitative levels required as compliant with EU regulations.

3.4.3. TSE laboratory supply and prion tests
Laboratory equipment and prion tests will be purchased under two separate supply contracts:

- The development of TSE laboratories is indispensable in order to avoid assumed zoonozis. The TSE prion tests that Poland needs to implement are available from EU countries.

- In the frame of the project the TSE laboratories operational in Poland and further developed under this project will receive in total about 390,000 prion tests (the calculated need for 17 months) and laboratory equipment to improve the capacity of TSE screening in Poland, as prescribed in Regulation (EC) No 999/2001 of the European Parliament and of the Council and Commission Regulation 1494/2002.

- The currently approved prion (rapid) tests are listed in the above mentioned Regulation. Considering the specificity of the prion test supply the technical specification may differ from a standard specification.

The supply of prion tests will be jointly co-financed out of Phare and Government resources. The Phare amount is binding as a maximum amount available for the project. The ratio between the Phare and the national amount is also binding and has to be applied to the final contract price. However, the Phare contribution cannot, under any circumstances, exceed the ceiling of 15€ per test.

3.5 Lessons learned
TSE control in Poland, stage II; this project has address a 2001 AP priority and will co-finance institution building, equipment and supplies to help Poland upgrade and speed up its screening for TSE (Transmissible Spongiform Encephalophaty), to implement technical harmonisation and to ensure that its laboratory network meets the required qualitative and quantitative levels of operations in this respect. The upgrading of TSE control forms an important element of the actions aimed at the modernisation of the meat producing and animal waste control sectors and this requires the introduction of appropriate levels and quality standards of testing and diagnosis as the basis for policy action. Part of the institution building of this project will be the subject of twinning light.

Under the Annual Assessment Report No. R/PL/AGR/00064 recommendations were made which are relevant to current project. The recommendations mentioned below will be taken into consideration while designing current project:

1. Satisfactory performance of some twinning teams will be predicted and additional or corrective measures will be allowed for in the project or other supplementary projects for the same sector.

2. The national budget will be prepared to withstand the burden of unexpected additional co-financing of actions initialised by Phare. Sometimes substituting Phare financing with State Budget resources, e.g. in covering the management costs, is necessary - then the project current stage will be parallel co-financed.

3. Financing the actions in line with the Commission recommendations out of the Polish national resources will be notified to the Commission Services so as to assure the adequate level of co-ordination for accession processes.

4. The role of regular monitoring based on Sectoral Monitoring Sub-Committees can easily be overestimated, so additional early warning systems will be ready to react to critical threats in contracting or disbursement of funds.

4. Institutional framework
4.1. Overall technical and administrative aspects of implementation and co-operation with the twinning partner shall be the responsibility of the Ministry of Agriculture and Rural Development, Department of Animal Production and Veterinary Control. Participating institutions (beneficiaries) will also include:
1. General Veterinary Inspectorate
2. Laboratory of Veterinary Hygiene in Warsaw
3. Laboratory of Veterinary Hygiene in Poznan
4. Laboratory of Veterinary Hygiene in Bialystok
5. Regional Veterinary Laboratory in Krosno.
6. Laboratory of Veterinary Hygiene in Gdansk
7. Laboratory of Veterinary Hygiene in Kraków
8. Laboratory of Veterinary Hygiene in Wroclaw
9. State Veterinary Research Institut in Pulawy

4.2. Furthermore prion (rapid) tests will be provided under the terms of the project to the following existing TSE laboratories:
1. Wroclaw
2. Kraków
3. Gdansk
4. Pulawy.
5. Warszawa
6. Poznan
7. Bialystok
8. Krosno

4.3 The twinning will enable or improve:
- better organisation of existing laboratory network
- harmonisation diagnostic methods in all units.
The twinning will improve:
- testing procedures;
- quality control;
- technical operations;
- equipment management and logistics of laboratory operations;
- human resources development and training

4.4. Voivodship Veterinary Inspection will be the owner of purchased equipment and will menage with diagnostic tests.

5. Detailed Budget

<table>
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<tr>
<th>PHARE financing</th>
<th>Investment support</th>
<th>Institution Building</th>
<th>Total PHARE (I+IB)</th>
<th>National co-financing</th>
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<td><strong>4.877</strong></td>
<td>-</td>
<td><strong>12.552</strong></td>
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</table>
National co-financing and funds for joint co-financing will originate from reserves at the disposal of the Ministry of Agriculture and Rural Development.

6. Implementation arrangements

6.1 Implementing Agency
The implementing Agency of the project is the Central Finance and Contracting Unit, which is responsible for tendering and contracting.

PAO: Mr Tadeusz Kozek, Under-Secretary of State in the Office of the Committee for European Integration, Aleje Ujazdowskie 9, Warsaw; phone 48 22 4555241; fax 4822 4555243
Central Financing and Contracting Unit (CFCU): Barbara Kasnikowska, Co-operation Fund, ul. Górnoślaska 4a, 00-400 Warsaw, phone: 4822 622 88 20, fax. 48 22 622 75 65
The CFCU is responsible for tendering, contracting and payments of contracts on behalf of the Ministry of Agriculture and Rural Development.

6.2 Twinning
Within the frame of the project a twinning light arrangement is foreseen to assist the Ministry of Agriculture and Rural Development, and other beneficiaries of the project.
The medium and short term experts will be placed at beginning of year 2004 in the Ministry of Agriculture and Rural Development Warsaw, ul. Wspólna 30. They will stay in Poland only during the few-day’s periods of planned work.
Contact person:
Maria Boratyn-Laudanska, Ministry of Agriculture and Rural Development, Department of Animal Production and Veterinary Matters.
Address: ul. Wspólna 30, Warsaw, Poland
tel. (+48 22) 6232307, fax (+48 22) 6232105 E-mail Maria.Laudanska@minrol.gov.pl

Polish Project Leader (PPL):
dr Jerzy Dowgiallo, Ministry of Agriculture and Rural Development, Department of Animal Production and Veterinary Matters.
Address: ul. Wspólna 30, Warsaw, Poland
Tel. (+4822)6231317, fax (+48 22) 6232105, E-mail Jerzy.Dowgiallo@minrol.gov.pl

6.3 Non-standard aspects
The “Practical Guide to contract procedures financed from the general budget of the European Communities in the context of external action” and Twinning Manual will be strictly followed in relation to the Twinning light covenant, training component and the Supply of Laboratory Equipment.
As per test kits according to Annex X of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 there are only three possible methods that can be utilised for rapid tests for BSE and each test is available only from one producing company. It is understood that the Phare contribution will, under no circumstances, exceed the amount of 15€ per test kit.

6.4. Contracts
- twinning light – Phare EUR 150 000
- Service contract (training) Phare EUR 150,000
  - Supply contract (lab. equipment) – Phare EUR 975 000 +Polish co-financing EUR 325 000 (joint co-financing)
  - Supply contract (BSE tests)– Phare EUR 6 375 000+Polish co-financing EUR 4 527 000 (joint co-financing)

7. Implementation schedule
7.1. Start of tendering: III q. 2003;
7.2. Start of project activity: I q. 2004;

8.Equal opportunity:
Participation of men and women shall be based on relevant EU standards, equal opportunity of employment being ensured. The participation of women results from the structure of employment and shall be measured by percentage indicator of the number of people participating in project. Based on this monitoring any necessary corrective actions will be taken to ensure equal opportunity.

9. Environment: N/A
10. Rates of return: not applicable

11. Investment criteria
11.1. Catalytic effect
Phare aid is a catalyst within the overall project area; without Phare aid the establishment of the full network of regional TSE laboratories and the attainment of the qualitative and quantitative benchmarks required under accession would only take place with help of Phare.

11.2. Co-financing
The project will be co-financed from Polish resources.

11.3. Additionality
Phare financing is not displacing private sector financing and is adding to the resources made available from the Polish national budget.

11.4. Project readiness and size
The project is ready for implementation and meets Phare requirements in terms of size and impact.

11.5. Sustainability
Project activities will proceed beyond the date of accession and the Polish institutions involved will continue to finance the activities supported under this project in the following years.

11.6. Compliance with state aid provisions
The project is fully compliant with the provisions of the European Agreement.

12. Conditionality and sequencing
12.1. Project financing will be conditional on:
- availability of Polish co-financing;
- attainment of required quality and quantity levels of testing;
- maintaining timetables set for continuation and compliance of full requirements in area of laboratory equipment and testing methods at the years 2004-2005;
- technical harmonisation, including the development of the final list of procurement of technical equipment and tests for the laboratories, to be done by the twinner.

12.2. Sequencing:
- Preparation of the terms of reference for the for technical assistance (III q.2003);
- Preparation of the technical specification for the supply contracts (IV q. 2003);
- Start of the tendering procedure (IV q.2003);
- Contracts signing (I q. 2004);

12.3. Milestones:
- Start of the tendering procedure (IV q.2003);
- Contracts signing (I q. 2004);
- Installation of the equipment (IV q. 2004);
- Training for the staff of the TSE laboratories and key veterinarian staff. (IV q. 2004).
- project completion by September 2005.

ANNEXES
Logical framework matrix in standard format
1. Detailed implementation chart
2-3. Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period)
ANNEX 1 Phare logical framework matrix

<table>
<thead>
<tr>
<th>Logframe Planning Matrix For TSE (Transmissible Spongiform Encephalopathie) Control in Poland</th>
<th>Project number</th>
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<tbody>
<tr>
<td></td>
<td>Contracting period expires: 30/11/2005</td>
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<td>Disbursement period expires: 30/11/2006</td>
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<td>Total budget: 12,552 M€</td>
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<td>Phare budget: 7,675 M€</td>
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<tr>
<th>Overall objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of verification</th>
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<tr>
<td>The completion of adoption of the EU disease control acquis</td>
<td>Positive assessment of the transposition of disease control Acquis by MARD</td>
<td>Reports of the General Veterinary Inspectorate</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Immediate objectives</th>
<th>Objectively verifiable indicators</th>
<th>Source of verification</th>
<th>Assumptions</th>
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<tbody>
<tr>
<td>TSE screening in Poland upgraded, so as to better enforce standards defined in the Regulation 999/2001/EC. Technical harmonisation implemented. Network of central units and laboratories meets required qualitative and quantitative levels of operations.</td>
<td>300000 pcs prion tests conducted per year General Veterinary Inspectorate and Department of Animal Production and Veterinary Control reach compliance standards. TSE screening network involves 8 fully compliant laboratories.</td>
<td>Reports of the General Veterinary Inspectorate on BSE tests Project reports</td>
<td>- All facilities in place for swift action in case of cattle testing BSE positive - Sustainable funds available for prevention and containment measures</td>
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<table>
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<tr>
<th>Results</th>
<th>Objectively verifiable indicators</th>
<th>Sources of verification</th>
<th>Assumptions</th>
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<tbody>
<tr>
<td>300 000 prion tests conducted annually Quality of tests meets EU conformity standards Capacities and network of laboratories conducting BSE testing upgraded in quantitative and qualitative terms</td>
<td>- All arrangements, studies, training services and supplies completed and delivered in time and at the right levels of quality, as planned</td>
<td>Procurement reports Progress reports by the General Veterinary Inspectorate Project reports</td>
<td>Trained staff can be retained by the General Veterinary Inspectorate</td>
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<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Assumptions</th>
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<tbody>
<tr>
<td>General Veterinary Inspectorate - Provides Staff and manages the project -- Prepares tenders and concludes supply contracts</td>
<td>- One twinning-light for the TSE control - One training component - One supply contract for laboratory equipment - One supply contract for laboratory consumables (prion tests)</td>
<td>High quality project management ensured throughout project period</td>
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</tbody>
</table>
Preconditions
- Staff and co-financing available when required
- Harmonisation of veterinary law

ANNEX 2 – 3 Implementation, contracting and disbursement schedule

<table>
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<tr>
<th>IMPLEMENTATION CHART:</th>
<th>Date of Drafting</th>
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<td>TSE (Transmissible Spongiform Encephalopathie) control in Poland</td>
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D = design of sub-projects  
C = tendering and contracting  
I = contract implementation and payment