STANDARD SUMMARY PROJECT FICHE

1. Basic Information

1.1 Désirée Number: 2002/000-282.05.05

1.2 Title: Improving BSE Detection Capacity

1.3 Sector: Agriculture

1.4 Location: Czech Republic

2. Objectives

2.1 Overall objective
Existence of functioning market economy, as well the capacity to cope with competitive pressure and market forces within the European Union. The ability to take on the obligations of membership, including adherence to the aims of political, economic and monetary union

2.2 Project purpose
Improvement of the capacity of the Czech Republic to ensure full compliance with Regulation 999/2001.

2.3 Accession Partnership and NPAA priority
AP: The Accession Partnership (2001) highlights:
    Short term: veterinary & phytosanitary sector – continue alignment and upgrade inspection arrangements
    Medium-term: veterinary & phytosanitary sector – complete system of animal identification; implement quality control system (Hazard Analysis Critical Control Point), animal waste treatment, modernisation of meat and dairy plants residue and zoonosis control programme.

    Veterinary checks concern imported food products of animal origin, live animals and feeding stuff. Animal health and food hygiene checks on the outer border are an essential part of the inspection arrangements in the veterinary sector (see short-term priority) and the zoonosis control programme must also be implemented partly through border checks (see medium-term priority). The other issues mentioned are not covered by the present project.

NPAA: The National Program for the Adoption of the Acquis (May 1999) foresees (chapter 7):
Furthermore, it is laid down under the accession partnership linked with SAPARD and Phare, eight priorities will have to be covered. Veterinary border checks including laboratory diagnostic are of the highest priority according to the ranking order.

2.4 Contribution to National Development Plan
n.a.

2.5 Cross Border Impact
n.a.

3. Description

3.1 Background and justification
This project involves the activity supporting laboratory diagnostics in the framework of veterinary supervision and harmonising the current animal health and food hygiene checks of the Czech Republic with those required by the EU. As the present Candidate Countries will form part of the extended territory of the EU and the Czech Republic will become part of the common managing of the EU, the EU principle of veterinary checks on live animals and food products of animal origin will have to be implemented. These animal health and food hygiene checks comprise samples collection and laboratory examination in State Veterinary Institutes. Laboratory results represent an integral part of documents for decisions taken by veterinary bodies in the field of animal health and safety of products of animal origin.
Several distinct transmissible spongiform encephalopathies (TSEs) have for a number of years been recognised as occurring separately in humans and animals. Bovine spongiform encephalopathy (BSE) was first recognised in bovine animals in 1986 and in the following years was recognised as occurring in other species of animal. A new variant of Creutzfeld-Jakob Disease (CJD) was described in 1996. Evidence continues to grow of the similarity between the BSE agent and that of the new variant of Creutzfeld-Jakob Disease.

Since 1990 the Community has adopted a series of measures to protect human and animal health from the risk of BSE. One of the most important is a Regulation (EC) No. 999/2001 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. This Regulation directly concerns public health and is relevant to the functioning of the internal market of EU.

As regards the protective measures taken in the Czech Republic related to BSE, the monitoring started in 1991, when the TSE Reference Laboratory has been established. Up to 1996 the number of tests was limited — only animals with clinical symptoms of nervous disease undergone the tests. Tests were performed using the classical histological technique. In the year 2001 the tests using the Western blot method (Prionics checks) have been introduced starting 1 February and the risk groups were tested. Two laboratories (State Veterinary Institute Prague and State Veterinary Institute Jihlava) have been charged with performing of the test. The State Veterinary Institute Olomouc has been charged with performing of the Enfer test starting October 2001.

The provisions are made for safeguard measures in the field of animal health and products of animal origin. The Czech Republic object is to declare this safety because of protection of consumers in the framework of EU market.

3.2 Linked activities
- Under PHARE 1998 there is a project to “Support to the State Veterinary Administration (SVA)” aiming at strengthening the technical capacity of the regulatory authority. Delivery of equipment, installation and basic staff training were realised in the second half of 2000. This project covered equipment for specialist “reference” veterinary laboratories for testing and identification of diseases; food analysis; residue analysis; and computer equipment for the state veterinary administration. The equipment supplied as part of this project is a necessary part of the inspection arrangements, but is not yet sufficient for full compliance.
- Under PHARE 2000 there is a project “Improvement of animal health and food hygiene inspection arrangements” aiming at strengthening the technical capacity of SVA in the field of laboratory diagnostics and information system. The translation and installation of communication software “Animo” and an architectural plans for a modernisation of BIP Prague Ruzyne airport (Phare 2002) are also parts of the project.
- Under PHARE 2001 there is a project “Completion of veterinary supervision institution building” aiming at modernisation of Veterinary Training Centre and procurement of technical equipment in the field of laboratory diagnostics and information system.
- Under PHARE 2002 there is also a project “Improvement of Border Veterinary Controls” aiming at modernisation of Veterinary BIP Prague Ruzyne — airport (Construction Works) and procurement of technical equipment for the BIP and SVA ; and training of veterinary border inspectors.

3.3 Results
A. All animals are tested as required by the Regulation of the European Parliament and of the Council No. 999/2001 :
A1) paragraph 9 of Preamble of EC Regulation No. 999/2001 — requirement for carrying out the annual programme for monitoring BSE
A2) Chapter I, Article 3, paragraph 1, letter 1 — definition of rapid tests
A3) Chapter III, Article 6 — description of the annual monitoring using rapid tests
A4) Chapter VI, Article 19 — testing must be done in reference laboratories. National reference laboratory is State Veterinary Institute in Prague
A5) System of BSE monitoring accorging to the Chapter A is mentioned in Annex III
A6) Requirements for accredited laboratories, sampling and laboratory testing methods are listed in Annex X
Rapid tests applicable for laboratory testing are specified in the Chapter VI of Annex X
- Western blot (Prionics checks test)
- Elisa test (Enfer test)
- Sandwich immunoanalysis (Bio-Rad Platelia test)

B. About 340,000 animals tested by the reference and accredited laboratories in 2 years

C. Only BSE-free meat in the shops

3.4 Activities

Investement (6.25 M€)

Delivery of the kits to ensure testing (3Q/02-2Q/04) of all required animals (app. 340,000 kits in app. 2 years). Indicative quantity proportion 70 Western blot: 30 Enfer test is expected. Such testing activity includes:

A1) data collection and registration by SVA
A2) rapid tests are practiced in 3 accredited laboratories
A3) SVA will submit structure of monitoring
A4) tests are operating in reference laboratory in Prague (Western blot), accredited laboratories Jihlava (Western blot) and Olomouc (Enfer test)
A5) taking of samples at the slaughterhouses
A6) fulfilling of conditions done by SVA and the supply company for laboratory equipment and staff training.

The necessary reference and accredited laboratories will have the appropriate capacity and trained staff to test 340,000 animals in 2 years and veterinary supervision on the whole territory of the Czech Republic and the activity of 3 State Veterinary institutes will proceed according to the EU and Czech legislation. Co-financing will be supplied from the Czech state budget as indicated in point 5 below.

3.5 Lessons learned
All relevant recommendations from previous projects have been taken into account.

4. Institutional Framework

The Ministry of Agriculture exercises control over the State Veterinary Administration (SVA). The SVA is composed of its headquarters in Prague and 73 Districts/Municipal Veterinary Offices acting as field services. There are also 18 Border Veterinary Posts and 7 State Veterinary Institutes and 1 Institute for State Control of Veterinary Biologicals and Medicaments. The strengthening of SVA, its information network and testing laboratories, has been underway since 1990, although this has primarily focused on development for national purposes rather than the need for a multilateral exchange of information with respect to objectives with EU in this context.

There are 14 newly defined regional administration offices from 2001. In the framework of newly established regions, there were appointed Heads of Regional Sections of SVA CR. It is supposed that future Regional Veterinary Offices will become real managing units with decision making competence from January 1, 2003. The present District and Municipal Veterinary Offices will be answerable to Regional Veterinary Offices. As regards the Laboratory Diagnostics of the SVA CR; there are 7 State Veterinary Institutes available (Prague, Brno, Jihlava, Hradec Kralove, Liberec, Olomouc, Ceske Budejovice); 3 of them are accredited and have laboratory capacities for BSE testing (Prague, Jihlava, Olomouc).

5. Detailed Budget (mil.€)

<table>
<thead>
<tr>
<th>Project Components</th>
<th>Phare Support</th>
<th></th>
<th>National Cofinancing</th>
<th>IFI</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Investment</td>
<td>Institution Building</td>
<td>Total Phare (=1+1B)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnostic kits (two direct agreements)</td>
<td>6.25</td>
<td>6.25</td>
<td></td>
<td>6.25</td>
<td></td>
</tr>
<tr>
<td>Diagnostic lab. material *</td>
<td></td>
<td></td>
<td>2.09</td>
<td>2.09</td>
<td>4.09</td>
</tr>
<tr>
<td>Total</td>
<td>6.25</td>
<td>6.25</td>
<td>2.09</td>
<td></td>
<td>8.34</td>
</tr>
</tbody>
</table>

There will be parallel co-financing.

* Diagnostic laboratory material comprises material for taking and preparation of samples, plastic unreplicated lab. material, gels and reagents for electrophoresis, material for chemiluminescence detection, taking sets.
The costs for an examination of 1 sample is about 45 EUR; 18.4 EUR of it is diagnostic kit, 6.2 EUR is other diagnostic laboratory material mentioned above. The rest (20.4 EUR) includes material for imunoblot, disinfection and waste liquidation means, protection clothes, transport, wages and information equipment. These costs are a part of investment and wage funds of State Veterinary Institutes, they are not provable and are not a part of financial requirements.

6. Implementation Arrangements

6.1 Implementing Agency
The CFCU is the Implementing Agency responsible for tendering, contracting and accounting. Responsibility for technical preparation and control will remain with the beneficiary: Ministry of Agriculture of the Czech Republic and State Veterinary Administration of the Czech Republic. The Contact person for Supplies is MVDr. Vladimír Brychta, State Veterinary Administration, Těšnov 17, 117 05 Prague 1, tel. 02/21 81 28 11, 02/21 81 26 62, fax. 02/21 81 29 43, e-mail: int@svs.aquasoft.cz

6.2 Twinning
n.a.

6.3 Non-standard aspects
Only 3 suppliers are recognised by Annex X, Chapter C, Paragraph IV of EC Regulation No 999/2001. Of these, only 2 are used by the relevant institutions in the Czech Republic (Prague, Jihlava –Western blot; Olomouc – Enfer). Since tendering for the equipment among the 3 possible suppliers could lead to necessary and expensive retraining of staff and replacement of equipment at these centres, the equipment will be purchased through 2 direct agreements, one for the company which supplies Prague and Jihlava, and the other which supplies Olomouc.

6.4 Contracts
Two direct agreements are foreseen to be financed by Phare = 6.25 M €. (Indicative quantity proportion 70% Western blot, 30% Enfer test is expected).

7. Implementation Schedule

7.1 Start of project activity 3Q/02

7.2 Project Completion 2Q/04

8. Equal Opportunity

Equal opportunity principles and practices in ensuring equitable participation by women and men in the Project will be guaranteed.

9. Environment
n.a.

10. Rates of Return
n.a.

11. Investment Criteria
n.a.

12. Conditionality and Sequencing
An amendment to the Veterinary Act will be proposed to the Czech cabinet at the latest by 30 June 2002, and should be in force by the end of 2002.

The project is conditional upon Czech co-financing.
ANNEXES TO PROJECT FICHE

1. Logical framework matrix in standard format
2. Detailed implementation chart
3. Contracting and disbursement schedule by quarter for full duration of programme
4. Indicative Supplies Needs Analysis
## LOGFRAME PLANNING MATRIX

<table>
<thead>
<tr>
<th>Project title: Improving BSE Detection Capacity</th>
<th>Programme number: <strong>2002/000-282.05.05</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Beneficiary institution:</strong> State Veterinary Administration of the Czech Republic</td>
<td><strong>Contracting period expires:</strong> 31/10/2004</td>
</tr>
<tr>
<td><strong>Overall objective</strong></td>
<td><strong>Disbursement period expires:</strong> 31/10/2005</td>
</tr>
<tr>
<td>Existence of functioning market economy, as well the capacity to cope with competitive pressure and market forces within the European Union</td>
<td></td>
</tr>
<tr>
<td>The ability to take on the obligations of membership, including adherence to the aims of political, economic and monetary union</td>
<td><strong>Total budget:</strong> 8,34 mil.€</td>
</tr>
<tr>
<td><strong>Objectively verifiable indicators</strong></td>
<td><strong>Sources of Verification</strong></td>
</tr>
<tr>
<td>Acknowledgement by the European Commission</td>
<td>EC Regular Report</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Project purpose</th>
<th><strong>Objectively verifiable indicators</strong></th>
<th><strong>Sources of Verification</strong></th>
<th><strong>Assumptions</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement of the capacity of the Czech Republic to ensure full compliance with Regulation 999/2001.</td>
<td>Increase of beef consumption by 10-20% by end of 2005 compared to the year 2001</td>
<td></td>
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<tr>
<td></td>
<td>Reduction of producers loss caused by increased costs for obligatory testing for minimum about 30% by end of 2005</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Positive impact of producers loss reduction on the purchase price about 1 Kč/kg of weight by end of 2005</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Annual report of the State Veterinary Administration, part “Veterinary sanitation and public health security” Situation and Outlook Report for Beef</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Annual report on situation in the Czech agriculture (“Green Report”)</td>
<td></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Results</th>
<th><strong>Objectively verifiable indicators</strong></th>
<th><strong>Sources of Verification</strong></th>
<th><strong>Assumptions</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. All animals are tested as required by the Regulation of the European Parliament and of the Council No. 999/2001: A1) paragraph 9 of Preamble of EC Regulation No. 999/2001 – requirement for carrying out the annual programme for monitoring BSE</td>
<td>Laboratory tests results approved by accredited labs (laboratory tests must be made by accepted procedures and in fixed range)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Results can be measured yes no by end of project</td>
<td>Information system of the State Veterinary Administration</td>
<td>Qualified staff available</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Continuation in international co-operation in the field of BSE</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Economics entities have information about food safety within the whole food chain</td>
</tr>
</tbody>
</table>
A2) Chapter I, Article 3, paragraph 1, letter 1 – definition of rapid tests
A3) Chapter III, Article 6 – description of the annual monitoring using rapid tests
A4) Chapter VI, Article 19 – testing must be done in accredited laboratories. National reference laboratory is State Veterinary Institute in Prague
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- Sandwich immunoanalysis (Bio-Rad Platelia test)

B. About 340,000 animals tested by the reference and accredited laboratories in 2 years
C. Only BSE-free meat in the shops

<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Assumptions</th>
</tr>
</thead>
</table>


Delivery of the 340,000 BSE test kits in 2 years to ensure testing (app. 4Q/02-app. 3Q/04) of all required animals (). Indicative quantity proportion 70 Western blot: 30 Enfer test is expected. Such testing activity includes:
A1) data collection and registration by SVA
A2) rapid tests are practiced in 3 accredited laboratories
A3) SVA will submit structure of monitoring
A4) tests are operating in reference laboratory in Prague (western blot), accredited laboratories Jihlava (western blot) and Olomouc (Enfer test)
A5) taking of samples at the slaughterhouses
A6) fulfilling of conditions done by SVA and the supply company for laboratory equipment and staff training

Two Direct Agreements:
Supply of diagnostic kits for 3 workplaces of the State Veterinary Institutes (Prague, Jihlava, Olomouc) – Western blot for reference laboratory in Prague, accredited laboratory Jihlava, Enfer test for accredited laboratory in Olomouc in the amount 6,25 MEUR (Phare financed)
Only 3 suppliers are recognised by Annex X, Chapter C, Paragraph IV of EC Regulation No 999/2001. Of these, only 2 are used by the relevant institutions in the Czech Republic (Prague, Jihlava –Western blot; Olomouc – Enfer). Since tendering for the equipment among the 3 possible suppliers could lead to necessary and expensive re-training of staff and replacement of equipment at these centres, the equipment will be purchased through 2 direct agreement, one for the company which supplies Prague and Jihlava, and the other which supplies Olomouc.
The supply will include app. 340,000 test kits which is needed for 2 years of operation.

Operational and material costs will be covered by the Czech budget in the amount of 2,09 MEUR

The reference and accredited laboratories have the appropriate capacity and trained staff to test 340,000 animals in 2 years

Veterinary supervision on the whole territory of the Czech Republic and the activity of 3 State Veterinary institutes according to the EU and Czech legislation

<table>
<thead>
<tr>
<th>Preconditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Legislative framework – veterinary act No. 166/1999 Coll. (valid version) - § 20 veterinary examination of animal products</td>
</tr>
<tr>
<td>- decree No. 287/1999 Coll. on requirements to animal products</td>
</tr>
<tr>
<td>- methodical guide of the State Veterinary Administration No. 7/2001 from October 8, 2001 (elaborated on basis of veterinary act and decree No. 287/1999 Coll.)</td>
</tr>
<tr>
<td>2. Material and technical base – 3 special labs of the State Veterinary Institutes (National reference laboratory for examination of the TSE (BSE) in Prague, 2 accredited labs in Jihlava and Olomouc)</td>
</tr>
<tr>
<td>Action</td>
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<tr>
<td>-------------------------</td>
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<tr>
<td></td>
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<tr>
<td>Contract signature</td>
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<tr>
<td>Project completion</td>
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CONTRACTING AND DISBURSEMENT SCHEDULE BY QUARTER FOR FULL DURATION OF PROGRAMME

Cumulative Quarterly Contracting Schedule (mil.€)

<table>
<thead>
<tr>
<th>Project</th>
<th>1Q/02</th>
<th>1Q/02</th>
<th>3Q/02</th>
<th>4Q/02</th>
<th>1Q/03</th>
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<th>3Q/05</th>
<th>4Q/05</th>
<th>Total</th>
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<tbody>
<tr>
<td>Improving BSE Detection Capacity</td>
<td></td>
<td></td>
<td></td>
<td>6,25</td>
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<td></td>
<td></td>
<td></td>
<td>6,25</td>
</tr>
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</table>

Cumulative Quarterly Disbursement Schedule (mil.€)

<table>
<thead>
<tr>
<th>Project</th>
<th>1Q/02</th>
<th>1Q/02</th>
<th>3Q/02</th>
<th>4Q/02</th>
<th>1Q/03</th>
<th>2Q/03</th>
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<th>3Q/05</th>
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<th>Total</th>
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<tr>
<td>Improving BSE Detection Capacity</td>
<td>1.25</td>
<td>2.25</td>
<td>3.25</td>
<td>4.25</td>
<td>5.25</td>
<td>6.25</td>
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<td>6.25</td>
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</table>
## Indicative Supplies Needs Analysis

### Diagnostic Kits Supplies for the SVI Prague, SVI Jihlava and SVI Olomouc (amounts in MEUR)

<table>
<thead>
<tr>
<th>Item</th>
<th>Phare 2002 (Investment)</th>
<th>National Co-Financing</th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
<td>Diagnostic kits (Indicative quantity proportion 70% Western blot, 30% Enfer test is expected)</td>
<td>6.25</td>
<td></td>
<td>6.25</td>
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<tr>
<td>Material for taking and preparation of samples, plastic unrepeat lab. material, gels and reagents for electrophoresis, material for chemiluminescence detection, taking sets.</td>
<td></td>
<td>2.09</td>
<td>2.09</td>
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<tr>
<td><strong>TOTAL ESTIMATED PRICE</strong></td>
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