STANDARD SUMMARY PROJECT FICHE

1. Basic Information:

1.1. Desiree Number: 2004/016-710.01.03
1.2. Twinning light SI04-AG-03
1.3. Title: Further enforcement of the Acquis in the Phytosanitary sector - Plant Protection Products
1.4. Sector: AGRICULTURE
1.5. Location: Slovenia

2. Objectives:

2.1. Overall objective:
The overall objective of this project is strengthening the Phytosanitary sector in the field of Plant Protection Products (PPPs) according to the principles and requirements of Directive EC 91/414.

2.2. Project purpose:
Strengthening the administration and technical capacity of the Republic of Slovenia in the implementation of the acquis relating to the Plant Protection Products.

2.3. Comprehensive Monitoring Report:
"In the field of phytosanitary legislation, the acquis on plant health has been largely transposed, both for harmful organisms and pesticides. However, legislation on seeds and propagating material remains to be adopted. In the phytosanitary sector a number of implementing decrees are still to be adopted." (Chapter 7: Agriculture, Veterinary and Phytosanitary Issues, p. 25).

2.4. Acquis Communautaire:
- Council Directive 91/414/EEC and a large number of related directives concerning the authorisation, placing on the market, use and control of plant protection products in commercial form, the placing on the market and control of active substances intended for use as plant protection products within the Community (See Annex 5).
- The PHYTOSANITARY ADMINISTRATION OF THE REPUBLIC OF SLOVENIA (PARS) will also be responsible for attending and negotiating in the EC decision making and scientific peer review meetings. It is vital that representatives at these meetings are sufficiently trained and have the required expert knowledge to ensure that the interests of Slovenia are effectively expressed.
3. Description

3.1. Background and justification:
Since Slovenia is a full member of EU, it has the obligation to implement the phytosanitary Acquis, plant protection products, with its enforcement and related institution building. With the aim to meet EU requirements in the field of plant protection products, Slovenia has already made efforts to harmonize EU legislation and through several Phare projects the training of Slovenian staff in EU legislation and procedures.

Previous Phare programs were successfully finished and have reached their aim. With their assistance a progress was achieved in the field of plant protection products. They strengthened administrative procedure for the authorization of PPP’s in Slovenia, the certain indistinctness on specific tasks (procedure, evaluations, and assessments) was removed, and the authorization team will be built up in the EU-structured way of working by the date of accession. Experts from institutes were trained under these projects for scientific evaluation of parts of the dossiers.

To meet the requirements of the EU review program of Directive 91/414/EEC for scientific evaluation of dossiers submitted for Annex I, inclusion of active substances, comments on prepared monograph of active substances present interest of Slovenia in the EC decision making, as well as evaluation of the dossiers for new plant protection products at national level, further cooperation between experts of both countries, further training in expertise and further Phare assistance is desired. Especially the continuation of the activities and very good cooperation within the Phare project SI 0201.02 (SI02/IB/AG/04/TL Placing Plant Protection Products on the Market) would reach this aim in practice.

3.2. Linked activities:
- PHARE NP: SL9602.03
  Assistance in this project has covered technical assistance (3 UK experts), training and equipment purchase in the field of plant health, including phytosanitary border control, and in the field of plant protection products. The programme was carried out between September 1997 and March 1999. The objective of the project was the review of existing plant health and plant protection products legislation, organization of Plant Protection Service, system of pest control with the aim to assist MAFF to draw up plant health action plan and new strategy for harmonization with the EU Single Market.

- PHARE NP: SL9704.01.02
  This project presented the continuation of the Phare 1997 covering technical assistance (3UK experts and 1 expert from Germany) and training in the field of plant health, including phytosanitary border control, and in the field of plant protection products. The programme was carried out between October 1999 and October 2000. The objective of this project was the assistance in the preparation of the Plant Health Act and the Plant Protection Act to be in line with the Acquis, preparation of the manual for phytosanitary inspectors, survey programs and inspection procedures for certain harmful pests and review of the existing system for authorisation of plant protection products.
• PHARE NP: SL99/IB-AG-02
1999 Phare project consists of twinning project with the Netherlands starting in October 2000 in the field of plant health and a small part in plant protection products and a project for equipment. The covenant was concentrated on the setting up the priorities and administrative procedures with regard to use of plant protection products and programme of monitoring pesticide residues in food of plant origin.

• PHARE NP: SI2001.01.03
A 2001 Institutional Twinning Programme for Implementation of the Phytosanitary EU-Acquis in Slovenia with the Netherlands in preparation started on 1 December 2001
According to this program in the field of Plant Protection Products the implementation of new administrative procedure for the authorization of PPP’s in Slovenia is finalised, certain unclear specific tasks (procedures, evaluations, assessments) are eliminated, the authorization team is built up in the EU-structured way of work by the completion of the project and some specialists are trained for scientific evaluation of parts of the dossiers by the completion of the project. Conclusion of the project was that the experts involved in the evaluation of plant protection products need further Phare assistance to be fully capable of working in line with EU requirements.

• PHARE NP: SI 0201.02
A Twining light project SL02/IB/AG/04/TL completes very successful and useful training programmes and activities of Slovene experts in both countries, Slovenia and UK. Training in procedures within authorization procedure for plant protection products and expertise in evaluation of several parts of dossiers submitted for plant protection product authorization was very well presented by the UK side and very well accepted by the Slovenian side. All goals of the project were achieved, all activities were completed as planned and cooperation between experts of the two countries was very well established. However there is a need for further cooperation and specialization in several expertises of evaluation to do all the scientific evaluation at the national level and also work related to the EU Peer Review process. Areas of weakness have, however, been identified which require remedial action. These include:

1. Communication between specialist disciplines needs to be improved,
2. all staff involved in the risk assessment process would benefit from further opportunities to evaluate data and prepare Draft Assessment Reports in accordance with the EU criteria, built upon their experiences to date,
3. Further experience in the evaluation of a range of applications, particularly those for which borderline decisions must be made, would reinforce the training received from this project as well as assist in the development of appropriate guidelines/procedures for use in Slovenia.

In addition, further technical training will be required on Operator Exposure, once the appropriate individuals responsible for this aspect of the risk assessment have been designated.

The continuation of cooperation between experts in this project would be the most appropriate way of further training.
3.3. Results:
- Experts that are involved in scientific evaluation of dossiers are capable for preparing assessments and proposals for authorization of PPPs in accordance with EU implemented legislation and EU working practice for national authorisation and in accordance with the EU review programme.

3.4. Activities:
- Assessment of the current level of preparedness and expertise of the staff will take place at the beginning of each experts visit.
- Advising on evaluation and commenting draft assessment reports of active substances for plant protection products related to ongoing EC peer review process and decision making for the EC meetings. This will include the procedures for the assessment of the prepared monograph, preparation of comments, scientific evaluation of dossiers (all involved disciplines) and changes of the institutional structure regarding additional work related to EC decision making process.
- A two-week study tour of Slovene experts from institutes (as stated at point 6.2. Beneficiary) in the competent authority of a Member State to gain first-hand experience in scientific evaluation of dossiers and assessments of the monograph in all scientific disciplines related to the attending and negotiating in the EC decision making and scientific peer review meetings (experts will assess dossiers and monograph and prepare the comments and opinions for the experts).

3.5. Lessons learned:
- PHARE NP: SL9602.03: Under this project Slovene legislation was compared with the requirements of Acquis. The most significant weakness was the not-harmonized legislation. The recommendations suggested harmonization of legislation (Final report of the Phare project, PHARE NP: SL9602.03).
- PHARE NP: SL9704.01.02: During this project the institutional building system in Slovenia was reviewed in the field of authorization of Plant Protection Products. Legal aspects of EU Plant Protection Products legislation in Comparison with the Slovene law were made. The Ministry of Health and the Ministry of agriculture, forestry and food were involved as the two competent authorities in this organization. It was suggested to designate one competent authority for authorization procedure and some amendments to be made to the draft Act on Plant Protection Products, which should clarify the responsibility between two involved authorities (Final report of the Phare project, PHARE NP: SL9704.01.02).
- PHARE NP: SL99/IB-AG-02: This project covered administrative and control procedures for the use of Plant Protection Products worked out and implemented in line with Acquis. Procedure for registration of plant protection products with Ad Meijs from CTB, the Netherlands was discussed. The structure in the Netherlands was explained. The procedures for hazard evaluation and risk management of plant protection products were worked out. Some disparities with secondary EU Directives were worked out and recommendations were given. The limiting factor which was recognized was the size of staff to participate in all international and Community activities and meet all requirements. The recommendations and proposals for the
administrative procedures were given during the visit of Mr Meijs from 3 September to 11 September 2001.

- **PHARE NP: SI2001.01.03**: The aim of the project was review of the current situation in Slovenia and advice on organizational aspects and national procedures for registration of Plant Protection Products via Acquis and procedures for evaluation of dossiers at EU level. Mr Ad Meijs and Mr Pieter Oomen form Dutch authorities gave their expert view and opinion on legislation and organization of Slovene body for plant protection products evaluation in view to EU review program of active substances and evaluation of new substances. Mr Meijs visited Slovenia three times in the year 2002 and Mr Oomen twice in the year 2002; each visit lasted three days. Not enough personnel and unsatisfactory structure for authorization process, in particular as concerns the responsibilities of different authorities, were stressed. The awareness of the problematic areas lead to the proposal of another project in the form of a Twinning light in 2003.

- **PHARE NP: SI2001.02**: The most significant outputs of the Twinning light project SL02/IB/AG/04/TL were to assist in the development of appropriate mechanisms for the authorization of Plant Protection Products (PPP) and to train staff in the evaluation of PPP’s in accordance with EC requirements. The main recommendations: Formal interactions between those responsible for the evaluation of PPP’s will need to be built into the procedural/administrative systems used to manage the authorisation process. This will help to ensure that the impact of any decisions taken in one area are considered and implemented in another. Particularly for specialists with critical links it would be advantageous if they were brought together at one location (e.g. fate and behaviour with ecotoxicology, toxicology with residues and operator exposure). If this is not possible it is essential that communication between specialists is improved.

4. **Institutional Framework**:

The Phytosanitary administration of the Republic of Slovenia, former Administration of the Republic of Slovenia for Plant Protection and Seeds (ARSPPS), within the Ministry of Agriculture, Forestry and Food of RS (MAFF) is the responsible authority for the process of authorization of PPP’s. ARSPPS co-ordinates the work in the field of toxicology and ecotoxicology with the Ministry of Health – National Chemicals Bureau (NCB) and the Ministry of Environment, Spatial Planning and Energy. Experts for scientific evaluation of the dossiers for authorization are employed in different institutes and they are contracted to evaluate the parts of the dossiers by ARSPPS.

Experts from institutes are contracted on the long-term basis to evaluate parts of documentation for authorization of Plant Protection Products as follows: Physical – chemical properties with analytical methods, toxicology, ecotoxicology, residues, fate and behaviour in the environment and efficacy.

The positive (or negative) opinion on authorization of a plant protection product is given by the Committee for Plant Protection Products. Members of the Committee
are appointed by three ministers (responsible for health, agriculture and environment).

MAFF, ARSPPS issues the decision on authorization with the agreement of the Ministry of Health, National Chemicals Bureau.

Basic legislation for Plant Protection Products:
- Plant Protection Products Act (OJ RS 11/01),

Several Institutes give technical and scientific support to MAFF:
National Agriculture Institute in Ljubljana,
Institute for Hops and Brewing Research Žalec,
Agriculture Centre in Nova Gorica,
Biotechnical Faculty in Ljubljana,
National Institute for Public Health, Ljubljana

Inspectorate of the Republic of Slovenia for Agriculture, Forestry, Hunting and Fisheries as the body of MAFF is responsible for inspection control.

On the basis of the new Plant Health Act the Administration of the Republic of Slovenia for plant protection.

5. Detailed budget:

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<th>TF Support (in M€)</th>
<th>Investment Support</th>
<th>Institution Building</th>
<th>Total TF (=I+IB)</th>
<th>National Co-financing</th>
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Project will be implemented as continuation of training for 6 months. For that reason national component is earmarked in the National Budget. The national co-financing (25% of the total amount) will cover travel costs (flight tickets) for short-term training in MS on the preparation and evaluation of dossier and monograph writing for plant protection products.
6. Implementing Arrangements:

6.1. Implementing Agency:
Ministry of Finance – CFCU
Mr. Peter Škofič, PAO
Beethovenova 11
SI – 1000 Ljubljana
tel.: +386 1 478 62 03
fax.: +386 1 478 62 04
e-mail: peter.skofic@mf-rs.si

Implementing Authority:
Ministry of Agriculture, Forestry and Food
Unit for International Relations
Contact person: Mr. Marko Verbič, Head of the unit
Dunajska 56-58
SI - 1000 Ljubljana
tel.: +386 1 4789116
fax. +386 1 478 9021
e-mail: marko.verbic@gov.si

6.2. Twinning
Beneficiary:
The Phytosanitary administration of the Republic of Slovenia (PARS)
Dunajska 58
SI - 1000 Ljubljana,
tel.: +386 1 3094 384
fax.: +386 1 3094 335

Project Manager of the Project
The Phytosanitary administration of the Republic of Slovenia (PARS)
Project Manager: Mr Jernej Drofenik, Ph.D., Assistant to the Director
Dunajska 58
SI - 1000 Ljubljana,
tel.: +386 1 478 93 16
fax.: +386 1 478 91 75
e-mail: jernej.drofenik@gov.si

Twinning-Trainers:
Institutes/experts for scientific evaluation of dossiers for authorisation of PPP’ will
be the Final beneficiaries of the project:
- Slovenian Agriculture Institute Ljubljana, Hacquetova 17, SI-1000 Ljubljana,
- Institute for Hops and Brewing Research Žalec, Žalskega tabora 2, 3310 Žalec,
- Agriculture Centre in Nova Gorica, Pod Hrasti 18, Nova Gorica,
- Biotechnical Faculty Ljubljana. Jamnikarjeva 101, SI-1000 Ljubljana,
The project is designed to be implemented as prolongation of a twinning light project, consisting of short-term experts, study tours and specialist training.

6.3. Non-standard aspects:
Not foreseen.

6.4. Contracts
Ministry of Agriculture, Forestry and Food will be the Contracting Authority for this project. There will be one contract (Twinning Covenant) with a selected Member State.

7. Implementation schedule:

7.1. Start of tendering/call for proposals:
October 2004

7.2. Start of project activity:
January 2005

7.3. Project completion:
July 2005

8. Equal opportunity:
Participation will be open to both: female and male personnel. Records of staff participating in training and other project activities will reflect this statement.

9. Environment
Not applicable.

10. Rates of return:
Not applicable.

11. Investment criteria:
Not applicable.

12. Conditionality and sequencing:
- Phytosanitary Administration staffs and experts at contracted Institutes are available for implementing this project.
- Parties’ commitment to the implementation of the proposed project is subject to receipt of TF funds for the budget set out in the Memorandum of Understanding.
- All experts are already contracted by the Administration for scientific evaluation and they are involved in registration of PPP’s at national level. The experts who are involved in the project will to share the knowledge and experience with other experts.
ANNEXES TO PROJECT FICHE

1. Logical framework matrix in standard format (compulsory)
2. Detailed implementation chart (compulsory)
3. Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period) (compulsory)
4. List of relevant Laws and Regulations (optional)
## LOGFRAME PLANNING MATRIX FOR

### Project

**FURTHER ENFORCEMENT OF THE ACQUIS IN THE PHYTOSANITARY SECTOR - PLANT PROTECTION PRODUCTS**  

<table>
<thead>
<tr>
<th>Overall objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
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</thead>
</table>
| • The overall objective of this project is strengthening the Phytosanitary sector in the field of Plant Protection Products (PPPs) according to the principles and requirements of Directive EC 91/414. | • The Administration will meet the requirements according to Directive 91/414/EEC for (by the end of the project):  
  - Scientific evaluation of dossiers and assessment of monograph of active substances in EU review program;  
  - The Administration and experts will be fully prepared for attending and negotiating in the EC decision making and scientific peer review meetings. | • Final report of the project  
• Reports of Short Term experts. |

<table>
<thead>
<tr>
<th>Project purpose</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
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</table>
| • Strengthening the administration and technical capacity of the Republic of Slovenia in the implementation of the acquis relating to the Plant protection Products. | • Administration of the Republic of Slovenia for Plant Protection Products will take an active part in EU review programme and EC decision-making process (by the end of the project).  
• Trained experts involved in scientific evaluation of dossiers will be capable for preparing assessments and comments to represent, defend and argue the interests of Slovenia in EC meetings. | • Final report of the project  
• Reports of Short Term experts | • Present policy orientation and process of EU integration remains government priority |

<table>
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<th>Results</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
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| • The administrative systems and procedures for authorisation and assessment is finalized | • Administration will be fully prepared to take an active role (attending and | • Final report of the project  
• Reports of Short Term experts | • The system for authorization of PPP’s in |
and in line with Acquis not only on national level but also no EU level.

- Experts that are involved in scientific evaluation of dossiers are capable for preparing assessments and proposals for authorization of PPPs in accordance with EU implemented legislation and EU working practice for national authorisation and in EU review programme and are able to represent Slovenian interests effectively at EC meetings and through the peer review process.

- Staff involved in authorization process at administrative and scientific level is well qualified for this purpose.

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<th>Activities</th>
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<td>Assessment of the current level of preparedness and expertise of the staff will take place at the beginning of each experts visit.</td>
<td>At the beginning of each training the level of preparedness and expertise of the staff will be assessed.</td>
<td>Final report of the project Monitoring and IE Reports.</td>
<td>All institutions are contracted for evaluation of PPP’s. Effective cooperation with institutions is in place.</td>
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<td>Advising on specific procedures related to ongoing EC peer review process and the EC meetings. This will include the procedures for the assessment of the prepared monograph, preparation of comments, scientific evaluation of dossiers (all involved disciplines) and changes of the institutional structure regarding additional work related to EC decision making process.</td>
<td>The current procedures for national authorisation of PPP and institutional structure will be reviewed.</td>
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<td>Two-week study tours of Slovene experts to the competent authority in a Member State to gain first-hand experience for scientific evaluation of dossiers and assessments of the monograph in all scientific disciplines related to the attending and negotiating in the EC decision making and scientific peer review meetings (experts will assess dossiers and monograph and prepare the comments negotiating) in EU review programme (by the end of the project).</td>
<td>Experts will be trained to evaluate the dossiers, to assess the monograph, to identify critical issues in the prepared monograph, to prepare the comments and to include the national interests.</td>
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<td>The experts will be advised on specific procedures related to the EC peer review process and the EC meetings.</td>
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and opinions for the experts who will represent, defend and argue the interests of Slovenia in EC meetings).

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<th>Preconditions</th>
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<td>• All experts are already contracted by the Administration for scientific evaluation and they are involved in registration of PPP’s at national level.</td>
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Annex 2: Detailed Implementation chart

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Annex 3a – Contracting schedule

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Annex 3b – Disbursement schedule

CUMULATIVE DISBURSEMENT SCHEDULE  (EUR million)

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Annex 3c – Contracting and Disbursement schedule

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Annex 4: List of Relevant Laws and regulations


- Commission Directive 96/12/EC of 8 March 1996;


