STANDARD SUMMARY PROJECT FICHE

1. **Basic Information**

1.1 Project Number: SI0201.02
1.2 Twinning Number: SI02/IB/AG/04/TL
1.3 Title: Placing Plant Protection Products on the Market (91/414/EEC and 79/117/EEC)
1.4 Sector: AGRICULTURE
1.5 Location: SLOVENIA

2. **Objectives**

2.1. **Overall Objective(s):**
Complete alignment and enforcement of the Acquis in the Phytosanitary sector

2.2. **Project purpose:**
- Strengthening the Administration of the Republic of Slovenia for Plant Protection and Seeds in the field of plant protection products authorisation
- Meet the requirements following from the Acquis in the field of Plant Protection Products

2.3. **Accession Partnership and NPAA priority**

Reference to AP:
- Continue alignment in the veterinary and phytosanitary sector notably: complete the veterinary and phytosanitary inspection system in particularly at future external borders; continue to implement the quality control system; complete animal identification; continue aligning animal welfare standards; animal waste treatment; modernization of meat and diary plants residue and zoonosis control programmes.

Reference to NPAA: (May 2001 version of NPAA)
- Phytosanitary Field - ref: 4.1.7 (d)

3. **Description**

3.1. **Background and justification:**

As pre-accession country Slovenia is fully aware of the fact that harmonisation and implementation of the phytosanitary Acquis, which includes the field of plant protection products, with its enforcement and related institution building needs serious attention. With the aim to meet EU requirements in the field of plant protection products, Slovenia has already made the efforts to harmonise EU legislation, to inform and train the Slovenian staff about EU legislation and procedures.

Previous Phare programs contributed to some extend to reaching this aim and were found very useful and helpful. With their assistance a certain progress was achieved in the field of plant
protection products. A project under Phare 2001 will strengthen administrative procedure for the authorization of PPP’s in Slovenia, the certain unclarities on specific tasks (procedure, evaluations, assessments) will be removed, the authorization team will be built up in EU structured way of working by the completion of the project and relevant specialists from institutes will be trained for scientific evaluation of parts of the dossiers by the completion of the project. Administration of the Republic of Slovenia for Plant Protection and Seeds (ARSPPS) will authorize the experts with the contract payment for their technical assistance to ARSPPS. They will be responsible for their work to the director of ARSPPS. Further Phare assistance in further specific scientific training that will not be covered under the Phare program 2001 would be wished-for.

To enable Slovenia to meet all EU requirements following from the whole Acquis in the field of plant protection products, Phare assistance would be helpful to complete activities in the plant protection products field. Slovene side will work out the issues, which will not be covered by this project, in order to achieve the NPAA.

The new Plant Protection Products Act has been approved by Parliament on 30 January 2001. The act presents the legal basis for implementing the relevant Acquis into national legislation. The key secondary legislation is also in the process of preparation and will be adopted shortly after the legal basis is in place.

3.2. Linked activities:

**PHARE**

- **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 harmonisation 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 with preparation of Plant Health Act and 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 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 is concentrated in setting up the priorities and administrative procedures with regard the use of plant protection products.

- PHARE NP: SI2001.01.03
  A 2001 Institutional Twinning Programme for Implementation of the Phytosanitary EU-Acquis in Slovenia with the Netherlands in preparation will start 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, the certain unclarities on specific tasks (procedure, evaluations, assessments) are removed, the authorization team is built up in EU structured way of working by the completion of the project and some specialist are trained for scientific evaluation of parts of the dossiers by the completion of the project.

**NATIONAL COMPONENT**

- Every year the annual program is prepared by MAFF on the basis of NPAA, setting up the results, activities and responsibilities of each of the fields in the phytosanitary sector, including in the field of plant protection products. The program includes some basic study tours and short training programs to Member States, which are covered by national budget.

**3.3. Results:**

- Implementation of EU guidelines on authorisation of plant protection products.
- Experience gained from expert training in the field of evaluation of dossiers in authorisation process.
- Experience gained from expert training for participation in EU review programme.
- Implementation of GLP and GEP practice in the field of PPPs.

**3.4. Activities:**

- Formulation and execution of training programs.
- Assistance in the preparation of the guidelines and procedures.

**3.5 Lessons learned**

The project is a logical continuation of the process of complete alignment and enforcement of the acquis in the Phytosanitary sector and it is expected that the Plant Protection and Seeds Administration will have the full capacity to implement the acquis by December 31, 2002. The project will strengthen the administrative procedure for the authorization of Plant Protection Products (PPP’s) in Slovenia.
The implementation of acquis in the way of »learning by doing« has proved to be one of the most successful ways and means to prepare adequate documentation and procedures, relevant to full alignment of the system the Phytosanitary sector.

It is expected that a certain lack of clarity on specific tasks (procedure, evaluations, assessments) will be removed and the authorization team will be built up in EU structured way of working and relevant specialists from institutes will be trained for scientific evaluation of parts of the dossiers, by the completion of the project.

4. Institutional Framework

The new Plant Health Act (OJ RS 45/01) and Plant Protection Products Act (OJ RS 11/01) have been approved and the competent authority for harmonisation and implementation of the plant protection products Acquis is the Administration for Plant Protection and Seeds with cooperation of Ministry of Health and Ministry of Environment and Spatial Planning.

The Administration for Plant Protection and Seeds was established on 1. August 2001 and work on organizational chart and system continues. The Administration is the competent authority for authorization of Plant Protection Products, co-ordination, exchange of information, international matters in the field and for reporting to the EU Commission. ARSPPS performs administrative and technical tasks in accordance with Plant Protection Products Act.

At the ARSPPS, Division of PPP, three persons are already in place. Two more are needed to be employed or hired until 30.06.2002.

Ministry of Health, National Chemicals Bureau is responsible for tox and ecotox evaluation and co-operates in drafting legislation.

Ministry of Environment and Spatial Planing co-operates in drafting of legislation.

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.

The project cannot start before rules under the Plant Protection Products Act are adopted:
   - Rules on the documentation required for the evaluation of active substance
   - Rules on the documentation required for the evaluation of plant protection products,
   - Rules on the uniform principled for the evaluation and authorization of plant protection products and
   - Staff is provided for the system of authorisation of plant protection products.

Inspectorate of Republic of Slovenia for Agriculture, Forestry, Hunting and Fisheries as the body of MAFF is responsible for inspection control.
Production of PPP, placing on the market for the needs of production of PPP, good laboratory practice, the convention on the prior informed consent procedure (PIC) for certain hazardous chemicals and pesticides in international trade, classification, packaging and labeling of PPP, are regulated by the Act and rules on chemicals which are the responsibility of Ministry of Health.

On the basis of the new Plant Health Act the Administration of the Republic of Slovenia for plant protection and seeds will be set up within the MAFF. It will be the competent authority for administration, preparation of legislation, control and coordination in the field of plant health, seeds and planting material, plant varieties rights, plant protection products and for communication with EU Commission. It is foreseen to have approximately 20 staff in total. Administration will be consisted of 5 divisions, of which one will be the division for plant protection products. The Chiefs of the divisions will be directly responsible to the director of the Administration, who will be responsible to the minister of MAFF. The headquarter will be in Ljubljana.

5. Detailed Budget

<table>
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<tr>
<th>Phare Support</th>
<th>Investment Support</th>
<th>Institution Building</th>
<th>Total Phare (=I+IB)</th>
<th>National Co-financing*</th>
<th>IFI*</th>
<th>TOTAL</th>
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<td>In MEURO</td>
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Project will be implemented as a twinning light project for 6 months. For that reason national component is earmarked in the National Budget. The national co-financing (29% of the total amount) will cover travel costs (flight tickets) and costs for training (10 days) in MS on the preparation and evaluation of dossier and reports for registration of plant protection products.

6. Implementation Arrangements

6.1. Implementing Agency

Ministry of Finance – CFCU
Responsible person: Mr. Peter Škofic, PAO.
Beethovenova 11,
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
Mr. Marko Verbic, Head of the unit
Dunajska 56-58
6.2. Beneficiary:
Beneficiary will be ARSPPS, MAFF.
ARSPPS
Project Manager will be Ms. Milena Koprivnikar, Head of the Plant Protection Products Division, Dunajska 58, 1000 Ljubljana,
tel.: +386 1 478 9133
fax.: +386 1 478 9021,
e-mail: milena.koprivnikar@gov.si

6.3. Twinning
The project is designed to be implemented as a twinning light package, consisting of short term experts, study tours and specialist training.

6.4. Non-standard aspects
PRAG for SAPARD, ISPA and PHARE will be strictly applied and followed.

6.5. 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
   3rd Quarter 2002
7.2 Start of project activity
   October 2002
7.3 Project Completion
   March 2003

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. Conditionality and sequencing
The new Plant Health Act (OJ RS 45/01) and Plant Protection Products Act (OJ RS 11/01) have been approved.

On 1st August 2001 the Administration for Plant Protection and Seeds was established and work on organizational chart and system continues. The Administration is the competent authority for authorization of Plant Protection Products, co-ordination, exchange of information, international matters in the field and for reporting to the EU Commission. ARSPPS performs administrative and technical tasks in accordance with Plant Protection Products Act.

Parties commitment to the implementation of the proposed project is subject to receipt of Phare funds for the budget set out in the FM.

The project can start if rules under the Plant Protection Products Act are adopted:
- Rules on the documentation required for the evaluation of active substance,
- Rules on the documentation required for the evaluation of plant protection products,
- Rules on the uniform principled for the evaluation and authorization of plant protection products.

These rules are implementing the requirements for the documentation for authorization of plant protection products and uniform principles for evaluation as in Annexes II, III and VI of Directive 91/414/EEC.

Staff (two more persons) is provided for employment at ARSPPS for plant protection products division until 30. June 2002. However, the training of scientists according to this program is provided for staff at institutes that are contracted to do the scientific work for the evaluation of plant protection products in the process of authorisation.
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. Reference to feasibility /pre-feasibility studies. For all investment projects, the executive summary of the economic and financial appraisals, and the environmental impact assessment should be attached (compulsory)
5. List of relevant Laws and Regulations (optional)
6. Reference to relevant Government Strategic plans and studies (may include Institution Development Plan, Business plans, Sector studies etc) (optional)
7. Terms of reference
### ANNEX 1: PHARE LOG FRAME

#### LOGFRAME PLANNING MATRIX FOR PROJECT

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<td>Disbursement period expires</td>
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<td>Total budget : 0.21 EUR million</td>
<td>Phare budget : 0.15 EUR million</td>
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**Overall objective**

- Complete alignment and enforcement of the acquis in the Phytosanitary sector

**Objectively verifiable indicators**

- Positive Commission opinion on the alignment and enforcement of the phytosanitary legislation by 31. December 2003
- Accession to the EU

**Sources of Verification**

- Commission regular reports on the progress with the approximation and adaptation of the phytosanitary legislation

**Project purpose**

- Strengthening the Administration of the Republic of Slovenia for Plant Protection Products authorisation
- Meet the requirements following from the Acquis in the field of Plant Protection Products

**Objectively verifiable indicators**

- Evaluation experts are trained according to EU working practice in the field of authorisation of PPP’s and are able to apply the EU working practice
- The system of authorisation is in line with the Acquis

**Sources of Verification**

- Final report of the project
- Commission regular reports on the progress with the approximation and adaptation of the phytosanitary legislation

**Assumptions**

- Present policy orientation and process of EU integration remains government priority
<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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</table>
| • Implementation of EU guidelines on authorisation of plant protection products. | • Experts for evaluation of dossiers of PPP’s are familiar with procedures, models and guidelines in the field of authorisation of PPP’s.  
• Experts and members of staff in the Plant Protection Products Administration of Slovenia are familiar with EU review programme and work of the bodies of EU Commission.  
• Experts from laboratories are familiar with GLP procedures.  
• Institutions for evaluation and performing efficacy tests are familiar with GEP and EPPO standards.  
• Uniform principles for evaluation are implemented. | • Final report of the project  
• Commission regular reports on the progress with the approximation and adaptation of the phytosanitary legislation  
• Set of documentation (guidelines, training programs, study tours reports, written procedures)  
• EC missions reports | • The system for authorization of PPP’s in Slovenia is fully in line with EU legislation  
• Staff involved in authorization process at administrative and scientific level is well qualified for this purpose |

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<tr>
<th>Activities</th>
<th>Means</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
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</table>
| • Formulation and execution of training programs.  
• Assistance in the preparation of the national guidelines and procedures. | • Technical assistance by short-term experts.  
• Training of Slovene staff with study tours, seminars, training programs. | • Final report of the project                                                                 | • None                                                                                          |
Preconditions

- Secondary legislation under new Plant Protection Products Act are adopted and in force:
  - Rules on the documentation required for the evaluation of active substance,
  - Rules on the documentation required for the evaluation of plant protection products,
  - Rules on the uniform principled for the evaluation and authorization of plant protection products
- Human resources available at institution level
Annex 2: Implementation time chart

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Annex 3: Contracting schedule (sheet 1)

NB See also sheet 2 for disbursement schedule

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### CUMULATIVE CONTRACTING SCHEDULE (EUR million)

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NB: all contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of FM
Annex 3: Disbursement schedule (sheet 2)

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Name and Number of programme


SI0201.02

CUMULATIVE DISBURSEMENT SCHEDULE  (EUR million)

NB all disbursements must be completed within 36 months of signature of the FM
Annex 3: Contracting and disbursement schedule (sheet 3)

Name and Number of programme

SI0201.02

CUMULATIVE CONTRACTING and DISBURSEMENT SCHEDULE (EUR million)

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NB: 1. all contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of FM
Annex 5: List of Relevant Laws and regulations


 TERMS OF REFERENCE – TWINNING LIGHT

Program Title: PLACING PLANT PROTECTION PRODUCTS ON THE MARKET
Project Number: SI 0201.02
Twinning Number: SI02/IB/AG/04/TL

1. Background

The overall objective of this twinning light project is to apply Acquis in the area of plant protection products.

2. Description of the Assignment

2.1. Beneficiary

Beneficiary:
Beneficiary will be ARSPPS (Administration of the Republic of Slovenia for Plant Protection and Seeds), MAFF.

ARSPPS
Project Manager will be Ms. Milena Koprivnikar,
Head of the Plant Protection Products Division,
Dunajska 58, 1000 Ljubljana,
tel.: +386 1 478 9133
fax.: +386 1 478 9021,
e-mail: milena.koprivnikar@gov.si

Institutes, where the experts for scientific evaluation of dossiers for authorization of PPP’s are employed, will be the final beneficiary for this project:
Administration of the Republic of Slovenia for Plant Protection and Seeds
Ministry of Health – National Chemicals Bureau.

Administration of the Republic of Slovenia for Plant Protection and Seeds is responsible authority for the process of authorization of PPP’s. ARSPPS co-ordinates the work in the field of toxicology and ecotoxicology with Ministry of Health – National Chemicals Bureau (NCB). Expert 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 and NCB.

Implementing Agency

Ministry of Finance – CFCU
2.2. Global and specific objectives

This project will support training of experts in the field of evaluation of dossiers for implementation of EU working practice into authorization process in the Republic of Slovenia.

2.3. Requested services

General services to be provide:
Advising and help with specific procedures within authorization process of PPP's.
Two week study tours of Slovene experts to authority in a Member State.

Specific tasks to be provide:

The following tasks should be done:
- Qualifying of experts for maintenance of the dossiers; completeness checking, parts of dossiers, detailed examinations, hazard and risk assessment, reporting and making proposals for the decisions,
- Evaluation of the dossier for authorization of PPP’s in the field of biological efficacy, implementation of GEP requirements, PPP assessment – efficacy,
- Evaluation of the dossier for authorization of PPP’s in the field of toxicology, PPP assessment - risk consumer, risk operator,
- Evaluation of the dossier for authorization of PPP’s in the field of fate and behavior,
- Evaluation of the dossier for authorization of PPP’s in the field of ecotoxicology, PPP assessment – risk environment (water, soil, air, organisms),
- Evaluation of the dossier for authorization of PPP’s in the field of biological products.
The commitment of the beneficiary

Activities under the responsibility of ARSPPS, MAFF, Dunajska 58, 1000 Ljubljana.
Ms.Milena Koprivnikar, Head of the Plant Protection Products Division, (tel.: +386 1 478 9133)

2.4. Expected results:

The system of authorization of PPP’s in the Republic of Slovenia is in line with Acquis in this field. Experts that are involved in scientific evaluation of dossiers are capable for preparing assessments and proposals for authorization in accordance with EU implemented legislation and EU working practice.

3. Experts profile:

Short-term expert:

Expert from authority responsible for authorization of PPP’s in a Member State with good knowledge of authorization procedure, especially knowledge of Directive 91/414/EEC and EU working practice, university degree, good communication skills, excellent knowledge of English language and computer literacy.

4. Location and duration:

The project shall start in October 2002 and conclude at the end of March 2003.
The short-term expert will visit Ministry of Agriculture, Forestry and Food.

4.1 Schedule and Number of Days for the Assignment

4.1.1 Time provision for Short-term expert:
- Expert in general, working through dossier for registration of PPP's with scientific experts in a working party – 15 days,
- Expert for biological efficacy testing – 10 days,
- Expert for toxicology evaluation of PPP's – 15 days,
- Expert for fate and behaviour evaluation of PPP’s – 15 days,
- Experts for ecotoxicological evaluation of PPP's – 15 days,
- Expert for evaluation of dossier for biological products – 10 days.

4.1.2 Study visits - training of experts involved in authorization process in terms of scientific evaluation of parts of dossiers:
- Training of experts for biological efficacy evaluation of PPP's in a MS – 30 working days,
- Training of two expert for toxicology evaluation of PPP's in a MS – 30 working days,
- Training of three experts for fate and behaviour evaluation of PPP's in a MS - 45 working days,
- Training of four experts for ecotoxicological evaluation of PPP's in a MS – 55 working days,
- Training of two experts for evaluation of dossier for biological products in a MS - 30 days.
5. Reporting

5.1 Content, language, format and number of reports
The contractor shall submit the following reports to the Implementing Authority, Ministry of Agriculture, Forestry and Food, Dunajska 56, 1000 Ljubljana (contact person: Mrs. Marko Verbic, tel. 4789116; fax 4789155), CFCU (Head of Unit, Mr. Peter Škofic, tel. 478 62 03; fax 478 62 04) and EC Delegation (Head of Phare/ISPA Section, Mrs. Bettina Kotzinger, tel. 4251 303; fax 4252 085):

- An Inception Report after two months of the signing of the contract. This report will cover the capacities and the methodology of work of all counterparts with recommendations for improvements; prepared separately by each expert (3 Inception reports).
- Final Report shall be submitted no later that two weeks after the end of the project and prepared in co-ordination with all experts (only 1 report).

All the Reports must include the description of all activities that have been performed as well as the problems encountered and solutions proposed. The Final Report should include the Executive Summary. Reports will be endorsed by the Ministry of Agriculture, Forestry and Food, who may make additional comments.

The reports shall be written in English language and follow the template included as Annex C in the twinning manual.

The Contractor shall produce 3 copies for each report.

5.2 Date of submission
- An Inception Report two months after the start of the project;
- Final Report shall be submitted no later than two weeks after the end of the project.