Standard Summary Project Fiche

1. Basic Information:

1.1. Desiree Number: CZ00-05-03
1.2. Title: Strengthening the Central Regulatory Capacity of Plant Protection Products Registration
1.3. Sector: Ministry of Agriculture (MoA); Ministry of Health (MoH)
1.4. Location: Czech Republic
   MoA - State Phytosanitary Administration / Division of Registration of Plant Protection Products in Brno (further only the "SPA"); and the MoH - National Institute of Public Health / National Reference Centre for Pesticides in Prague (further only the “NIPH”)

2. Objectives

2.1. Wider Objectives:
   • To adopt and implement the acquis communautaire in the areas of the internal market and agriculture, in relation to plant protection products (further PPP) - EC Directives 91/414/EEC, 97/57/EC; Regulation 451/2000;

2.2. Immediate Objectives
   • Strengthen and complete the nation-wide central regulatory capacity of the Czech Republic in the frame of registration/authorisation of the PPP/active ingredients, post-registration control of the market with and handling these products in the Czech Republic.

By implementing the project full capacity for the implementation of and full harmony with the relevant acquis for the whole sub-sector of the registration of the PPP will be accomplished.

2.3. Accession Partnership and NPAA Priority

AP short-term priorities - agriculture
   • phytosanitary sector: continue alignment and upgrade inspection arrangements

NPAA - short/medium term - agriculture
   • introduction and implementation of a harmonised registration/authorisation system for the plant protection products

3. Description

3.1. Background / Justification:

The project concerns the sub-sector of the plant protection products. The State Phytosanitary Administration (SPA) and the National Institute of Public Health (NIPH) are the central & official authorities of the Czech Republic in the sub-sector (according to the Art.2 (11) and Art 17 of the Council Directive 91/414/EEC) and they are responsible for the full implementation in the Czech Republic of the acquis requirements in the field of plant protection products.

The State Phytosanitary administration has to ensure the fulfilment of the EU requirements as follows:
• evaluation and authorisation of active ingredients in frame of the EU work programme (Directive 91/414/EEC, Art.5, 6, 8.2; Regulation No.451/2000);
• application of the uniform principles for the evaluation of the PPP (Directive 91/414/EEC, Art.18.1, Annex VI);
• implementation of EC provisions as related to data submission, data protection and confidentiality (Directive 91/414/EEC, Art. 13).

In particular the following has to be implemented:

- the registration authority (State Phytosanitary Administration) enables the applicants to submit their registration dossiers in the electronic form,
- continuous official checking of the authorised plant protection products must be performed to see whether they comply with the EU requirements as to their efficacy and impact to the environment, crops, users and consumer,
- all the activities during the PPP assessment must be realised in conformity with the principles of Good Laboratory Practice and Good Experimental Practice (within both the registration and supervisory processes),
- the assessment system of active ingredients and the list of authorised active ingredients must be completed,
- the system of PPP toxicological risk assessment must comply with EU standards.

The project is intended to complete adequate implementation capacity for the assessment of the plant protection products and active ingredients in accordance with the requirements of the Council Directives 91/414/EEC, 97/57/EC and 79/117/EEC as well as of the relevant Commission Guidance Documents.

At present the insufficient quantity and standard of information technology and laboratory equipment do not reach the level that could ensure implementation of the regime required by the acquis.

The insufficient implementation capacity of the SPA and NIPH for assessment and registration (authorisation) of the active substances and products in accordance with the requirements of the relevant EC Directives was indicated in the course of the screening proceedings in Brussels (November 1999).

3.2. Linked Activities

The current project is complementary - in terms of strengthening the regulatory capacity of the SPA - to the Phare support to the plant quarantine (i.e. “plant health - harmful organisms”) sub-sector in the Czech Republic, as provided in frame of Phare projects CZ9703-01-02-04 and CZ9903-02. These projects started in the IV.Q/1999 and I.Q/2000 respectively and the contract will terminate by IV.Q/2000, IV.Q/2001 respectively, at the latest.

A bilateral activity was realized between the Czech republic and Germany. On request of the Director of the SPA three senior officials from the Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA) Braunschweig (Germany) were sent by the President of the BBA to the SPA at the end of 1999. The principal aim of their mission was to assess the capacity of the SPA for the full implementation of the EU registration and supervision regime in the field of the plant protection products. The result of the mission was described in a document “Dienstreisebericht über einen Arbeitsbesuch von BBA – Mitarbeitern in der State Phytosanitary Administration der Tschechischen Republik in Brno vom 6. Oktober bis 8. Oktober 1999”. The BBA Experts mentioned therein the necessity of the completion of the SPA capacity especially in laboratories and information system. The assessment of the document from the requested audit was the main impulse for the preparation of the project.
Preparation of the amendment of the Act No. 147/1996, thus reaching full compliance between the Czech legislation and relevant acquis and providing for its full enforcement in the Czech Republic. It will be promoted throughout the bilateral co-operation with Germany and with the help of TAIEX.

With reference to Co-ordination Regulation 1266/99 Articles 2 & 4 on Phare / SAPARD aid, the present project will take into consideration the measures that may be set up under SAPARD programme as for phytosanitary standards (the SAPARD Agriculture and Rural Development still has to be approved by the Commission).

3.3. Results/Outputs

- full capacity achieved for evaluation and authorisation/registration of the PPP and active ingredients thereof, complying with the provisions for data submission / protection / confidentiality
- ensured implementation capacity for the process of the active substance assessment according to the EU regime on the level of the Rapporteur Member States (according to the Regulation 933/94 and 3600/92) and plant protection products registration according to the Directive 91/414/EEC, Annex VI. (Directive 97/57/EC)
- ensured capacity for the implementation of all relevant Commission Guidance Documents and their requirements as to the Good Laboratory Practice (GLP) and Good Experimental Practice (GEP)
- post-registration control over the products on the market and over the users established in accordance with EU acquis
- speeded up process of the documentation dossiers for the plant protection products registration assessment by the implementation of the computerised information system analogous and compatible with EU systems (CADDY) which will facilitate the situation of the applicants (especially from EU-member states)
- fully compatible software with EU and increased hardware capacity to the level necessary for the implementation of EU system
- ensured capability of being effective as a “rapporteur” state within the active ingredient evaluation.

Activities / Inputs

PHARE activities:
Investment in institutional building:
Part (1)
⇒ SW, HW - see details in Annex 7
Procurement of the specific SW, which is used by the Member States for assessment of dossiers on active substances and products, compatible with EU systems
Acquisition of programmes for mathematical models of fate and behaviour of products, active substances and residues in accordance with requirements of EC-directives and Commission Guidance Documents. Further the SW for formation of the database on properties of the products etc. The supplies comprise short/brief training of users.
Acquisition of the relevant HW.

Part (2)
⇒ Laboratory equipment - see details in Annex 6

Exchange (modification) and complementation of the instrumental equipment of the SPA and NIPH laboratories (located in Brno - SPA and in Prague - NIPH) for registration and post – registration supervision over the plant protection products for completion the sufficient capacity for the implementation of the requirements of EC-directives (Good Laboratory Practice, Good Experimental Practice). The supplies comprise short/brief training of users. It is foreseen, that a single contractor will supply the whole set of the laboratory equipment.

Detail Technical specification will be prepared in close co-operation with Twinning expert (Phare 1999).

Activities financed by the Czech side

Laboratory Equipment, Inspection & Sampling

Equipment of the ecological-risks laboratories, testing laboratory in Application Technique Department and the laboratories for the assessment and post-registration check up on the chemical products (assessment of biological efficacy, phytotoxicity, resistance) and on the biological products for completion the sufficient capacity for the implementation of the requirements of EC-directives (Good Laboratory Practice, Good Experimental Practice). The supplies comprise short/brief training of users.

Transport devices for inspection activity and transfer of samples for safeguarding the supervision of handling the plant protection products in accordance with EU requirements.

Building reconstruction, Administrative equipment

Reconstruction of the technical library of the SPA, establishment of the registration documentation archives, building reconstruction and mechanisation of the glasshouse provided with boxes for evaluation needs, post-registration check-up and verification of indications for minor indications and reconstruction and renovation of other technical facilities for completion the sufficient capacity for the implementation of the requirements of EC-Directives (Good Laboratory Practice, Good Experimental Practice).

Acquisition of copying machines and scanners for the capacity increase in accordance with EU requirements on the registration dossiers assessment and handling.

4. Institutional Framework

State Phytosanitary Administration (SPA) is directly subordinated to the Ministry of Agriculture and functions as the national single and central authority of the Czech Republic in the phytosanitary field for the “plant health (harmful organisms)” and “plant health (pesticides)” sub-sectors, according to the Act N° 147/1996 of the Law Book and in accordance with Art.2(11) and 17 of the Council Directive 91/414/EEC. The Division of Plant Protection Products and Means for Application (seated in Brno) is responsible for the plant protection products registration and supervision of handling them. The Department of Application Techniques is also involved in the registration process. It evaluates packaging of the plant protection products and application methods.

National Institute of Public Health (NIPH) is directly subordinated to the Ministry of Health. Its role is the protection of public health and health promotion.

The National Reference Laboratory for Pesticides is responsible for the assessment of toxicological properties of plant protection products as concerned to the human health during the registration process.

The implementation of the project will ensure the full discharge of the responsibilities of both the institutions with the requirements of the EU and Czech legislation.
5. Detailed Budget (in M €)

<table>
<thead>
<tr>
<th>Project Components</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>
</tr>
</thead>
<tbody>
<tr>
<td>Investment in IB</td>
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<td>part (1) – SW, HW</td>
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<tr>
<td>part (2) - laboratory equipment</td>
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<tr>
<td>Czech Co-financing:</td>
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<td>Laboratory equipment, Inspection &amp; Sampling</td>
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<td>Building reconstruction, Administrative equipment</td>
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</table>

* The Ministry of Finance confirms that the Czech financial resources for the project are included in the State Budget

6. Implementation Arrangements

6.1. Implementing Agency
Responsibility for the administration related to the procedural aspects of procurement, contracting and accountancy will rest upon the CFCU.
Responsibility for the administration related to the preparation, technical control and implementation will rest with the Ministry of Agriculture and Ministry of Health.
The contact person of the project is:

Mr. Stepan KUZMA - SPA, Plant Protection Products Division, Head;
Mail: Tesnov 17, CZ-11705, Praha 1;
Office: Zemedelska 1a, CZ-61300, Brno
Tel.: +420.5.45137039; answering mach.tel.: +420.5.573196 /Fax: +420.5.45211078;
E-mail: kuzma@srs.cz

6.3 Non–Standard Aspects
DIS Manual procedures will be followed. One direct contract for special PPP SW is expected

6.4. Contracts:
One procurement contract is foreseen = 2 M €.

7. Implementation Schedule

Project duration: 12 months
7.1 Start of tendering/launch: I/ Q 2001
7.2 Start of project activity II / Q 2001
7.3. Project Completion II/Q 2002

8. Equal Opportunity
Equal opportunity principles and practices in ensuring equitable gender participation in the Project will be guaranteed.

9. Environment

No negative direct environmental impact is foreseen. The project will have a positive effect on the environment (the reduction of the environmental load in the Czech republic as well as in the neighbouring states).
10. Rates of return : N/A

11. Investment criteria: The investment is to be tendered immediately. Specifications will be reviewed by independent experts within the framework of twinning where possible and appropriate.

12. Conditionality and sequencing

− The important assumption of the full implementation of the relevant acquis is the approval of the amendments of the Act N° 147/1996, which is expected to take place in two steps, coming into force on 01-01-2001 and 01-01-2002 respectively.
− Allocation in the national budget of the Czech Republic of needed funds for co-financing of the Project is the fundamental presumption for the full achievement of the project objectives.
− Spatial and personal adjustments within the NIPH prior to the supplies of laboratory equipment are essential element of the correct sequencing.
− The realisation of the project will ensure the full implementation and enforcement of the Czech harmonised legislation in the frame of the plant protection products registration and supervision of handling them by 31 December 2002 and thus undertaking the full regime required by acquis communautaire before the assumed date of the Czech Republic accession to the EU.

ANNEXES TO PROJECT FICHE

1. Logical framework matrix
2. Detailed implementation chart
3. Contracting and disbursement schedule
4. List of relevant Laws and Regulations
5. Reference to relevant government and other strategic plans and studies
6. Proposal of technical specification of SPA supply
7. Detailed information on SW supply
### Logframe Matrix

<table>
<thead>
<tr>
<th>Wider Objectives</th>
<th>Indicators of Achievement</th>
<th>Measurement of Indicators</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>⇒ To adopt and implement the <em>acquis communautaire</em> in the areas of the internal market and agriculture, in relation to plant protection products (further PPP) - EC Directives 91/414/EEC, 97/57/EC; Regulation 451/2000</td>
<td>⇒ “rapporteur state” complied management of the evaluation of the PPP active substances, ⇒ 391L0414, Annex VI complied management of the evaluation/authorisation of the PPP by II Q 2002</td>
<td>⇒ Ministry of Agriculture (MoA), ⇒ Ministry of Health (MoH), ⇒ State Phytosanitary Administration (SPA) ⇒ National Institute of Public Health (NIPH)</td>
<td>⇒ consistent policy and legal flexibility towards harmonisation, ⇒ shortage of financial co-financing resources and/or in running costs legal amendments enforced</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immediate Objectives</th>
<th>Indicators of Achievement</th>
<th>Measurement of Indicators</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>⇒ Strengthen and complete the nation-wide central regulatory capacity of the Czech Republic in the frame of registration/authorisation of the PPP/active ingredients, post-registration control of the market with and handling these products in the Czech Republic</td>
<td>increased quality of the system of registration of the PPP in the Czech Republic - EU uniform principles applied, EU fully harmonised regime achieved by II.Q 2002, strengthening/extension of capacity for the PPP registration to 35 authorised PPP per year (in 1999 - 6 PPP per year); ⇒ post-registration control of the PPP carried out according to Article 17 of the EC Directive 91/414/EEC, ⇒ filled in the “indicational gaps” within the minor crops by 10 gaps annually by II.Q 2002</td>
<td>⇒ project manager, contact persons and experts from relevant technical departments and institutions</td>
<td>⇒ consistent policy and legal flexibility towards harmonisation, ⇒ shortage of financial co-financing resources and/or in running costs legal amendments enforced</td>
</tr>
</tbody>
</table>
### Outputs

| ⇒ control over the products on the market and over the users in accordance with EU legislation requirements |
| ⇒ the speeding up of the process of the documentation dossiers for the plant protection products registration assessment by the implementation of the computerised information system analogous and compatible with EU systems (CADDY) which will facilitate the situation of the applicants (especially from EU-member states) |
| ⇒ practising all the activities during the process of assessment and supervision in accordance with EU standards |
| ⇒ lessening of the number of the indication gaps (minor use indications) |

### Indicators of Achievement

| ⇒ the relevant acquis including “guidance documents” implemented in the Czech Republic by II Q 2002 |
| ⇒ ⇒ start of submission of the registration dossiers in the electronical (computerised) form by II Q 2002; ⇒ start of assessment of all parts of the registration dossier in the electronical (computerised) form by II Q 2002; |
| ⇒ number of annually authorised PPP increased from 6 (in 1999) to 35 by II Q 2002; |
| ⇒ PPP post-registration control operated in compliance with Article 17 of 91/414/EEC Directive; ⇒ 10 „indication gaps“ (minor use) filled in yearly by II.Q 2002 |

### Measurement of Indicators

| ⇒ contractors and their experts, ⇒ contracting authority, ⇒ project manager |

### Assumptions and Risks

| ⇒ good co-operation of the contractors with technical departments, shortage of national funds for future maintenance |

### Inputs

| ⇒ software procurement/upgrade, ⇒ supplies of the laboratory equipment ⇒ hardware supplies |

### Indicators of Achievement

| ⇒Software, laboratory equipment, hardware supplied and in function by II Q 2002. |

### Measurement of Indicators

| ⇒ contractors and their experts, ⇒ departments at ministries/SPA/NIPH |

### Assumptions and Risks

| ⇒ legal amendments of the Act 147/1996 enforced ⇒ capability of supervisors |
### Detailed Implementation Chart for the Project

<table>
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<tr>
<th>Detailed Project Implementation</th>
<th>2000</th>
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<th>2002</th>
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<tr>
<td>- Tender Launch</td>
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<tr>
<td>- Contract Signature</td>
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<td>Project completion</td>
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### Cumulative Contracting and Disbursement Schedule for the Project (M €)

**Annex 3**

#### Cumulative Quarterly Contracting Schedule (M €)

<table>
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<tr>
<th>Project</th>
<th>3Q/00</th>
<th>4Q/00</th>
<th>1Q/01</th>
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#### Cumulative Quarterly Disbursement Schedule (M €)

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<th>1Q/03</th>
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</table>
List of Applicable Laws

Czech Legislation

The Act No 147/1996 of the Law Book on the Phytosanitary Care

Decree of the Ministry of Agriculture No 84/1996 of the Law Book (as amended) of 4 April 1997, regulating the authorisation process for plant protection products, handling these products and technical and technological requirements for plant protection application techniques and testing of these techniques

The Act No 157/1998 of the Law Book on Chemical Substances and Chemical Preparations and on Amendments to Some Other Acts, including its implementative decrees

EU – legislation


Commission Guidance Documents: 7109/VI/96, 1694/VI/95, 4952/VI/95, 6476/VI/96, 7617/VI/96, 7017/VI/95, 1663/VI/94, 1654/VI/94, 1614/VI/95, 1663/VI/95, 7600/VI/95, 7860/VI/97, 7860/VI/97

Reference to relevant government and other strategic plans and studies

• Biologische Bundesanstalt für Land-und Forstwirtschaft (BBA) Braunschweig (Germany)


CZ 00-05-03
PHARE Activities:

part (1) - SW, HW:
Procurement of the specific SW, which is used by the Member States for assessment of dossiers on active substances and products, compatible with EU systems

Acquisition of programmes for mathematical models of fate and behaviour of products, active substances and residues in accordance with requirements of EC-directives and Commission Guidance Documents. Further the SW for formation of the data bank on properties of the products etc. and training of users.

part (2) - Aquisition of the HW:
renewal and complementation of the computer net of the SPA in Brno and NIPH in Prague

- server for the SPA (Brno) 1 piece
- the PC for the SPA 50 sets
- and NIPH 15 sets
- laser-quality printers for the SPA 35 pieces
- and for NIPH 15 pieces
- Presumed investment 0,62 M€

Exchange (modification) and complementation of the instrumental equipment of the SPA and NIPH laboratories for registration and post – registration supervision over the plant protection products:

SPA:
- verification of chemical composition of the active substances and products for plant protection
- verification of physical, chemical and technical properties of the plant protection products
- verification of analytical methods

NIPH:
- estimation of the content of the residues of the active substances and relevant metabolites in / on treated crops and plant products regarding setting of safety intervals and MRLs.
- Target post – registration supervisions over the residues of the active substances and relevant metabolites
- Verification of the guidelines used in the activities to the items a) and b).

- Gas chromatograph 5 pieces
- High Pressure Liquid Chromatograph equipment 3 pieces
- Gas chromatograph with mass spectrometer detector 2 pieces
- Apparatus for capillary electrophoresis 1 piece
- Laboratory centrifuge 2 pieces
- High Pressure Liquid Chromatograph equipment with mass spectrometer detector 2 pieces
- Laser particle size analyser 1 piece
- Thermal analysis equipment 1 piece
- Automatic tensiometer 1 piece
- Densitometer 1 piece
- Viscometer 1 piece
- Infra-red spectrometer 1 piece
- Accelerated solvent extractor 1 piece
Activities financed by the Czech side

Building up and equipment of the biological-risks laboratories, testing laboratory in the Department of Application technique and laboratories for assessment and post-registration check up on the chemical products (assessment of biological efficacy, phytotoxicity, resistance) and on the biological products

Microscopes and optics

<table>
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<tr>
<th>Item</th>
<th>Quantity</th>
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<td>stereomicroscope</td>
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<td>digital photo for documentation of small plots experiments</td>
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Presumed investment 0,11 M€

Laboratory equipment

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<td>autoclave – vapour sterilization</td>
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<td>bio-thermostat/dark</td>
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<td>bio-thermostat/light</td>
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<td>biobox</td>
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<td>laboratory weight</td>
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<td>analytic weight</td>
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<td>precise weight</td>
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<tr>
<td>register temperature and air humidity</td>
<td>7 pieces</td>
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<tr>
<td>heatair drying house with air conditioning</td>
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<tr>
<td>expandable ion analyser</td>
<td>1 piece</td>
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<td>gas-specific ammonia-electrode</td>
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<td>ion selective nitrate-electrode</td>
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Presumed investment 0,08 M€

Application technique equipment

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<td>sprayer for small plots experiments</td>
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<tr>
<td>test stand with 100 mm wide and at least 80 mm deep grooves</td>
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<tr>
<td>test facility for measuring liquid flow</td>
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<tr>
<td>for measuring pump capacity</td>
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<td>for checking flowmeters</td>
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<td>for testing manometers</td>
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<td>test facilities to measure the single nozzle output of sprayers</td>
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<tr>
<td>and air-assisted sprayers for high crops</td>
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Presumed investment 0,06 M€

Inspection and samples

Transport devices for inspection activity and transfer of samples

Presumed investment 0,10 M€
Building reconstruction

Reconstruction of the technical library of the SPA and establishment of the registration documentation archives; building reconstruction and mechanisation of the glasshouse provided with boxes for evaluation needs, post-registration check-up and verification of indications for minor indications and reconstruction and renovation of other technical facilities, reconstruction and spatial adjustment of the NIPH laboratories.

Presumed investment 0,27 M€

Administrative equipment

copying machines 6 pieces
scanners 5 pieces

Presumed investment 0,05 M€
Detailed Information on SW:

PHARE Activity : SW - CADDY

CADDY system is an electronic dossier interchange and archiving format for plant protection products registration applications (Computer Aided Dossier and Data Supply). It facilitates the provision of dossiers for pesticides to regulatory authorities (enables the use of CD-ROMs replacing the need to supply multiple paper submissions and standardises EU format), the long-term archiving of such dossiers and the accessibility of information contained in a cost-effective manner using electronic media.


References:
- Document Interchange Format For Pesticides Registration Applications Format Specification CADDY 1.1 / September 23, 1997
  Joint EU Member States / ECPA Data Transfer Steering Group
- CADDY Standard Retrieval Software
  Software Specification Version 0.3 / February 7, 1997

PHARE Activity : SW

Software necessary for the evaluation of behaviour of pesticides in the environment in the process of pesticide authorisation – for the estimation of PEC values (predicted environmental concentrations) in soil, surface and ground water.

Based on the PELMO, PESTLA etc. mathematical models.


Points 9.1.3. Estimation of expected concentrations in soil,
  9.2.1. Estimation of expected concentrations in groundwater
  9.2.3. Estimation of expected concentrations in surface water