Standard Summary Project Fiche for the Transition Facility

1. Basic Information

1.1 CRIS Number: 2004/016-764.01.01
1.2 Title: Strengthening of Control Systems in the area of Food Safety
1.3 Sector: Agriculture
1.4 Location: Slovak Republic

- Ministry of Agriculture (MoA SR) – Central Control and Testing Institute of Agriculture (CCTIA), The Forestry Research Institute, Research Station in Banská Štiavnica (FRI), Research Institute of Animal Production in Nitra, Institute of Apiculture in Liptovský Hrádok (IAC), State Agricultural Testing Institute SKTC-106 in Rovinka (SKTC-106), The State Veterinary and Food Administration of the Slovak Republic (SVFA)
- Ministry of Health - Public Health Office (PHO)
- Ministry of Environment - Water Research Institute (WRI)
- Ministry of Education - National Reference Laboratory of the University of Veterinary Medicine (NRL UVM)

2. Objectives

2.1 Overall Objective(s):


2.2 Project purpose:

- to check whether pesticides were used correctly and to prepare maps of vulnerable areas using appropriate lab equipment/ HPLC;
- to facilitate effective control of primary inputs into food chain by quality control of plant protection products (pesticides) formulations and feeds; by monitoring of harmful organic compounds namely the pesticide residues in raw agricultural products of plant origin and in agricultural products produced in organic farming system (raw unprocessed bio products), as well as assistance to introducing the residues content control of forbidden substances in animal products into practice, in accordance with Commission Regulation 2002/657/EC;
2.3 Justification

Chapter 7 of the Comprehensive monitoring report: Agriculture

2.3.1 According to the Comprehensive monitoring report on Slovakia’s preparations for membership from 5 November 2003 most legislation on plant protection products is in place, but controls at the user level should be improved in order to ensure full implementation. Coordination on food safety issues within the Ministry of Agriculture should be enhanced.

Moreover, Slovakia must pay particular attention to implementation in the water sector, especially as regards drinking water quality, and must finalise the necessary programmes.

2.3.2 Veterinary and phytosanitary issues:

- Attention must be given to improving the implementation of control systems in relation to residues and veterinary medicinal products.
- Controls in the area of pesticide residues in food need to be strengthened through the extension of the range of analysis and enhanced laboratory capacity.
- Further adjustments are needed in order to ensure full alignment with the European food safety framework.

3. Description

3.1 Background and justification:


However, experts and administrative staff involved in plant protection products registrations have no practical experience as regards the implementation of Council Directive 91/414/EEC. Experts and administrative staff involved in the area of plant protection, products registration and evaluation must have appropriate knowledge in risk assessment, management and administrative procedures.

3.1.1. Justification of laboratory equipment for Water Research Institute (WRI)

Article 17 of Council Directive 91/414/EEC reads: „Member States shall make the necessary arrangements for plant protection products which have been placed on the market and for their use to be officially checked to see whether they comply with the requirements of this Directive and in particular with the requirements of the authorization and information appearing on the label.“

After the application of pesticides by farmers, the WRI checks the proper application of pesticides in the framework of the monitoring programme as stated in Water Law no. 184/2002 and takes samples of ground or surface water using the HPLC chromatograph to
verify whether the concentration of pesticide residues/metabolites falls within the legal limits. If not, the pesticides were applied incorrectly and there is a scientific based proof for penalisation of farmers that used pesticides in the wrong way.


The proper implementation of Annex I to Council Directive 91/414/EEC and Council Directive 97/57/EC requires information on vulnerable soil and climatic areas of the Slovak Republic. Crops produced for further processing in agriculture or food sector are under the systematic control and chemical protection. Plant protection treatment is executed mainly by chemical substances that leave residues in the soil. To ensure the stability of the environment and its protection it is necessary to monitor the values/level of residues in the ground and surface water that can damage the environment in general. For this purpose (where it is not possible to calculate residue/metabolite concentrations using the FOCUS model) it is necessary to use the HPLC chromatograph.

According to the Slovak Water Law, the responsibility for conducting such analysis using HPLC equipment lies with the WRI.

Remark: Additionally, this HPLC chromatograph can be used for scientifically oriented research on pesticide residues in water.

The current legal framework:

Council Directives 91/414 EEC and 97/57EC are transposed by the Act No. 471/2001 Coll. on plant health care (as last amended) and by the Decree of the Ministry of Agriculture No. 3322/3/2001-100 on details about plant protection products.


The institutions mentioned in point 1.4 (except The State Veterinary and Food Administration of the Slovak Republic) have to ensure the fulfillment of the EU requirements in the field of plant protection products as follows:

- (re) registration of plant protection products,
- evaluation of active ingredients in frame of the EU working programme (Directive 91/414/EEC, Art. 5, 6, 8.2; Regulation No. 451/2000, 1490/2002, 1112/2002);
- implementation of the Uniform principles for purposes of the (re) registration of the PPPs (Annex VI to Council Directive 91/414/EEC);
- implementation of Art. 13 (Directive 91/414/EEC) provisions as related to data submission, data protection and confidentiality;
- implementation of GEP (Good Efficacy Practise), GAP (Good Agricultural Practise) principles into methods for PPPs biological field/forestry trials.

To control the quality of compounds (mainly pesticides) entering the food chain, is one of the government main goals. It is performed by the Central Control and Testing Institute in
Agriculture (CCTIA) as a state institute governed by the Ministry of Agriculture in the Slovak Republic. The CCTIA performs the monitoring of pesticide residues in raw agricultural products of plant origin along with the quality of bio products (raw agricultural products produced in the framework of the organic farming system), and therefore focuses its activity on the detection of pesticide residues. The CCTIA performs the state quality control including pesticide residues analyses of agricultural raw products of plant origin used for feeds.

In order to assure Slovak and foreign consumers that products made in the Slovak Republic and products imported from third countries are safe, it is necessary to strengthen the control of these products as regards the content of residues of forbidden substances.

Commission Regulation 2002/657/EC sets out the limits for some forbidden substances and the sensibility of laboratory techniques which are used for their detection. Implementation of this regulation, hence, requires very efficient and sensitive laboratory equipment, which the State veterinary and Food Administration in the SR currently does not dispose of in sufficient amount. The regulation also defines a new approach in method validation, which necessitates appropriate training of the laboratory staff. As an EU Member State the Slovak Republic will have to carry out checks on the external border inspection posts of the European Union. Controls are performed in accordance with Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market. Based on the above, it is necessary to strengthen laboratory capacities which will be used for analyses of imported products of animal origin. The State Veterinary and Food Administration of the Slovak Republic provides the veterinary controls in the State Veterinary and Food Institutes in Bratislava, Nitra, Dolný Kubín and Košice.

3.1.2. Justification of equipment for State Veterinary and Food Administration

In the European Union various substances have been banned from use in animal food production:

Commission Regulation 1442/95 for furazolidon, Regulation 2901/93 for other nitrofurans, modification of Annex IV of Council Regulation n° 2377/90 with the Commission Regulation n° 1430/94 for chloramphenicol.

It is necessary to provide harmonised levels for the control of these substances to ensure the same level of consumer protection throughout the Community. For this purpose the COMMISSION DECISION of 13 March 2003 amending Decision 2002/657/EC as regards the setting of minimum required performance limits (MRPLs) for certain residues in food of animal origin was enacted. In this Decision the level for harmonised MRPLs for these substances has been agreed in consultation with the Community Reference Laboratories, national reference laboratories and Member States. Member States shall ensure that the analytical methods used for detecting the following substances meet the minimum required performance limits (MRPLs) set out in Annex, against the matrixes referred to in that Annex:

(a) chloramphenicol;
(b) nitrofuran metabolites;
(c) medroxyprogesterone.
Minimum required performance limits can only be measured with Chromatography / Mass spectrometry (ultra sensitive) equipment.

**Current state of National Reference Laboratories of the SVFA:**

Slovak Republic has declared its National Reference laboratories in the Act of Accession.

**SVFI Dolný Kubín** - The national reference laboratory for antibacterial substances, (tetracyclines, sulphonamides, quinolones) and other pharmacologically active substances, colouring agents and some prohibited substances (B1, B2f, B3e, A6 – chloramphenicol, nitrofuranes);

**SVFI Nitra** - The national reference laboratory for following substances: stilbenes, derivates of stilbenes and their salts and esters, steroids, lactones of rezorcylic acid including zeranol, beta-agonists;

**SVFI Košice** - The national reference laboratory for chemical risk elements, mycotoxines, antihelmintics, anticoccidics, sedatives and tyreostatics;

**SVFI Bratislava** - The national reference laboratory for organochlorinated substances and PCB, organophosphates, carbamates and pyrethroides, non-steroid and anti-inflammatory drugs and some prohibited substances (B3a, B3b, B2c, B2e, A6 – metronidazole, ronidazole, dimetridazole);

SVFI Dolný Kubín and SVFI Bratislava are supposed to be fully ready and operational from 1 May 2004. New laboratory equipment is needed to increase the laboratory capacity, since an increase in the number of samples is expected after accession.

Since SVFI Nitra and SVFI Košice are not provided with relevant laboratory equipment for confirmatory analyses, they have entered into agreements with laboratories in new member states.

The national reference laboratory for hormonal substances in Nitra made contract for the confirmation of some types of hormonal substances with the Institute for State Control of Veterinary Biopreparations and Medicinals in Brno, Czech Republic, for 7 types of hormones (beta-agonists, gestagens, nortestosterone, stilbenes, testosterone, trenbolone and zeranol).

The national reference laboratory in Košice made contract for the confirmation of mycotoxines with the State Veterinary Institute Jihlava, Czech Republic, for confirmatory analyses of mycotoxines.

**Current state of National Reference Laboratories of the CCTIA**

In accordance with the competences of the CCTIA and related legislation, the Department of Molecular Biology of CCTIA provides supervisory testing of the presence of genetically modified organisms in varieties, seeds, propagation and raw materials and products as well as in feeding stuffs and products of organic farming and issued certificates of non-GMO origin and GMO-free products as well supervisory diagnostics of quarantine and harmful plant pathogens (bacteria, phytoplasmas, etc.) and supervisory testing of seeds and varieties (varietal purity of seeds, genetic homogeneity and stability of varieties, etc.).
The Department of Molecular Biology started with molecular testing of GMOs and with molecular diagnostics of plant pathogens in 1999 as the first laboratory in Slovak Republic in the frame of the State research project RVT 27-11 (1999-2002). It, hence, has most experiences in these areas. The Department is under accreditation process in accordance with EN ISO/IEC 17025 for molecular testing of GMOs and plant pathogens.

The CCTIA is a Member station of ISTA and the Department participated in ISTA Proficiency Tests on GMO Testing in 2003 with completely correct results.

The Department is a registered laboratory in the European Network of GMO Laboratories of the JRC EC Ispra, which includes above 45 testing laboratories in EU countries that search for GMO. The JRC EC through the ENGL harmonises laboratories across Europe. The new regulations on GMO food and feed specify that the JRC becomes the community reference laboratory.

The Department is officially nominated as a member of the enlarged European Network of GMO Laboratories (ENGL) and has been officially appointed to the ENGL on April 29, 2004 at the Inauguration Ceremony in Prague.

The Department has been asked by the JRC EC to participate in validation studies of GMO detection methods in 2004 and to participate in research projects in the area of GMO sampling and testing in the frame of Food quality and safety of the FP6 (Sixth Framework Programme – European research programme within the European Research Area for the period of 2002-2006).

The CCTIA and the Department participate in EPPO (European Plant Protection Organisation) Panels for Diagnostics and Bacterial Diseases.


Scope of responsibilities of institutions (i.e. CCTIA, FRI, IAC, SKTC-106) working under the Ministry of Agriculture of the Slovak Republic:

- **Central Control and Testing Institute of Agriculture (CCTIA)**
  - administrative procedure within the authorisation for plant protection products (from the receipt of applications and dossiers to the preparation of decisions) and management of authorisation process,
  - co-ordinating the national activities and review procedures within the evaluation of active substances as regards their inclusion in Annex I of the Directive 91/414/EEC,
  - (re) registration within authorisation procedure of plant protection products,
  - (re) evaluation of plant protection products in relation to the identity and physical and chemical properties of active substance and PPPs,
  - evaluation of active substances as regards their inclusion in Annex I of the Directive 91/414/EEC; completion of the EU - Monograph as regards the identity and physical and chemical properties of PPPs,
  - granting of minor uses (i.e.: authorisation of the plant protection products, mutual recognition),
  - carrying out biological field trials and evaluation of the results of these trials;
  - performance of state quality control of plant protection products focused to determination of physico-chemical properties and identification and quantification of active substances,
monitoring of raw agricultural products for appearance of pesticide residues.

The Forestry Research Institute, Research Station in Banská Štiavnica (FRI)
• carrying out biological fields (forestry) trials and evaluation of the results of these trials;

Research Institute of Animal Production in Nitra, Institute of Apiculture in Liptovský Hrádok (IAC)
(re) evaluation of plant protection products as regards their impact on bees and other beneficial arthropods,
evaluation of active substances as regards their inclusion in Annex I of the Directive 91/414/EEC; completion of the EU Monograph as regards the impact of PPPs on bees and other beneficial arthropods- IAC,
testing of potentially adverse effects of PPPs on honey bees;

State Agricultural Testing Institute SKTC-106 in Rovinka (SKTC-106)
testing and evaluation of plant protection product application technique before its placing on the market and inspection activities;

Scope of responsibilities of the PHO working under the Ministry of Health of the Slovak Republic:
• (re) evaluation of plant protection products within the authorisation procedure as regards a) toxicology,
b) evaluation of residues field trials,
c) setting of Maximum Residue Limits (MRLs),
d) operator safety,
evaluation of active substances as regards their inclusion in Annex I of Directive 91/414/EEC; completion of the EU - Monograph as regards points a) to c);

Scope of responsibilities of the WRI working under the Ministry of Environment of the Slovak Republic:
• (re) evaluation of plant protection products as regards their impact on water,
• evaluation of active substances as regards their inclusion in Annex I of Directive 91/414/EEC; completion of the EU - Monograph as regards the impact of PPPs on water,
• testing of potentially PPPs adverse effects on water conducted by lysimetric tests,
• preparing map of groundwater vulnerability;

Scope of responsibilities of the NRL UVL working under the Ministry of Education of the Slovak Republic:
• (re) evaluation of plant protection products as regards their impact on animals except bees and other beneficial arthropods,
• evaluation of active substances as regards their inclusion in Annex I of Directive 91/414/EEC; completion of the EU - Monograph as regards the impact of PPPs on animals except honey bees;

3.2 Linked activities:
No similar projects connected with the implementation of Council Directive 91/414/EEC have been implemented in the past and no equipment has been bought for the purposes outlined above.

So far no project concerning food safety control within the agricultural sector in the Slovak Republic focused on quality control of pesticides and monitoring of pesticide residues in raw agricultural products, including feeding stuff from domestic and/or foreign production has been implemented.

Activities carried out and financed from the Slovak state budget:

State Research Project RVT 27-11, CU05/VE03: Development and standardisation of biochemical and molecular techniques for description and identification of plant varieties including GMOs detection in seed, varieties, raw material, feeding stuffs and selected foods;

State Research Project RVT 27-11, CU05/VE03: Molecular diagnostics of quarantine and harmful plant pathogens (focused to bacteria and phytoplasmas);

These projects were carried out at the Department of Molecular Biology of CCTIA in the course of the years 1999 - 2002.

In 2003 TAIEX organised workshops in Reference Laboratories of the EU, which were oriented towards the establishment of contacts between these workplaces and reference laboratories of SR in the field of residues, contaminants, pesticides and forbidden substances.

The following Phare food safety projects are being implemented by the Programme Implementation Unit, Ministry of Agriculture SR:

**Equipment Supply for Harmonisation in Agriculture (SR 9808-02-01) - Germany as the MS Twinning Partner of T.A. "Harmonisation and Internal Market Legislation". The project had the following main components:**

- Building a PC LAN/WAN network at the phytosanitary inspection working stations at the CCTIA including the link-up of Hanulova-Matušková Streets, as well as the PCs upgrading and the required user training

- Building a PC LAN/WAN network at the phytosanitary inspection working stations of Zvolen and Košice;

- Setting up posts of phytosanitary inspectors, Border Inspection Points, and establishing diagnostic laboratories.

Within the Phare Twinning Project basic laboratory equipment for molecular diagnostics of plant pathogens, such as thermal cycler, electrophoretic systems, homogenisators, centrifuges, and visual system, was procured, which has been since then used for detection of GMOs and animal DNA.

Support of Market Surveillance System in Consumer and Health Protection (SR0104.01)

*Overall objective:* Alignment of Food Safety Legislation with acquis communautaire

*Project Purpose:* Integrated market surveillance system in the food sector developed and strengthened

*Results:*
Training carried out in The Netherlands for 6 laboratory experts and 3 high ranked officers
Training carried out for approximately 50 MoA/MoH and Inspection Bodies Managers on GFL related implementation issues
Training carried out for approximately 150 inspectors on technical GFL aspects
Training carried out for approximately 150 food control experts in the utilisation of Rapid Alert System for foodstuffs
Testing laboratory equipment for diagnostics delivered and fully operational (SAFI, SVA)

Under this project following technical equipment had been supplied:

- LC-MS-MS – 2 pieces – SVFI Bratislava a SVFI Dolný Kubín (specification has been proposed in 2001. In that time, there were not any regulations defining MPLR for forbidden substances. This equipment do not have in present time required sensitivity and capacity.
- Real time PCR - ŠVPU Bratislava – laboratory equipment for determination of GMO.

Control TSE (Transmissible Spongiform Encephalopathy) - food safety (2002/000.610-05)
**Overall objective:** Decrease of the TSE risk – consumers protection
**Project Purpose:** To facilitate the introduction of TSE screening and eradication in Slovakia as stated in the Regulation 999/2001/EC.

Results:
SVFA and CCTI able to execute tests in accordance with the related EC and national legislation testing requirements
prevention of PrP res circulation control of cross contamination at production of compound feedingstuffs for ruminants
prevention of the penetration of disease agent into the food chain

Laboratory equipment for TSE diagnostics e.g. – , equipment for histological analysis (Autostainer, Coverslipper…), equipment for molecular biology (Automatic DNA Sequencer, Genetic Analyzer…) and common laboratory equipment.

Support of agricultural food chain in comprehensive food safety policy (2003-004-995-03-02)
**Overall objective:** Harmonise legal standards, regulations and institutions in the agricultural sector of the Slovak Republic with the food safety Acquis, including, in particular, the relevant acquis elements concerning the phytosanitary area, veterinary area, and the consumer protection.
**Project Purpose:**
- Complete the veterinary and phytosanitary services infrastructure required for the food safety acquis
- Monitor foreign bodies in agricultural products and protect the consumers
- Broaden the activities of both the Slovak Veterinary and Food Inspection Authorities (SVFA) and of the Central Control and Testing Institute of Agriculture (CCTIA) to improve the performance of their tasks

Results:
Proper interpretation and implementation of the legislation relating to the food safety acquis and that of the veterinary vertical one, followed by effective veterinary controls in the establishments in order to ensure safety of foodstuffs of animal origin;
Well-trained control staff available at all relevant laboratories, including a cadre of five or six CCTIA officials specialised in molecular testing of GMOs and diagnostics of pathogens;
Upgraded equipment of State Veterinary and Food Institutes that perform laboratory controls on safety of foodstuffs of animal origin;

Equipment of laboratory system modernised and completed and specialised National Reference Laboratories upgraded with equipment for:

- control of the presence, quantification and labelling of GMOs and GMO products as undesirable substances in products of organic farming and animal nutrition, based on the DNA-tests;
- testing, description, control of presence, quantification and labelling of GMOs in varieties, seeds, propagation and raw materials and products, based on the DNA-tests;
- phytosanitary control of quarantine and harmful plant pathogens based on the DNA-tests, fatty acid profiling and microscopy.

The CCTIA Reference laboratories interlinked with the European network of GMO Laboratories

In this project we require laboratory equipment in the area of microbiology. Selection and supply of laboratory equipment has not been realized yet.

1. Spiral platter – equipment for detection of total amount micro-organisms in foodstuff
2. Autopreparator and pump for filling-up of media to the Petri’s dishes
3. Ultracentrifuge mill for processing of samples for Round ready soya
4. Laminar box BIOHAZARD
5. Monitoring system for automatic control of temperature, atmospheric pressure and humidity in laboratories
6. Homogenizer
7. Microbiology: Autopreparator with
   - peristaltic pump
   - anoxomat
8. Automatic monitoring of moisture and temperature for refrigerator and thermostats
9. Autoclave (45 l)

3.3 Results

Results of the Activity 1 (Twinning)

- Quality of existing administrative, expert and technical capacities in the field of registration and authorisation of plant protection products improved,
- Testing, evaluation and (re) registration of PPPs in line with appropriate EU legislation, EPPO, OECD methods and EU best practise,
- The Slovak Republic will be able to participate on the EU review programme of active substances,
- Structural links, procedures, database and CADDY use and information exchange,
- The quality and expertise of post-registration control of plant protection products in the areas of residues, labelling, formulation and use will increase,
- The quality of post-registration control of PPPs will increase,
- Recommendations and assistance in the implementation of a registration system,
- The twinning project improves, builds-up existing administrative, experts and technical capacities consequently the quality and safety food chain and environment will be increased.

Results of the Activity 2 (Twinning light)
The CCTIA’s demands will result in reaching the EU level in the field of analyses of raw agricultural products from plant origin (raw agricultural products intended for food & feed production) and to reach the EU level in field of state quality control of plant protection products.

Results of the Activity 3 (Equipment supply)
- Upgraded equipment of State Veterinary and Food Institutes that perform laboratory controls on safety of foodstuffs of animal origin
- State veterinary and food administration with this laboratory equipment will be able to provide harmonised levels for the control of banned substances to ensure the same level of consumer protection throughout the Community.
- Water quality can increase because it will be possible to monitor proper using of pesticides,
- WRI will have knowledge about residue ground water concentrations in certain parts of the Slovak Republic.

3.4 Activities:

The following activities are foreseen:

(1.) Training in the field of risk assessment and management of plant protection products, post approval monitoring of residues of plant protection products and their formulations; labelling and usage of plant protection products (Twining)

Twining – RTA- must have a minimum of 8 year experience in the field of the evaluation or registration (authorisation) of PPPs in member states’ institutions. The RTA will assist institutions listed under point 1. 4 in the implementation of the *acquis communautaire* covered by the project. The RTA will also be responsible for overseeing the implementation and delivery of the training of Slovak experts by MS experts in the Slovak Republic and MS, inputting to training as appropriate.

Training will be conducted in the following areas:

1. EU issues and obligations to include CADDY training and dossier completeness of checking administrative issues within the authorisation procedure of plant protection products,
2. legal issues within the authorization procedure of plant protection products,
3. PPPs biological efficacy, biological dossiers preparing, Good Efficacy Practise,
4. identity of active substance, equivalence of checking, PPPs and their physical and chemical properties, monographs preparing,
5. toxicology, monographs preparing,
6. operator exposure, monographs preparing,
7. fate and behaviour in the environment (see table below item 7/1-3), monographs preparing,
8. risk assessment of PPPs based on the micro organisms,
9. National procedures: information exchange, parallel import, mutual recognition, re-registration of plant protection products,
10. Residues and Consumer Risk Assessment (including MRL’s). Use of EU consumption models and databases. Monograph preparation and MRL setting

11. Post-registration quality control of PPPs state quality control) and monitoring of pesticide residues in raw agricultural products of plant origin

12. Plant protection product application technique.

The training will be provided for Slovak experts and administrative capacities responsible for evaluation of plant protection products in the above-mentioned areas. It will be divided into two parts: each MS expert will spend approx. one month in the Slovak Republic and each SK expert will spend approx. 1 month in the MS.
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<thead>
<tr>
<th>1. Area</th>
<th>2. Institution</th>
<th>3. Number of trained experts from Slovak institutions in MS</th>
<th>4. Number of Slovak experts which will be trained by MS experts in Slovak Republic</th>
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<tr>
<td>1. EU issues and obligations to include CADDY training and dossier completeness of checking administrative issues within the authorisation procedure of plant protection products,</td>
<td>CCTIA</td>
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<td>2. legal issues within the authorization procedure of plant protection products,</td>
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<td>3. PPPs biological efficacy, biological dossiers preparing, Good Efficacy Practise,</td>
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<td>4a. parallel import</td>
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<td>5. toxicology, monographs preparing,</td>
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<td>6. operator exposure, monographs preparing,</td>
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<td>7/1 a) fate and behaviour in the environment- part1 wild life animals, soil organisms</td>
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<td>8. risk assessment of PPPs based on the micro organisms,</td>
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<td>10. Residues and Consumer Risk Assessment (including MRL’s). Use of EU consumption models and databases. Monograph preparation and MRL setting</td>
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<td>11. post- registration control activities</td>
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<td>of PPPs (residues, formulation monitoring and use, inspections, labelling, safety and storage)</td>
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<td>12. plant protection product application technique SKTC - 106</td>
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<td>Total</td>
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<td>57**</td>
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*Some Slovak experts will be trained in MS in more than 1 area, therefore the total sum of 35 corresponds in reality to a lower number - approx. 26 persons in reality (Slovak experts, who will be trained abroad).

**Some Slovak experts will be trained in Slovak Republic in more than 1 area, therefore the total sum of 57 corresponds in reality to a lower number - approx. 32 persons in reality (Slovak experts, who will be trained by 15 MS experts in Slovakia).

Profile requirements of 16 MS short term experts:

1) 2 MS experts, one for EU issues and obligations to include caddy training and dossier completeness of checking, and the another one for administrative issues within the authorisation procedure of plant protection products
   • University degree of agriculture or chemistry or human toxicology or ecotoxicology
   • 5 years experience with caddy and dossier completeness of checking
   • Excellent knowledge of English language
   • Computer literacy.

2) 1 MS expert for legal issues within the authorization procedure of plant protection products/ PPPs
   • University degree of agriculture or chemistry or human toxicology or ecotoxicology
   • 10 years experience with the authorization procedure of PPPs
   • Excellent knowledge of English language
   • Computer literacy

3) 1 MS expert for PPPs biological efficacy, biological dossiers preparing, good efficacy practice
   • University degree in the agriculture
   • 10 years experience with biological efficacy evaluation of PPPs
   • Excellent knowledge of English language
   • Computer literacy

4) 1 MS expert for identity of active substance, equivalence of checking, PPPs and their physical and chemical properties, monographs preparing
   • University degree of chemistry
   • 10 years experience with evaluation of physical and chemical properties of the PPPs
   • Appropriate communication skills and ability to give lectures
   • Excellent knowledge of English language
   4a) 1 MS expert for parallel import
   • University degree of chemistry
   • 10 years experience with evaluation of parallel import of PPPs
• Appropriate communication skills and ability to give lectures
• Excellent knowledge of English language

5) 1 MS expert for operator exposure, Residues and Consumer Risk Assessment (including MRL’s), MRL setting, Use of EU consumption models and databases. Monograph preparing,
• University degree of human toxicology
• 10 years experience with evaluation of toxicology dossiers
• Appropriate communication skills and ability to give lectures
• Excellent knowledge of English language

6) 1 MS expert for fate and behaviour in the environment- wild life animals, soil organisms, non targeted arthropods, monographs preparing
• University degree of ecotoxicology
• 10 years experience with evaluation of ecotoxicology dossiers
• Appropriate communication skills and ability to give lectures
• Excellent knowledge of English language

7) 1 MS expert for fate and behaviour in the environment- ground water, FOCUS modelling, monographs preparing
• University degree of ecotoxicology
• 10 years experience in the area fate and behaviour
• Appropriate communication skills and ability to give lectures
• Excellent knowledge of English language

8) 4 MS experts for risk assessment of PPPs based on the micro organisms
• University degree of agriculture and chemistry, human toxicology, ecotoxicology
• 10 years experience with evaluation of ppps containing microorganisms
• Appropriate communication skills and ability to give lectures
• Excellent knowledge of English language
• Computer literacy

9) 1 MS expert for National procedures: information exchange, mutual recognition, re-registration of plant protection products
• University degree of one of above mentioned
• 10 years experience with ppps registration
• Appropriate communication skills and ability to give lectures
• Excellent knowledge of English language

10) 1 MS expert for post- registration control activities of PPPs (residues, formulation monitoring and use, inspections, labelling, safety and storage)
• University degree of chemistry
• 10 years experience with post registration control of PPPs
• Appropriate communication skills and ability to give lectures
• Excellent knowledge of English language

11) 1 MS expert for plant protection product application technique
• University degree of agriculture or machinery
• 10 years experience with testing of application technique
• Appropriate communication skills and ability to give lectures
• Excellent knowledge of English language
Each Slovak expert from an institution indicated in column 2 will be trained by MS expert(s) in area as is indicated in column 3 approx. 1 month. As is shown in annex I - List of relevant Laws and Regulations there is huge amount of legislative texts and appropriate guidance documents. This is a reason why must Slovak experts spend approx. 1 month in MS. On the other side Slovak experts must know registration system in MS with all details to understand decision making process in MS.

MS experts will spend approx. 1 month in Slovak Republic to understand legislation background of present Slovak registration system of plant protection products to give best advice to Slovak experts with connection to EU best practice in this area.

(2.) **Training in the field of determination of organic contaminants and quality control of pesticides (Twinning light)**

- **Training of laboratory staff** (8 persons - 4 university graduates and 4 technicians working in the field of pesticide residues, 2 MS experts) of the Dept. of Environmental Protection, Organic Farming, Fertilizers, Analyses of Pesticides and their Residues (from the Central Agricultural Control and Testing Institute) **in the field of determination of organic contaminants**, namely residues of pesticides in different types of raw agricultural products of plant origin including feeds (including **method validation**).

- **Training** of the laboratory staff (5 persons - 4 university graduates and 1 technicians working in the field of quality control of plant protection products, 2 MS experts) of the Dept. of Environmental Protection, Organic Farming, Fertilizers, Analyses of Pesticides and their Residues (from the Central Agricultural Control and Testing Institute) **in the field of quality control of pesticides**, namely determination of physico-chemical properties and content of active ingredients along with harmful impurities and additives (including **method validation**).

The training should be carried out by the performance of determinations of pesticide residues in the laboratories at the CCTIA, Hanulova 9A according to the methodologies valid in the EC Member States, including introduction of yet not applied methods of extraction, cleaning, identification and determination of residues of pesticides, including validation of methods and other performances in accordance to the requirements of the EN 17 025.

The 4 Slovak CCTIA employees should visit a similar laboratory and should be trained for the above mentioned field of activities.

The training of the laboratory staff for the pesticide formulation analyses should be focused on the determination of physico-chemical properties of the pesticide formulations and identification – quantification of the active substances in the frame of state quality control of plant protection products – including method validation. The 4 Slovak CCTIA employees should visit a similar laboratory for quality control of plant protection products and should be trained for the above mentioned field of activities.
## EXPERTS PROFILE

<table>
<thead>
<tr>
<th>Area of expertise</th>
<th>Time provision</th>
<th>Experts profile</th>
</tr>
</thead>
</table>
| 1) Two experts in the field of determination of pesticide residues in agricultural products of plant origin | 70 working days including preparation of any documents as methodological procedures, evaluation procedures, etc. | • University degree in chemistry or related field of study  
• 5 and more years of experience in the field of pesticide residues analyses in agricultural products of plant origin  
• Experience with work in accredited pesticide residue laboratories  
• Appropriate knowledge of written & spoken English in the related field  
• Computer literacy  
• Knowledge of the valid EC pesticide residue legislation |
| 2) Two experts for quality control of plant protection products | 70 working days including preparation of any documents needed for the progress of the analytical work | • University degree in agrochemistry or chemistry or related field of study  
• 5 and more years of experience in the field of pesticide analyses, namely in field of identification & quantification of active substances in formulations and in the field of determination of physico-chemical properties of the pesticide formations  
• Experience with work in pesticide laboratory with GLP system or EN 17 025 accreditation system  
• Knowledge of spoken & written English in the field of pesticides  
• Computer literacy  
• Knowledge & experience in the valid EC legislation in field of pesticides |

### Requirements for all experts:

Professional skills and practical experience along with theoretical knowledge on the required topic. Ability to arrange training for Slovak experts from the Central Control & Testing Institute of Agriculture in MS country:
- for 4 persons in field of pesticide residues, for 2 times - 5 working days  
- for 4 persons in field of pesticide formulation analyses, for 2 times - 5 working days

A coordinator from the MS is to be selected from the above-described experts or an additional person can be proposed for the coordination activities in the MS. The work of coordinator will include preparation of the Final report. Ten working days for the coordination activities are needed.
(3.) Equipment for upgrading the performance of veterinary laboratories and the observation of pesticide residues in water (Equipment supply)

- **Equipment for upgrading the performance of veterinary laboratories** is attached in Annex 5 (Completion of the laboratory equipment) by necessary apparatus of 4 institutes, which attest official control of products of the animal origin for analyses of residues of Chloramphenicol, metabolits of nitrofuran and medroxyprogesteron-acetat (State veterinary and Food Institutes).

- **Equipment for upgrading the observation of pesticide residues in water** is attached in Annex 5.

3.5 Lessons learned:

The beneficiary organisations will provide an adequate number of qualified staff for the training component to ensure a rapid uptake of the advice rendered by the twinning advisers of the project.

4. Institutional Framework

The overall responsibility for phytosanitary and veterinary control relating to food safety is the Ministry of Agriculture, which has authorised the Central Agricultural Control and Testing Institute (CACTI) and the State Veterinary Food Administration (SVFA) to carry out the project. Project activities will be co-ordinated by the Programme Implementation Unit of the Ministry, in co-operation with the Agriculture and Trade Section, and the Food Section of the same Ministry.

**Phytosanitary sector:**

Central Agricultural Control and Testing Institute is responsible for the control of primary inputs into the food chain and into the agricultural production (pesticides and feeds), it also performs quality monitoring of raw agricultural products of plant origin.

Beneficiary institution for training in field of analyses of raw agricultural products of plant origin and for pesticide analyses is the Dept. of Environmental Protection and Organic Farming, (CACTI) Bratislava, Hanulova 9A.

**Veterinary sector:**

State Veterinary and Food Administration is responsible organisation for the control of products of animal origin and analysts for residues of veterinary drugs and hormones. It consists of Central Office, four State Veterinary and Food Institutes, eight Regional Veterinary and Food Administrations, forty District Veterinary and Food Administrations and two workplaces – the Laboratory of Veterinary Biomedicine and the Veterinary Drug Control Institute.

In accordance with the provisions of Act No. 471/2001 Coll. as last amended on plant health care and in accordance with Decree of the Ministry of Agriculture No. 3322/3/2001-100 on details about plant protection products the CCTIA is responsible for PPPs registration. In the registration process are involved – Central Control and Testing
Institute of Agriculture (CCTIA), The Forestry Research Institute, Research Station in Banská Štiavnica (FRI), Research Institute of Animal Production in Nitra, Institute of Apiculture in Liptovský Hrádok (IAC), State Agricultural Testing Institute SKTC-106 in Rovinka (SKTC-106) which are directly subordinated to the Ministry of Agriculture of the Slovak Republic, Public Health Office (PHO) which is directly subordinated to the Ministry of Health Ministry of the Slovak Republic, Water Research Institute (WRI) which is directly subordinated to the Ministry of Environment of the Slovak Republic, National Reference Laboratory of the University of Veterinary Medicine (NRL UVM) which is directly subordinated to the Ministry of Education of the Slovak Republic.

5. Detailed Budget in EURO

<table>
<thead>
<tr>
<th>Transition facility</th>
<th>Support</th>
<th>Total TF (=I+IB)</th>
<th>National Co-financing*</th>
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<tr>
<td></td>
<td>Investment</td>
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</tr>
<tr>
<td></td>
<td>Support</td>
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<td>Twinning light</td>
<td>0.15</td>
<td>0.15</td>
<td></td>
<td>0.15</td>
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<tr>
<td>Twinning</td>
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<td>0.5</td>
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<td>0.915</td>
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<td>1.22</td>
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<tr>
<td>equipment</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>0.915</td>
<td>0.65</td>
<td>1.565</td>
<td>0.305</td>
</tr>
</tbody>
</table>

The co-financing of the investment component will be assured with a minimum contribution of 25%. National joint co-financing of the Investment component (equipment) will be included into the 2005 state budget.

6. Implementation Arrangements

6.1 Implementing Agency

Central Finance and Contracting Unit
PAO: Mrs. Silvia Czuczorová, Director of CFCU
Štefanovičova Street 5, 817 82 Bratislava 15, Slovak Republic
Tel.: +421 2 595 824 46
Fax: +421 2 595 825 59

The CFCU is responsible for the administrative and financial implementation of the project. The MoA SR is responsible for the technical implementation of the project.

6.2 Beneficiary Institutions for the Twinning:

Ministry of Agriculture of the Slovak Republic
Contact person: Mr. Ladislav Dobos, Director General
Agriculture and Trade Section
Dobrovičova Street 12, 812 66 Bratislava, Slovak Republic
Tel.: + 421 2 59 266 351
Fax: + 421 2 59 266 352
Central Agricultural Control and Testing Institute
Contact person: Ms Anna Vitariusová, Director General
Matúškova Street 21, 833 16 Bratislava, Slovak Republic
Tel.: + 421 2 54 77 5369
Fax: + 421 2 54 651 202

State Veterinary and Food Administration of the Slovak Republic
Contact person: Prof. Jozef Bíreš, Director General
Botanická Street 17, 842 13 Bratislava, Slovak Republic
Tel.: + 421 2 654 20 258
Fax: + 421 2 654 20 745

Beneficiary institutions will be the institutions listed under point 1.4 and the Ministry of Agriculture of the Slovak Republic.

6.3 Non-standard aspects
Not envisaged, PRAG and the Twinning Manual will be strictly followed.

6.4 Contracts

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
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</thead>
<tbody>
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<td>Twinning light</td>
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</tr>
<tr>
<td>Twinning</td>
<td>500,000.00 €</td>
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<tr>
<td>Supply of laboratory equipment</td>
<td>1,220,000.00 €</td>
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</tbody>
</table>

7. Implementation Schedule

7.1 Start of tendering/call for proposals
3rd quarter 2004

7.2 Start of tendering (supply)
1st quarter 2005

7.3 Start of project activity
1st quarter 2005

7.4 Project Completion
1st quarter 2006

8. Sustainability

Relevant policies and regulations of the Slovak Government ensure that all activities funded under the scheme will yield results that comply with the European Union norms and standards. The scope of the project and its ambitions implicitly guarantee the sustainability of the project.

The beneficiary will provide adequate staff and financial resources to maintain
administrative function.

The beneficiary has foreseen coverage of costs for the maintenance and update of the equipment.

9. **Conditionality and sequencing:**

To the extent possible all preparatory work on the Slovakia side has been completed and the project is ready for implementation as given in the implementation schedule. Technical specifications will have to be discussed and confirmed with the help of a Member State-twinning partner. Sequencing will be in line with the implementation schedule presented in Annex III.
Annexes to project Fiche

1. List of relevant Laws and Regulations
2. Logical Framework Matrix in Standard Format
3. Time Implementation Chart
4. Cumulative Contracting and Disbursement Schedule
5. Indicative list of equipment
Annex 1  List of relevant Laws and Regulations

27. COMMISSION REGULATION (EC) 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market
28. COMMISSION DECISION 2003/181/ES of 13 March 2003 amending COMMISSION DECISION 2002/657/ES determines limits for some forbidden substances and the sensibility of laboratory techniques which are used for their detection
30. WHITE BOOK on food safety COM(1999) 719 FINAL from 12.01.2000 concerning “from farm to table” or “from soil to soil”
33. COUNCIL DIRECTIVE 1999/29/EC contents list of undesirable substances as amended by COUNCIL DIRECTIVE No. 2001102/EC
34. COUNCIL DIRECTIVE 91/516/EEC contents List of prohibited substances and products for animal nutrition
35. COUNCIL DIRECTIVE 97/47/EC contents categories of compound feed ingredients, which may be used in the labelling of compound feed
36. COUNCIL DIRECTIVE 79/373/EEC contents conditions for the use and marketing of compound feeds
37. COUNCIL DIRECTIVE 70/524 contents conditions for putting into circulation of additives
38. REGULATION No. 2380/2001/EC contents list of additives
39. COUNCIL DIRECTIVE No. 95/69/EC (98/51/EC) contents conditions for the approval and Registration of establishment and intermediaries producing or marketing additives, mixtures of additives, compound feedingstuffs containing such additives, ingredients with high contents of undesirable substances and feed ingredients

GUIDANCE DOCUMENTS
2. 1694/V1/95, 4952/V1/95, 6476/V1/96 and 7617/V1/96: Guidance document within the SCPH with regard to the modelling of fate and behaviour of plant protection products in the environment (in groundwater, surface water and soil) - FOCUS.
3. 7017/V1/95 rev.4: Guideline developed within the SCPH with regard to the acceptability of data, whether or not performed in accordance with the principles of Good Laboratory Practice (GLP).
4. 1663/V1/94 rev. 8 of 22.4.98: Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EEC (Articles 5.3 and 8.2).
5. 1654/V1/94 rev. 7 of 22.4.98: Guidelines for preparation of monographs by rapporteur Member States.
7. SANCO/3029/99 rev. 4: Guidance for generating and reporting methods of analysis in support of preregistration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414 - adopted by the SCPH on 13.7.00.
8. SANCO/3030/99 rev. 4: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414 - adopted by SCPH on 13.7.00.
9. 9188/V1/97 rev. 8: Guidance Document on Persistence in Soil - noted by the SCPH on 13.7.00.
10. a) 2021/VI/98 rev. 7: Guidance Document on Terrestrial Ecotoxicology - noted by the SCPH on 13.7.00.
b) SANCO/10329/2002 rev 2 final: noted by the SCFA on 18.10.2002 – see Annex I 5.1.1 for details.
11. a) SANCO/3268/2001: Guidance Document on Aquatic Ecotoxicology - noted by the SCPH on 2.10.01.
b) SANCO/3268/2001 rev.4 (final): noted by the SCFA on 18.10.2002 – see Annex I 5.1.1 for details
14. SANCO/223/2000 rev. 9: Guideline developed within the SCPH concerning parallel trade of plant protection products within the EU and the EEA.
18. SANCO/221/2000 rev. 10: Guidance document on relevant metabolites - noted by the SCFA on 26.2.03.
19. SANCO/3989/2001 rev.2: Guideline developed within the Standing Committee on Plant Health concerning instructions for industry on dossier submission - noted by the SCPH on 7.12.01.
22. 1614/VI/95 rev. 7: Working document for guidance to the Member States with regard to the implementation of Articles 6 and 7 of Regulation (EEC) No 3600/92, developed in the Legislation working group of the SCPH.
23. 1663/VI/95 rev. 2 of 16.6.96: Working document for guidance to the MS with regard to the implementation of Article 6 of Directive 91/414/EEC for new active substances, developed in the Legislation working group of the SCPH.
24. 7860/VI/97 rev. 5E of 15.7.98: Aide mémoire with regard to certain aspects of the procedures for the evaluation of EXISTING active substances in view of a possible inclusion into Annex I of Directive 91/414/EEC.
25. 7860/VI/97 rev. 5N of 15.7.98: Aide mémoire with regard to certain aspects of the procedures for the evaluation of NEW active substances in view of a possible inclusion into Annex I of Directive 91/414/EEC.
Slovak legislation for pesticide residues and food safety

National quality control of pesticides according to the Art. 12 of Slovak Phytosanitary Law No. 285/1995 conformed Law No. 471/2002 and it amends

These laws relates to Slovak Phytosanitary Law No. 471/2002:

- Law No. 163/2001 about chemical materials
- Directive 206/1988 about toxicant and other injurants
- Law No. 223/2001 about waste
- Law No. 152/1995 about foodstuffs
- Law No. 272/1994 about people’s health protection
- Law No. 184/1993 about feedingstuffs
- Decree 41/2002 which specified detailed requirements for performance of phytosanitary care

Soil monitoring before its registration into the organic farming system. According to the provision of Slovak Law No. 224/1998 and the Slovak Ministry of Agriculture Decree No. 3259/1999-100 on Organic Farming and Biofood and obligatory soil monitoring on present of organic and inorganic soil pollutants.

Adopted Amendment of the Food Act 23/2002 to Law No. 152/1995 established basis for implementation of Rapid Alert System for Foodstuffs. National Contact Point for RASF in Slovakia was established in 2002.

With effect from 1 March 2002, the amendments to three Ordinances of the Ministry of Agriculture implementing Act No. 185/93 Coll. on Feedstuffs were issued:

- Ordinance of 31 January 2002 No. 39/1/2002-100, which amends MoA Ordinance of 7 October 1997 No. 1497/1/1997-100 on the ingredients used in the production of compound feeds and farm feedingstuffs;
- Ordinance of 31 January 2002 no. 39/2/2002-100, which amends MoA Ordinance of 7 October 1997 No. 1497/2/1997-100 that lays down the requirements for technological equipment and technological processes employed in the production of compound feeds and specifies the indicators of nutritional value and the use of compound feeds;


Act No. 163/2001 Coll. on chemical substances and chemical preparations including its implementation decrees.
Ordinance of the Government No 320/2003 Coll. where the Commission Decisions are transposed as follows:


Commission Decision 97/747/EC (OJ No. L 303, 6.11.1997, p. 12);

Commission Decision 98/179/EC (OJ No. L 65, 5.3.1998, p. 31);
## Logical Framework Matrix in Standard Format

<table>
<thead>
<tr>
<th>LOGFRAME PLANNING MATRIX FOR Project</th>
<th>Programme name and number 2004/016-764.01.01</th>
<th>Contracting period expires: 15 December 2006</th>
<th>Disbursement period expires: 15 December 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengthening of Control Systems in the area of Food Safety</td>
<td></td>
<td>Total budget: 1,87 MEUR</td>
<td>TF budget: 1,565 MEUR</td>
</tr>
</tbody>
</table>

### Overall objective
- Risk assessment and management of plant protection products in accordance with Council Directive 91/414/EEC, post approval monitoring of residues of plant protection products in water and in agricultural products of plant origin and quality control of plant protection products and formulations; their labelling and usage of plant protection products,
- Control of primary inputs into food chain and environment, monitoring of forbidden substances in animal products to ensure consumer and environmental protection;

### Objective verifiably indicators
- Registration decisions of plant protection products (including risk management such plant protection products) which respect plant health, human health and environment of the Slovak Republic within the frame of implementation of 91/414/EEC.
- Positive assessment of the transposition of primary inputs into food chain.
- EU Food safety control standards met.
- Acknowledgement of the EC

### Sources of Verification
- Screening Reports

### Project purpose
- to check whether pesticides were used correctly and to prepare maps of vulnerable areas using appropriate lab equipment/ HPLC;

### Objectively verifiably indicators
- Proper control results achieved and confirmed by EU standards
- Improved control of primary inputs into food chain (plant as well as animal origin)
- Improved control related to food safety
- Training of staff which is involved in registration process, 91/414, 97/57 by

### Sources of Verification
- Regular Reports of the State Veterinary and Food Administration
- Official records of MoA SR, CACTI and SVFA
- Annual Report of the CCTIA
- Twinning project reports
- Reports of short term and study visits

### Assumptions
- Financial resources dedicated for the control of primary inputs into food chain
- Phyto/veterinary inspectors aware about the control procedures
- Laboratories equipped
- Fulfilment of all other
• to facilitate effective control of primary inputs into food chain by quality control of plant protection products (pesticides) formulations and feeds; by monitoring of harmful organic compounds namely the pesticide residues in raw agricultural products of plant origin and in agricultural products produced in organic farming system (raw unprocessed bio products), as well as assistance to introducing the residues content control of forbidden substances in animal products into practice, in accordance with Commission Regulation 2002/657/EC;

1 Q 2005 with the particular regard to the implementation of the EU-wide harmonised registration/authorisation/procedures

• Appropriate decisions of SNAS on accreditation

Indicators will be verifiable by audit EU experts no later than one year after finishing of Project.

Requirements of the acquis

Results of the Activity 1 (Twinning)

Results

Objectively verifiable indicators

Sources of Verification

Assumptions

- Quality of existing administrative, expert and technical capacities in the field of registration and authorisation of plant protection products improved,
- Testing, evaluation and (re) registration of PPPs in line with appropriate EU legislation, EPPO, OECD methods and EU best practise,
- The Slovak Republic will be able to participate on the EU review programme of active substances,
- Structural links, procedures, database and CADDY use and information exchange,
- The quality and expertise of post-registration control of plant protection products in the areas of residues, labelling, formulation and use will increase,
- The quality of post-registration control of PPPs will increase,
- Recommendations and assistance in the implementation of a registration system,
- The twinning project improves, builds-up existing
- Appropriate registration decisions for plant protection products which will be prepared on the base of EU best practice and in line with EU Acquis
- The training of experts involved in pesticide area (evaluation, authorization, legislation)
- Harmonised registration/authorisation/system will be in place and applied by 1 Q 2005 in the CCTIA and other institutions involved in registration process
- 5-8 experts trained in the field of determination of organic contaminants, including method validation (Central Agricultural Control and Testing Institute)
- 5-8 experts trained in the field of pesticides quality control, including method validation (Central Agricultural Control and Testing Institute)
- Regular PAA’s Reports
- Regular Monthly Progress Reports
- Audit Reports
- Annual reports on monitoring of pesticide residues in feedingstuffs and raw agri-products of plant origin in SR
- Annual reports on monitoring in organic farming in SR.
- Twinning final report
- Project reports
- Checks on the spot by EU experts

• Appropriate staff from MS which will train Slovak administrative and expert capacities
• Related legislation will be in force from 3 Q 2004
• Suitable and good-class twinning partner
• All arrangements, educational courses and training services successfully accomplished in proper level and quality
• All supplies completed and delivered in time, at the right quality and quantity
• Project is adequately funded
administrative, experts and technical capacities consequently the quality and safety food chain and environment will be increased.

Results of the Activity 2 (Twinning light)
- The CCTIA’s demands will result in reaching the EU level in the field of analyses of raw agricultural products from plant origin (raw agricultural products intended for food & feed production) and to reach the EU level in field of state quality control of plant protection products.

Results of the Activity 3 (Equipment supply)
- Upgraded equipment of State Veterinary and Food Institutes that perform laboratory controls on safety of foodstuffs of animal origin
- State Veterinary and Food Administration with this laboratory equipment will be able to provide harmonised levels for the control of banned substances to ensure the same level of consumer protection throughout the Community.
- Water quality can increase because it will be possible to monitor proper using of pesticides.
- WRI will have knowledge about residue ground water concentrations in certain parts of the Slovak Republic.

<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Trainings</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1. Training for Slovak experts and administrative capacities responsible for evaluation of the plant protection products in below mentioned areas.</td>
<td>Through model registration of plant protection product, through model preparing of draft assessment report</td>
<td>• Qualified staff assigned to the training provided by the project and high quality project management.</td>
</tr>
</tbody>
</table>
| 1. EU issues and obligations to include CADDY training and dossier completeness of checking administrative issues within the authorisation | 1. **SUPPLY of equipment:**  
Indicative list in Annex 5.  
2. 1 twinning project  
3. 1 twinning light project | • Properly designed technical specifications  
• Co-financing of the equipment /List is |
procedure of plant protection products,
2. legal issues within the authorization procedure of plant protection products,
3. PPPs biological efficacy, biological dossiers preparing, Good Efficacy Practise,
4. identity of active substance, equivalence of checking, PPPs and their physical and chemical properties, monographs preparing,
5. toxicology, monographs preparing,
6. operator exposure, monographs preparing,
7. fate and behaviour in the environment (see table below item 7/1-3), monographs preparing,
8. risk assessment of PPPs based on the microorganisms,
9. National procedures: information exchange, parallel import, mutual recognition, re-registration of plant protection products,
10. Residues and Consumer Risk Assessment (including MRL’s). Use of EU consumption models and databases. Monograph preparation and MRL setting
11. Post- registration quality control of PPPs state quality control ) and monitoring of pesticide residues in raw agricultural products of plant origin
12. plant protection product application technique.
13.

1.2. Training of administrative and expert capacities involved in pesticide registration process in the implementation of the acquis covered by the project.

• **Training of laboratory staff** (8 persons, 2 MS experts) of the Dept. of Environmental Protection, Organic Farming, Fertilizers, Analyses of Pesticides and their Residues (from the Central Agricultural Control and Testing Institute) in field enclosed in Annex 5/.
of determination of organic contaminants, namely residues of pesticides in different types of raw agricultural products of plant origin including feeds (including method validation). **8 persons of the staff in total means 4 university graduates and 4 technicians working in the field of pesticide residues.**

- **Training** of the laboratory staff (5 persons, 2 MS experts) of the Dept. of Environmental Protection, Organic Farming, Fertilizers, Analyses of Pesticides and their Residues (from the Central Agricultural Control and Testing Institute) in **field of quality control of pesticides**, namely determination of physico-chemical properties and content of active ingredients along with harmful impurities and additives (including method validation). **5 persons of the staff in total means 4 university graduates and 1 technicians working in the field of quality control of plant protection products.**

2. **Delivery of equipment**

Completion of the laboratory equipment by necessary apparatus of institutes, which attest official control of products of the animal origin for analyses of residues of Chloramphenicol, metabolites of nitrofuran and medroxyprogesteron-acetat (State veterinary and Food Institutes).

**Delivery of equipment** to: WRI

**CONTRACTS:**
1. Twinning 0.5 MEUR
2. Twinning light 0.15 MEUR
3. INV – Phare 1.22 MEUR

INV – SK –co-financing 0.305 MEUR.
<table>
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</tr>
</thead>
<tbody>
<tr>
<td>• Co-financing available</td>
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<tr>
<td>• High-quality twinning partner</td>
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Annex 3  Time Implementation Chart

Project number 2004/016-764.01.01
Project title: Strengthening of Control Systems in Food Safety

<table>
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<th></th>
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<tr>
<td>1.2. Twinning Light</td>
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<tr>
<td>1.3. Investment</td>
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</tbody>
</table>

**Annex 4 Cumulative Contracting and Disbursement Schedule**

Project number: 2004/016-764.01.01

Project title: Strengthening of Control Systems in Food Safety

**Twinning:** 500 000 EUR

<table>
<thead>
<tr>
<th></th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracted</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disbursed</td>
<td></td>
<td></td>
<td>0,15</td>
<td>0,35</td>
</tr>
</tbody>
</table>

NB: 1. All contracting should normally be completed within 6-12 months and must be completed by 15 December 2006
2. All disbursements must be completed by 15 December 2007

**Twinning light:** 150 000 EUR

<table>
<thead>
<tr>
<th></th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
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</thead>
<tbody>
<tr>
<td>Contracted</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disbursed</td>
<td></td>
<td></td>
<td>0,15</td>
<td>0,5</td>
</tr>
</tbody>
</table>

NB: 1. All contracting should normally be completed within 6-12 months and must be completed by 15 December 2006
2. All disbursements must be completed by 15 December 2007
Supply: 915 000 EUR

<table>
<thead>
<tr>
<th></th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
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</thead>
<tbody>
<tr>
<td>Contracted</td>
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<tr>
<td>Disbursed</td>
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</tr>
<tr>
<td>0.6</td>
<td>0.915</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.13</td>
<td>0.475</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.730</td>
<td>0.915</td>
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</tr>
</tbody>
</table>

NB: 1. All contracting should normally be completed within 6-12 months and must be completed by 15 December 2006
2. All disbursements must be completed by 15 December 2007
Annex 5  Indicative list of equipment
Project Transition Facility

<table>
<thead>
<tr>
<th>Specification of equipment</th>
<th>Pcs</th>
<th>Place of delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot No. 1 – Chromatography / Mass spectrometry (ultra sensitive for banned substances)</td>
<td>2</td>
<td>SVFA SR (laboratories: Dolny Kubin, Nitra)</td>
</tr>
<tr>
<td><strong>LC-MS ultra sensitive</strong> equipment consists from:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. <strong>MS/MS Atmospheric pressure ionisation (API) triple quadrupole mass spectrometer.</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mass range at least 5 –3000 at unit mass resolution across entire range is required.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min. scan speed 2000 amu/sec. Mass stability at least 0.1 amu over 8 hours with normal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>operating temperature. Direct injection to the mass spectrometer is required too.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electronic control switching of mobile phase to source or to waste during analyse is</td>
<td></td>
<td></td>
</tr>
<tr>
<td>required (prevent of contamination of source). Scan modes includes full scan, selected</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ion monitoring (SIM), MS/MS product ion scan, selected reaction monitoring (SRM),</td>
<td></td>
<td></td>
</tr>
<tr>
<td>multiple reaction monitoring (MRM) – at least 7 MRM with short dwell time without</td>
<td></td>
<td></td>
</tr>
<tr>
<td>cross-talk, Automated Methods development (AMD) for developing of optimal collision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>conditions parent ions. Flow injection pump with 1 ml glass syringe is required too.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional automated features includes automatic gain control (AGC), autotune, autogain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>and auto flow for API source gases. Positive and negative ions detection with on-the-fly</td>
<td></td>
<td></td>
</tr>
<tr>
<td>polarity switching between positive and negative ion mode. High sensitivity ion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>detection system is required. High efficient collision cell are required too. API-ESI flow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>rate up to at least 1ml/min. APCI flow rate up to at least 2 ml/min. Software selectable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>source combining ESI and APCI is required. Sensitivity: 5 pg of reserpine should give</td>
<td></td>
<td></td>
</tr>
<tr>
<td>minimum Signal to Noise ratio 500:1, RSD&lt;10%. Pressure reduction regulator with metal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>membrane for inert gas (inlet pressure: 200 bars, outlet pressure: up to 10 bars). All</td>
<td></td>
<td></td>
</tr>
<tr>
<td>necessary components for installation. Installation and basic training with service</td>
<td></td>
<td></td>
</tr>
<tr>
<td>technician and 3 days at company facility for 2 operators including instruction for</td>
<td></td>
<td></td>
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<tr>
<td>routine maintenance.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. <strong>Nitrogen generator</strong>, minimum 15 l/min 99% N₂.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. <strong>Quaternary low pressure gradient liquid pump</strong> (including four channel vacuum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>degaser) for using with classical and narrow bore HPLC columns. Flow range minimum 10-500</td>
<td></td>
<td></td>
</tr>
<tr>
<td>000 µl/min. Composition precision &lt; 0.5% RSD at 0.2ml/min. Maximum pressure at least 340</td>
<td></td>
<td></td>
</tr>
<tr>
<td>bars. Flow precision &lt;0.5% RSD. All necessary components for installation.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. <strong>Autosampler with sample capacity minimum 50x2ml vials.</strong> Minimum temperature range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>from +5 to +40°C. Injection volume range at least from 0.1 µl to 100 µl, precision &lt;0.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RSD. Carryover &lt;0.1%. Minimum 200pcs amber screw top vials.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. <strong>Column thermostat</strong> (ambient temperature to at least +60 °C) with column switcher</td>
<td></td>
<td></td>
</tr>
<tr>
<td>for at least 2 installed analytical HPLC columns – electronic controlled via software.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Including temperate of mobile phases in this some temperature range as column thermostat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>is required too.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. <strong>Application software and hardware</strong> package including:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
- PC station for instrument control with record/rewrite CD ROM, min 17” LCD monitor, laser printer.
- Application software for full control of LC-MS device except nitrogen generator.

Lot No. 2 – Chromatography / Mass spectrometry

**LC-MS** equipment consists from:

1. **MS/MS Atmospheric pressure ionisation (API) triple quadrupole mass spectrometer.** Mass range at least 5–2000 at unit mass resolution across entire range is required. Min. scan speed 2000 amu/sec. Mass stability at least 0.2 amu over 24 hours with normal operating temperature. Direct injection to the mass spectrometer is required too. Electronic control switching of mobile phase to source or to waste during analyse is required (prevent of contamination of source). Scan modes includes full scan, selected ion monitoring (SIM), MS/MS product ion scan, selected reaction monitoring (SRM), multiple reaction monitoring (MRM) – at least 40 MRM with short dwell time without cross-talk, Automated Methods development (AMD) for developing of optimal collision conditions parent ions. Flow injection pump with 1 ml glass syringe is required too. Additional automated features includes automatic gain control (AGC), autotune, autogain and auto flow for API source gases. Positive and negative ions detection with on-the-fly polarity switching between positive and negative ion mode. High sensitivity ion detection system is required. High efficient collision cell are required too. API-ESI flow rate up to at least 1ml/min. APCI flow rate up to at least 2 ml/min. Software selectable source combining ESI and APCI is required. Sensitivity: 5 pg of reserpine should give minimum Signal to Noise ratio 10:1, RSD<10%. Pressure reduction regulator with metal membrane for inert gas (inlet pressure: 200 bars, outlet pressure: up to 10 bars). All necessary components for installation.

2. **Nitrogen generator**, minimum 15 l/min 99% N₂.

3. **Quaternary low pressure gradient liquid pump** (including four channel vacuum degaser) for using with classical and narrow bore HPLC columns. Flow range minimum 10-5000 µl/min. Composition precision < 0.5% RSD at 0.2ml/min. Maximum pressure at least 340 bars. Flow precision <0.5% RSD. All necessary components for installation.

4. **Autosampler with sample capacity minimum 50x2ml vials.** Minimum temperature range from +5 to +40°C. Injection volume range at least from 0.1 µl to 100 µl, precision <0.5% RSD. Carryover <0.1%. Minimum 200pcs amber screw top vials.

5. **Column thermostat** (ambient temperature to at least +60 °C) with column switcher for at least 2 installed analytical HPLC columns – electronic controlled via software. Including temperate of mobile phases in this some temperature range as column thermostat is required too.

6. **Application software and hardware** package including:
   - PC station for instrument control with record/rewrite CD ROM, min 17” LCD monitor, laser printer.
   - Application software for full control of LC-MS device except nitrogen generator.

| SVFA SR (laboratories: Bratislava, Kosice) |
### Specification of Equipment

<table>
<thead>
<tr>
<th>Equipment Description</th>
<th>Pcs</th>
<th>Place of delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Spectrophotometer (Lange)</strong></td>
<td>1</td>
<td>WRI</td>
</tr>
<tr>
<td>High speed double ray UV/VIS spectrophotometer with impulse xenon lamp.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **2. HPLC chromatography (complete)**                                     | 1   | WRI               |
| Binary Pump, Continuous Seal Wash Option, Solvent Selection Valve,       |     |                   |
| Micro Vacuum Degasser, Thermostatted Autosampler, Thermostatted          |     |                   |
| Column Compartment, Column Switching Option                               |     |                   |
| Variable Wavelength Detector, Standard Flow Cell, LC/MSD IONTRAP         |     |                   |
| Detector, LC/MSD APCI Source, Oil-Less Compressor, Nitrogen Gas Generator, |     |                   |
| Valve for Sample Enrichment, Stainless Steel Capillary with Fittings,    |     |                   |
| 90 x 0.17 mm i.d., Stainless Steel Capillary with Fittings, 180 x       |     |                   |
| 0.17 mm i.d.                                                             |     |                   |
| PC complete, software ChemStation                                         |     |                   |

### INVESTMENT SUMMARY TABLE IN EURO

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
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<tr>
<td>Transition Facility INV</td>
<td>915 000</td>
</tr>
<tr>
<td>National Co-financing</td>
<td>305 000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1 220 000</strong></td>
</tr>
</tbody>
</table>