Standard Summary Project Fiche for the Transition Facility

1. Background information
   1.1 CRIS number: 2006/018-175.05.03
   1.2 TWL number: SK 06-IB-SO-04-TL
   1.2 Title: Improving analyses and risk assessments regarding residue pesticides
   1.3 Sector: Health
   1.4 Location: Ministry of Health, Public health Authority of the SR, Slovak Republic

2. Objectives
   2.1 Overall objectives:

   Ensuring complete and effective protection of consumers from exposure to health risky food products due to residue pesticide content placed on the market (Ensuring Consumer Health Protection and Food Safety).

   2.2 Project purposes:

   - Improvement and upgrading of Public Health Authority of the SR (PHA SR) capacities in the area of human health protection related to foodstuffs containing residue pesticides.
   - Improvement and upgrading of present knowledge on Risk assessment and analyzing in the field of residue pesticides issue especially in infant and baby food.
   - Strengthening the laboratory capacities of PHA SR (the main institution responsible for analysis of residue pesticides in foodstuffs) in the field of analyzing of residue pesticides in foodstuffs (especially in infant and baby food) due to official control and monitoring purposes.

   2.3 Justification

   The project helps to achieve one of the priorities of the Comprehensive monitoring report on Slovakia’s preparations for membership from November 2003: Chapter 1: Free movement of goods referring:

   1.1.1. Improvements to administrative capacity should continue particularly as regards market surveillance to ensure full operational efficiency by the date of accession.

   The project helps to achieve also one of the tasks that arise from overall conclusions of Final report of a mission carried out in the Slovak republic from 4 to 8 April 2005 concerning controls of pesticides in food of plant origin (document No. DG (SANCO)/7631/2005 – MR Final):

   1.1.2. Further improvement is necessary. The control system for marketing and use of plant products needs to be strengthened particularly in the areas of training, planning and numbers of controls at both marketing and user levels.

   In order to have confidence in proposals from other Member States, it is necessary to have a detailed understanding of the risk assessment for pesticides. Complex methods are under continual development. For chronic, acute and probabilistic assessments.

   Above-mentioned mission was carried out by FVO Dublin (Directorate F – Food and Veterinary Office). It was focused on controls of pesticides in food of plant origin in Slovakia and all institutions under the competence of the Ministry of Health of the SR, Ministry of Agriculture of the SR and Ministry of Environment of the SR responsible for controls of pesticides took part in it.
Relevant EU legislation:

3. Description

3.1 Background and justification
The pesticides and plant protection products are chemical substances used for protection of plants, foodstuffs and feeds against pests. In 2004, there were about 3,464 tones of plant protection products used in Slovakia. Beside the positive results that arise from the use of pesticides, there are also negative impacts – direct real acute and chronic risks for human health.

In the Slovak Republic the area of health protection, including the protection against the negative impact of pesticides and plant protection products on human health through foodstuffs is under the responsibility of PHA SR. PHA SR is also responsible for protection of health and safety when using the chemical agents. PHA is established as a budgetary organization of the Ministry of Health of the Slovak Republic (MoH SR).

PHA SR carries out the enforcement and monitoring of pesticides residues in baby food on the base of following legislation:

• Commission Recommendation of January 18, 2006 concerning a co-ordinated Community monitoring programme for 2006 to ensure compliance with maximum levels of pesticide residues in and on cereals and certain other products of plant origin and national monitoring programmes for 2007,

Presently, the laboratory of PHA SR is able to control 14 residue pesticides from total amount of 16 residue pesticides, which determination is mandatory due to the official food control and also some pesticides from the total amount of 69 residue pesticides prescribed, for the monitoring by EU. However most of the residue pesticides failed to be monitored according to the program because of the missing laboratory technique.

Experts from the Department of Nutrition and Food Safety PHA SR deal with the pesticide residues and they are responsible for the evaluation of data and conduct risk assessment relating to mammalian toxicology, crop residues and operator exposure. They also set maximum residue limits. On the other and, they still need to be trained and need to get more practice in applying the EU Directive 91/414/EEC, taking in account they are responsible for the evaluation of the plant protection product placed on the market in the Slovak Republic from the consumer
safety concern. Their capability of making such evaluations and the risk assessment according to the up-to-date technical and scientific knowledge should be upgraded.

**National legislation** related to residue pesticides in foodstuffs and using of chemical agents is following:
- Act No. 152/ 1995 Coll. on Foodstuffs,
- Act No. 330/ 1996 Coll. on Health and safety at work with chemical agents and preparations, as amended,
- More specially Act No. 272/ 1994 Coll. on Human health protection, as amended,
- Government Regulation No.45 / 2002 Coll. on Health protection at work with chemical factors,
- Government Regulation No.46 / 2002 Coll. on Health protection at work with carcinogenic and mutagenic factors.

**Relevant EU legislation:**
- Council Directive 79/ 117/ EEC as amended, prohibiting the use and placing plant protection products containing certain active substances on the market,

There is a transition period for the Slovak Republic to apply above-mentioned Directives in the practice, what is considered as an advantage. During this period it is necessary to upgrade and strengthen the capacities and skills of the relevant authorities, which will be fully responsible for their implementation.

In the frame of this twinning light project it is expected to improve and upgrade the knowledge and capacities of PHA especially in the following areas:
1. Global harmonized system of C and L (Classification and labeling) and its impact on Member States of EU
2. Calculations (NEDI – national estimated daily intake)

The relevance of this project is supported by these documents:
- Directive 94/ 79/ EEC - Exposure risk assessment for formulation based on Good agricultural practice (GAP),

Furthermore, one of the very important part of ensuring the food safety in the field of residue pesticides especially in infant and baby food is correct analysis of residue pesticide in above-mentioned foodstuffs, both for official food control and food monitoring by methods on the base of EU requirements. As a EU member state, Slovak Republic is obliged to fulfil these requirements. Acquiring the knowledge on these procedures and methods will be sufficiently achieved by seminars and trainings focused on following
methods: GC- ECD, NPD, GC/MSMS triplequad, GPC/HPLC, APCI-LC/MSMS, on preparation of sample before analysis. Receiving foreign know-how provided by Member countries’ experts will provide conditions for more efficient protection of consumers from exposure to dangerous foodstuffs (due to content of residue pesticides) placed on the market of the Slovak Republic.

3.2 Linked activities

The project is related to:

**Phare Twinning Project „Strengthening of Prevention and Control System in the area of Food Safety“ SK 2004/IB/AG/01.**

Collaboration between Great Britain and Slovak Republic.

The main aim of the project is to strengthen the organisation, technical proficiency and administration steps of existing Slovak Institutions by providing of effective implementation of Directive 91/414 EEC in the field of plant protection products. The project is also focused on strengthening the assessment process of plant protection products from the view of human health safety and safety for environment (residues, mammalian toxicology, operator exposure, ecotoxicology, efficacy, fate and behaviour, EU procedures and national procedures). This project is not focused on global harmonized system of C and L (Classification and Labelling) and its impact on Member States of EU, calculation of NEDI – national estimated daily intake and procurement of necessary laboratory equipment for analysis of residue pesticide in foodstuffs. The project has formally started in October 24, 2005 and will continue until the end of October 2006.

3.3 Results

The project realization should meet the following results, listed in chronological order:

**3.3.1. The Laboratory at PHA SR technically strengthened, the knowledge database created**

The Laboratory at PHA SR responsible for analysis of residue pesticides in foodstuffs, will be technically strengthened by acquisition of inevitable, special equipment and material (specification in Annex 4), which is needed for exact and precise provision of methods. All this will enable the laboratory at PHA SR SR responsible for analysis of residue pesticides in foodstuffs analyze all residue pesticides in foodstuffs (especially in infant and baby food) which determination is mandatory according to EU law and documents both due to official control and monitoring purposes and which determination before the project failed to be monitored according to the program because of the missing laboratory technique.

Additionally, all necessary and most recent information material relating to Global harmonized system of C and L and calculations (NEDI – national estimated daily intake) (last editions of books, publications) will be provided to create a knowledge database in disposal and for support of the experts of specialized Nutrition and Food Safety Department PHA SR who are responsible for the evaluation of data and conduct risk assessment relating to mammalian toxicology, crop residues and operator exposure. They also set maximum residue limits.
3.3.2. Theoretical background and practical analytical skills of the Slovak experts (laboratory workers and professionals) improved throughout specialised sets of trainings and practical exercises:

a.) PHA SR professionals trained
5 experts of specialized Nutrition and Food Safety Department PHA SR will be trained on residue pesticides and plant protection product issue to be able to implement new knowledge and skills received from EU experts in everyday practice. They will be able to use new knowledge on Global harmonized system of C and L (Classification and Labeling) and calculations of NEDI – national estimated daily intake in the process of evaluation of data and risk assessment relating to mammalian toxicology, crop residues and operator exposure and at setting maximum residue limits.

b). Training materials and methodical procedure guide produced
Training materials and methodical guide on Global harmonized system of C and L (Classification and Labeling) and calculations of NEDI – national estimated daily intake would be produced to supplement the training of PHA SR professionals. These materials will assist Slovak experts to evaluate and analyze the risks in the field of residue pesticides and plant protection product in foodstuffs.

c) Laboratory workers responsible for laboratory analysis of residue pesticides in infant and baby food trained
Laboratory workers responsible for laboratory analysis of residue pesticides in infant and baby food will be able to analyze all residue pesticides in the infant and baby food) by using methods on the base of EU requirements which determination is mandatory according to EU law and documents both due to official control and monitoring purposes and which determination before the project failed to be monitored according to the program because of the missing laboratory technique.

d.) Training materials and methodical procedure guide on using new analytical methods in analyzing of residue pesticides in infant and baby food produced
Prepared training materials and methodical procedure guide will be supplement to training of the laboratory workers. They will assist them to analyze residue pesticides in infant and baby food by using methods on the base of EU requirements. Training materials and methodical procedure guide will focus on following methods: GC- ECD, NPD, GC/MSMS triplequad, GPC/HPLC, APCI-LC/MSMS, on preparation of sample before analysis.

e.) Professionals of PHA SR as well as of 36 Regional Public Health Authorities (RPHA) trained on principles of risk analysis in the field of residue pesticides in foodstuffs and especially with respect to vulnerable population groups (particularly infants and babies).

Professionals of PHA SR as well as of 36 Regional Public Health Authorities (RPHA) will have upgraded their knowledge and improved their skills regarding principles of risk analysis in the field of residue pesticides in foodstuffs and especially with respect to vulnerable population groups (particularly infants and babies.
3.4 Activities

3.4.1. Procurement of the special equipment, material and publications for the Laboratory at PHA SR responsible for analysis of residue pesticides in foodstuffs and acquisition of publications for experts of PHA SR

The Laboratory at PHA SR will be technically strengthened by acquisition of inevitable, special equipment and material (specification in annex 4) necessary for provision of relevant methodologies.

The support of the professionals of specialized Nutrition and Food Safety Department PHA SR will include the acquisition of all necessary and most recent information material (last editions of books, publications) relating to Global harmonized system of C and L and calculations (NEDI – national estimated daily intake). The required sources of theoretical and experimental (practical) information that are mostly issued abroad and are hardly available in sufficient range to the Slovak experts would create a knowledge database in disposal to PHA SR staff.

MEANS: activity will be provided in the framework of the supply contract

3.4.2. Provision of a set of specialized trainings and seminars for experts of RPHA and PHA SR (professionals and laboratory workers)

a.) Intensive training and seminar of professionals.

The training component consists of trainings and seminars in overall duration of 10-days, which will be organized for 5 Slovak professionals of the Department of Nutrition and Food Safety PHA SR that are responsible for below-mentioned area. Trainings and seminars will take place in Bratislava. They will consist mostly of explanation and description of the residue pesticides and plant protection product issue. They will focus on widening, improvement and upgrading of present knowledge and receiving of new professional skills.

The training and seminar will be focused on two topics:
1. Global harmonized system of C and L (Classification and Labeling) and its impact on Member States of EU,
2. Calculations of NEDI (national estimated daily intake).

Working language (during trainings, seminars) is English by using translation to the Slovak language due to complexity of the topic.

b.) Development and production of training materials and methodical procedure guide.

Prepared training materials and methodical procedure guide on Global harmonized system of C and L (Classification and Labelling) and calculations of NEDI will assist Slovak experts to evaluate and analyze the risks in the field of residue pesticides and plant protection products in foodstuffs. All materials (training materials and methodical procedure guide) will be translated into Slovak language, printed and distributed for Slovak professionals of the Department of Nutrition and Food Safety PHA SR in appropriate number of copies.

Training materials and methodical procedure guide will be focused on:
1. Global harmonized system of C and L (Classification and Labeling) and its impact on Member States of EU,
2. Calculations (NEDI – national estimated daily intake),
and shall include instructions for evaluation of risk rising from residue pesticides in foodstuffs, shall reflect WHO/FAO and possibly EU requirements for evaluation of this risk.

c.) Intensive trainings for laboratory workers on new analytical methods in analyzing of residue pesticides in infant and baby food
This training component (theoretical and also practical) consists of 2 trainings (each of 5-days) for 6 laboratory workers responsible for laboratory analysis of residue pesticides in infant and baby food. Trainings will take place in Bratislava. As one of the very important part of ensuring food safety in the field of residue pesticides especially in infant and baby food is correct analysing of residue pesticide in above-mentioned foodstuffs both for official food control and food monitoring by using methods on the base of requirements of the European Union. Therefore seminars and trainings will focus on following methods: GC- ECD, NPD, GC/MSMS triplequad, GPC/HPLC, APCI-LC/MSMS, on preparation of sample before analysis.

**Specification of 1. training:**
5 days training on determination of pesticides in food on GC/MS/MS-triplequad, GC-ECD, NPD, including:
- extraction and clean up of samples,
- methods for determination of pesticides by GC/MS/MS-triplequad, GC/-ECD, NPD,
- interpretation of results by using of software.

**Specification of 2. training:**
5 days training on determination of pesticides in food on LC/MSMS-APCI, GPC/HPLC, automated clean and fraction collection, ASE, including:
- extraction of and clean up of samples,
- clean up of samples by GPC/HPLC,
- methods for determination of pesticides by APCI-LC/MS/MS, interpretation of results by using of software.

Both trainings will consist of a theoretical section (presentations, discussions) directly followed by practical laboratory training/demonstration focused on the actually lectured topics.

d.) Preparation of training materials and methodical procedure guide on using new analytical methods in analyzing of residue pesticides in infant and baby food
Prepared training materials and methodical procedure guide will assist laboratory workers to analyze residue pesticides in infant and baby food by using methods on the base of EU requirements. Materials should be focused on following methods: GC- ECD, NPD, GC/MSMS triplequad, GPC/HPLC, APCI-LC/MSMS, on preparation of sample before analysis. All materials (training materials and methodical procedure guide) will be translated into Slovak language, printed and distributed for laboratory workers responsible for laboratory analysis of residue pesticides in infant and baby food.

e.) Provision of a seminar focused on principles of risk analysis in the field of residue pesticides in foodstuffs and especially with respect to vulnerable population groups (particularly infants and babies).

2-days seminar will be organized for professionals of PHA SR and representatives of 36 RPHA (about 40 people) that are responsible for below-mentioned area. The seminar will take place in Bratislava and will consist mostly of explanation and description of the residue pesticides and plant protection product issue and evaluation and risk analysis in this field and experiences gained during previous trainings. It will focus on widening,
improvement and upgrading of present knowledge on and receiving of new professional skills of wider spectrum of public health professionals from whole Slovakia.

**MEANS:** activities 3.4.2. a) b) c) d) e) will be implemented in the framework of one twinning light arrangement, more specially the activities 3.4.2. c) d) will be implemented in close collaboration with the supplier team.

For the courses needs, the required equipment (activity 3.4.1.) is not a pre-condition for the launch of the training activities 3.4.2a.) and 3.4.2 b.). However, its availability during the training courses combined with the presence of experienced lecturers and supervisors able to demonstrate its advantages in toxicological analyses, would significantly improve the quality and usefulness of the practical trainings.

On the other hand, the equipment is necessary for provision of the others training activities as 3.4.2 c.) and 3.4.2. d.). Hence, the equipment will be supplied in the first phase of the project to ensure its functioning and availability for the planned courses.

In the framework of the twinning light contract one TWL Project Leader is envisaged to be supported by pool of short-term experts.

**The TWL Project Leader should fulfil the following criteria:**

**TWL expert – MS Project leader**

- he/she must have university education in chemical, medical or pharmaceutical field
- must have at least 8 years of experience in toxicology
- must have deep experience at consumer risk assessment methodologies for pesticides used within the EU regulatory framework, detailed knowledge of existing methodologies for chronic and acute assessments and of methodologies under development for probabilistic and cumulative assessments
- must have proven team leading experience in working with international teams
- should come from an equivalent institution to recipient institution of this project
- a good command of English is required (spoken, written)
- should have good communication skills
- should have proven lecturer skills

The TWL expert should be responsible for:

- professional and managerial supervision over the entire project
- coordination of partial tasks of the project, sequencing of their realisation
- coordination of STE/STEs
- coordination and direct professional participation in provisions of trainings with cooperation of STE/STEs – elaboration of all training materials and recommended standard procedures
- together with STE/STEs – provision of all training requested
- methodical supervision of whole activity 3.4.2.
- coordination with the supplier team

The following pool of short-term experts (as a part of the TWL team) will support the TWL project leader:

**TWL Short-term expert 1:**

- must have at least 6 years of experience in toxicology
- must have deep experience at consumer risk assessment methodologies for pesticides used within the EU regulatory framework, detailed knowledge of existing methodologies for chronic and acute assessments and of methodologies under development for probabilistic and cumulative assessments
should come from an equivalent institution to recipient institution of this project

a good command of English is required (spoken, written)

should have good communication skills

should have proven lecturer skills

STE 1 will be responsible for the following issues:

- in cooperation with the TWL Project Leader – provision of trainings, seminars (activity 3.4.2.a) b.)
- in cooperation with the TWL Project Leader – elaboration of all related training materials and methodical procedures

TWL Short-term expert 2:

- must have university education in chemical or natural fields
- minimum 8 years experience in analytical chemistry and chemical laboratory,
- practical knowledge in field of analytical chemistry, with extraction samples of food for determination of pesticides and in determination of pesticides in food
- at least 2 years practical experiences analysis pesticides by gas chromatography GS/MS/MS triplequad and GC/ECD,NPD using the equipment supplied
- should come from equivalent institution to recipient institution of this project,
- should come from laboratory accredited and use standard practical procedures for determination of pesticides residue in foodstuff or fulfill good laboratory practises (GLP),
- good command of English (written, spoken)
- experiences in working with international teams,
- should have good communication skills,
- should have proven lecturer skills,

TWL Short-term expert 3:

- must have education in chemical field (chemical or natural)
- 8 years experience in analytical chemistry and chemical laboratory,
- practical knowledge in field of analytical chemistry, with extraction samples of food for determination of pesticides and in determination of pesticides in food
- at least 2 years practical experiences with liquid chromatography LC/MS/MS-APCI, GPC/HPLC, extraction system – ASE using the equipment supplied
- should come from equivalent institution to recipient institution of this project,
- should come from laboratory which is accredited and use standard practical procedures for determination of pesticides residue in foodstuff or fulfill good laboratory practises (GLP),
- good command of English (written, spoken)
- experiences in working with international teams,
- should have good communication skills
- should have proven lecturer skills

STE 2 and STE 3 will be responsible for the following issues:

- in cooperation with the TWL Project Leader – provision of trainings, seminars (activity 3.4.2.c) d.)
- in cooperation with the TWL Project Leader – elaboration of all related training materials and methodical procedures
<table>
<thead>
<tr>
<th>Expert</th>
<th>Activity</th>
<th>Time-frame (sequence of months from the supply of equipment under 3.4.1., in which the activity is realized)</th>
<th>M/days</th>
</tr>
</thead>
<tbody>
<tr>
<td>MS PL</td>
<td>all activities</td>
<td>1-6</td>
<td>22</td>
</tr>
<tr>
<td>STE 1</td>
<td>3.4.2. a.) 3.4.2.b.) 3.4.2.e.)</td>
<td>4-6</td>
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<td>STE 2</td>
<td>3.4.2.c.) 3.4.2.d.)</td>
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<tr>
<td>STE 3</td>
<td>3.4.2.c.) 3.4.2.d.)</td>
<td>1-3</td>
<td>15</td>
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</table>

3.5 Lessons learned:

There are many positive experiences acquired by the beneficiary as well as recipient institution from implementing other Phare projects in recent years. Our practical experience proves that for successful project implementation a good cooperation and communication among all stakeholders and organization of regular working meetings is very important.

The MoH SR as a beneficient has serious experience with managing and coordinating of PHARE projects. The managing structure that was successfully tested is to have overall coordination at the ministerial level (also because the recipient institutions are subordinate of the MoH SR) and the professional guidance is on the recipient level. Project managers from Project Unit of Foreign Aid of MoH SR actively manage and in close cooperation with MS experts and Slovak recipient institutions prepare and ensure all activities and organizational issues. Projects, which MoH managed were successfully finished and objectives and results were achieved.

There were no recommendations made during previous interim evaluation that might be applied to this project.

4. Institutional framework

The Ministry of Health SR (MoH SR) will be the beneficiary institution and main partner in the project. It will have the overall responsibility for the management and control of the project. The PHA SR will be the final recipient of the project benefits.

Monitoring of and supervision over the progress and development of the entire project will be provided by a Steering committee (SC) which will be attended by representatives of the MoH SR, PHA SR, the Twinning Light partner, Office of Government SR and Central Finance and Contracting Unit (CFCU) and Suplier. The Steering committee meetings will be held on regular quarterly basis or often if required.
The Project leader on the Slovak side will be:
Ms. Zuzana Škublová
Project Unit for foreign aid
Ministry of Health of the Slovak Republic
Limbova 2
837 52 Bratislava, Slovakia
Tel.:00421/2 593 73 268, Fax: 00421/2 547 77 465
E-mail: zuzana.skublova@health.gov.sk

Contact person on behalf of the PHA SR:
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e-mail: truskova@uvzsr.sk

5. Detailed budget

<table>
<thead>
<tr>
<th>M €</th>
<th>Transition Facility support</th>
<th>Co-financing</th>
<th>Total cost (TF plus cofinancing)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Investment Support</td>
<td>Institution Building</td>
<td>Total Transition Facility (=I+IB)</td>
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<tr>
<td>TWL (contract 1)</td>
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<td>0,150</td>
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<tr>
<td>Supply (contract 2.1) equipment</td>
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<tr>
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</table>

(*) contributions from National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises
(**) private funds, FIs loans to private entities

The amounts for national co-financing indicated in the table correspond to cash co-financing. Contributions from the Slovak administration for effective implementation of twinning light may be further detailed in the twinning contract. Unless otherwise indicated joint co-financing is provided.

VAT does not constitute eligible expenditure except where it is genuinely and definitely borne by the final beneficiary. VAT which is considered recoverable, by whatever means, cannot be considered eligible, even if it is not actually recovered by the final beneficiary or individual recipient.
6. Implementation Arrangements

6.1 Implementing Agency
PAO: Mrs. Silvia Czuczorova
Director of CFCU
Ministry of Finance SR
Štefanovičova 5
817 82 Bratislava
Slovak Republic
tel.: + 421 2 5958 2546
fax: + 421 2 5958 2559
e-mail: cfcu.czuczorova@mfsr.sk

6.2 Twinning
The institutional twinning light partner will be the Ministry of Health of the Slovak Republic, which will assume overall responsibility for the project. The Ministry of Health will co-operate in project implementation with other institutions, in particular with the Public Health Authority of the Slovak Republic, which will be the recipient institution and will be responsible for professional aspects of the entire project. The short-term experts will be deployed at the office of the PHA SR.

National Contact Point for Twinning involved in Twinning projects management:
Mrs. Jana Minarovičová
Office of Government SR
Námestie slobody 1
813 70 Bratislava
Tel.: 00421/2 57 295 514
E-mail: jana.minarovicova@government.gov.sk

Contact person on behalf of the PHA SR:
MUDr. Iveta Trusková
Head of Department of Nutrition and Food Safety, Public Health Authority of the Slovak Republic
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Tel. +421 2 444 55 643, Fax: +421 2 444 55 643
e-mail: truskova@uvzsr.sk

6.3 Non-standard aspects
N/A

6.4 Contracts
The project will be implemented with the following contracts:
Twinning light arrangement: 0,150 M€
Supply contract (equipments, materials) 0,400 M€
Supply contract (publications, books) 0,005 M€

7. Implementation Schedule
7.1 Start of tendering 1st Q 2007
7.2 Call for proposals: 2nd Q 2007
7.3 Start of project activity: 3rd Q 2007
8. **Sustainability**

Relevant policies and regulations of the Slovak Government ensure that all activities funded under the project will yield results that comply with the European Union norms and standards. Slovak professionals of the Department of Nutrition and Food Safety PHA SR responsible for evaluation of data and risk assessment related to mammalian toxicology, crop residues and operator exposure and at setting maximum residue limits are regular employees of PHA SR which is as a part of state administration funded by state budget. PHA SR is also according to legislation responsible for above-mentioned part of residue pesticide issue. Laboratory workers as the regular employees of PHA SR laboratory are part of public administration funded by state budget and PHA SR is according to law responsible for analyzing of residue pesticides in the infant and baby food.

9. **Conditionality and sequencing**

For the a success of this project the supply of equipment, material and publications (activity 3.4.1.) is inevitable in the first phase. Its availability during the training courses combined with the presence of experienced lecturers and supervisors able to demonstrate its advantages in toxicological analyses, would significantly improve the quality and usefulness of the practical trainings. The supply will be followed by specialised training and furthermore by delivery of required training materials and guides.

**ANNEXES TO PROJECT FICHE**

1. Logical framework matrix in standard format (compulsory)
2. Detailed implementation chart (compulsory)
3. Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period) (compulsory)
4. Framework specification of the equipment required
5. Description of the publications and books needed
## Transition Facility log frame

<table>
<thead>
<tr>
<th>LOGFRAME PLANNING MATRIX FOR Project</th>
<th>Programme name and number 2006/018-175.05.03</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improving analyses and risk assessments regarding residue pesticides</td>
<td>Contracting period expires 15 December 2008</td>
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<tr>
<td></td>
<td>Disbursement period expires 15 December 2009</td>
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<tr>
<td></td>
<td>Total budget: 0,555 M € TF budget: 0,450 M €</td>
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### Overall objective

**Ensuring complete and effective protection of consumers from exposure to health risky food products placed on the market due to residue pesticide content (Ensuring Consumer Health Protection and Food Safety).**

**Objectively verifiable indicators**

- Performance of official food control and monitoring of residue pesticides in foodstuffs according to EU legislation since 2nd 2008

**Sources of Verification**

- National Report of official food control and monitoring in the field of residue pesticides in the foodstuffs

### Project purpose

- **Improvement and upgrading of PHA SR capacities in the area of human health protection related to foodstuffs containing residue pesticides.**
- Improvement and upgrading of present knowledge on Risk assessment and analyzing in the field of residue pesticides issue especially in infant and baby food.
- Strengthening the laboratory capacities of PHA SR (the main institution responsible for analysis of residue pesticides in foodstuffs) in the field of analysing of residue pesticides in foodstuffs (especially in infant and baby food) due to official control and monitoring purposes.

**Objectively verifiable indicators**

- fully strengthening of administrative capacities PHA SR in the field of human health protection related to the foods containing residue pesticides since 2nd 2008
- fully functional (Equipment, Staff,) Laboratory at PHA SR responsible for analysis of residue pesticides in foodstuffs (especially in infant and baby food) due to official control and monitoring at the end of 2007

**Sources of Verification**

- official statements elaborated by experts from PHA SR
- regular reports elaborated by Laboratory at PHA SR on analysis of residue pesticides
- laboratory equipment received

**Assumptions**

- good cooperation between stakeholders

### Results

**Objectively verifiable**

**Sources of Verification**

**Assumptions**
1. Necessary special equipment and material for the Laboratory at PHA SR responsible for analysis of residue pesticides in foodstuffs and publications for experts of PHA SR provided.
2. Theoretical background and practical analytical skills of the high quality of the Slovak experts (both laboratory and professionals) improved.

<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Assumptions</th>
</tr>
</thead>
</table>
| 1. Procurement of the special equipment and material for the Laboratory at PHA SR responsible for analysis of residue pesticides in foodstuffs and acquisition of publications for experts of PHA SR | Supply contract 2.1 /equipment/  
Supply contract 2.2 /publications/  
One Twinning light contract |  
0,400 M Euro  
0,005 M Euro  
0,150 M Euro  
• Effective cooperation between all stakeholders  
• Technical equipment on place in time  
• the Slovak experts an relevant staff will be timely available for project implementation  
• relevant staff will be available for trainings  
• minimal fluctuation rate of relevant staff  
• organizational changes in PHA SR (particularly in laboratory part) |
| 2. Provision of a set of trainings and seminars for responsible employees of PHA SR (professionals and laboratory staff) and RPHA in SR | | |

| indicators |  
- Routine analysis of residue pesticides due to official food control and monitoring purposes in laboratory of PHA SR performed  
- Employees of PHA SR (both professionals and laboratory staff) trained by the end of the project | • minutes  
• interim report  
• final report  
• evaluation reports  
• Implementation Status Report  
• staff remained on the positions that was trained  
• no organizational changes in PHA SR (particularly in laboratory part) |
Time Implementation Chart

Project number: 2006/018-175.05.03  
Project title: Improving analyses and risk assessments regarding residue pesticides

<table>
<thead>
<tr>
<th>Project component</th>
<th>2007</th>
<th>2008</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st Q</td>
<td>2nd Q</td>
<td>3rd Q</td>
</tr>
<tr>
<td>Twinning light</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supply contract – equipment and material delivery</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supply contract – publications and books delivery</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Training of laboratory workers including production of training materials and guides</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training of professionals including production of training materials and guides</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Cumulative Contracting and Disbursement Schedule

Project number: 2006/018-175.05.03
Project title: Improving analyses and risk assessments regarding residue pesticides

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracted</td>
<td>0.300</td>
<td>0.450</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disbursed</td>
<td>0.300</td>
<td>0.420</td>
<td>0.450</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Annex No. 4**

**Framework specification of the equipment required:**

<table>
<thead>
<tr>
<th>No.</th>
<th>Kind of equipment</th>
<th>Pieces</th>
<th>Price /piece (EUR)</th>
<th>Price in common (EUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>Gas chromatograph MS MS triplequad</strong> – analysis of low concentration of pesticides separated in gas phase – fungicides, herbicides, insekticides - for example triadimenol, triadimefon, spiroxamine, quinoxyfen, pyriproxyfen, mepanipyrim, iprovalicarb, diphenylamin, chlorpropham, metalaxyl-M, metalaxyl, carbaryl, cyprodinil e.g.</td>
<td>1</td>
<td>185 000</td>
<td>est.185 000</td>
</tr>
<tr>
<td>2.</td>
<td><strong>Gas chromatograph with ECD, NPD</strong> – analyses of pesticides – fungicides, herbicides, insekticides - for example organochlorine pesticides, nitrogen compound, pyretroids pesticides, triazines herbicides or organophosphorus pesticides e.g.</td>
<td>1</td>
<td>47 000</td>
<td>est.47 000</td>
</tr>
<tr>
<td>3.</td>
<td><strong>Extraction system ASE</strong> – extraction pretreatment of samples prior to analysis of pesticides</td>
<td>1</td>
<td>75 000</td>
<td>est.75 000</td>
</tr>
<tr>
<td>4.</td>
<td><strong>Autosampler-bio compatible to LS/MS/MS VARIAN 1200</strong> – automated and precise sample injection to instrument for pesticides analyses</td>
<td>1</td>
<td>15 000</td>
<td>est.15 000</td>
</tr>
<tr>
<td>5.</td>
<td><strong>GPC/HPLC automated clean and fraction collection.</strong> – samples preparation for pesticides determination with fats and oils</td>
<td>1</td>
<td>45 000</td>
<td>est.45 000</td>
</tr>
<tr>
<td>6.</td>
<td><strong>APCI interface to an existing VARIAN 1200 LCMSMS system</strong> – analyses of another group of pesticides – for examples thiabendazole, prochloraz, imidaclorpid,</td>
<td>1</td>
<td>12 000</td>
<td>est.12 000</td>
</tr>
</tbody>
</table>
hexythiazox, fenhexamid, chlormequad, benomyl, acetamiprid, aldicarb

7. **Analytical Balance** – analytical weighing – it is necessary for pesticides

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>10 000</th>
<th>est.10 000</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IN COMMON</strong></td>
<td></td>
<td></td>
<td>est.389 000</td>
</tr>
</tbody>
</table>

**Consumption material** estimated 10 000 EUR

Chemical standards of pesticides
Laboratory glass
Laboratory gasses
Chemicals for extraction
GC-columns, LC-columns
Another consumption material for GC and LC

The cost of above-mentioned equipment required is cca. 399.000.- EUR

**Specification of the equipment required:**

1) **GPC/HPLC automated Clean Up req.**

**Instrument specification**

- Flow rate up to 10ml/min, pressure 30MPa, overpressure safety shutdown
- Automatic stop flow after last sample for solvent saving
- Compatibility with all solvents used for GPC
- Step gradient – minimum 6 solvent selection
- Accessories a valve for column back-flush cleaning
- Minimum 15 samples in 4ml vials
- Collection directly into flasks 25 – 100ml for rotary evaporator
- Collection of elution profile with separation into up 30 fraction
- Possibility to re-inject collected fraction
- PC control Software with GLP features
- Control PC with XP, 17”LCD

**Consumables etc.**
- Collection flasks 25, 50, 100ml
- Vials 4ml with screw caps
- Septa for 4ml vials
- GPC glass column 10x500 Bio-beads SX-3 conditioned in chloroform
- Set of pump and autosampler/fraction collector consumables

Automated SPE system req.

- Off-line or On-line sample preparation by SPE
- Possibility to use 1ml, 3ml and 6ml standard SPE columns incl. Immuno-affinity
- Minimum capacity 20 samples for 3ml SPE
- Sample volume from 0.5ml to 40ml
- Minimum selection of 8 solvents, 4 of solvents in 2,5 l bottles minimum
- Results can be stored in 2ml sealed vials
Accessories for columns drying by nitrogen

Simple transfer of manual SPE methods
Control of SPE procedure including collection of different fractions and column drying
Controlled flow rate via SPE columns
Other sample preparation tasks like dilution, adding IS, derivatization
Possible interfacing with HPLC
PC control Software with GLP features
Control PC with XP, 17”LCD
Colour printer common for both systems

Consumables: tubes, vials, septa, SPE columns……
Set of pump and autosampler/fraction collector consumables

2) Gas chromatograph with ECD and NPD detector

- Split/Splitless injector
  Temperature Range (Isothermal): ambient +4º C to 450º C
  Pneumatic Control: manual control standard with optional Electronic Flow Control (EFC)
  Pressure Range: 0-60 psig manual, 0-100 psig EFC
  Split Ratio Range: 5:1 to 10,000:1 (column dependent with EFC)

- NPD detector

- ECD detector

- Autosampler for Liquid & Headspace Injection
  XYZ robot
  Positioning precision: ± 0.1 mm
  Injection mode: automatic recognition of syringe type

Liquid Injection
Liquid injection syringes: 2 µL, 10 µL, 25 µL, 100 µL, and 250 µL
Syringe cleaning: wash station with two different solvents
Injection speed: 0.01 µL/sec to 500 µL/sec

Headspace Injection
Headspace syringes: 1 mL, 2.5 mL, and 5.0 mL
Syringe temperature range: 30ºC to 150ºC
Syringe cleaning: inert gas purge
Injection speed: 0.01µL/sec to 1000 µL/sec
Incubator Oven/Orbital Shaker module: standard
Heated vial positions: six
Incubation temperature range: 30ºC to 200ºC
Agitation: interval shaking from 250 rpm to 750 rpm

Sample Capacity
Sample trays: two, standard and expandable to four
Tray types: 98 x 2 mL vials; 200 x 1 mL vials; 32 x 10 mL/20 mL vials;

3) Gas chromatograph GC/MS/MS with triple stage quadrupole

Gas chromatograph with daul mass detectore

Triple stage quadrupole
Elektrospray interface – ESI
Regime: Full scan, SIM, SRM, MRM, Precursor, Product and Neutral Loss scan MS/MS
Possibility to join to LC/MS/MS
Maximum signal with optimized use of ion guides and no lenses between quadrupoles
Unequalled detection limits, especially for complex matrices, due to the elimination of background chemical noise

- **Split/Splitless injector**
  Temperature Range (Isothermal): ambient +4°C to 450°C
  Pneumatic Control: manual control standard with optional Electronic Flow Control (EFC)
  Pressure Range: 0-60 psig manual, 0-100 psig EFC
  Split Ratio Range: 5:1 to 10,000:1 (column dependent with EFC)

- **Autosampler for Liquid & Headspace Injection**
  XYZ robot
  Positioning precision: ± 0.1 mm
  Injection mode: automatic recognition of syringe type

**Liquid Injection**
Liquid injection syringes: 2 µL, 10 µL, 25 µL, 100 µL, and 250 µL
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**Sample Capacity**
Sample trays: two, standard and expandable to four
Tray types: 98 x 2 mL vials; 200 x 1 mL vials; 32 x 10 mL/20 mL vials;

**4) Extraction system ASE**

Instrument specification

1. possibility to use combination of solvents under set pressure and temperature
2. conditions
3. extractor shall be capable of oven temperature control up to **200°C** and cell pressure
4. control up to **100 atm**
5. extractor must have **min. of 12** position sample carousel with one rinse position for
6. unattended operation
7. extractor shall have the ability to use **34ml, 66ml and 100ml extraction cells**
8. interspersed on the sample carousel
9. cells must be of **hand closure type** /no wrenches and mechanical tightening required /
10. automatic rinsing between samples as a user selectable option
11. extractor shall have automatic pressure sensor and pressure relief during extraction
12. cell heat up
13. possibility of **multiple sequential extractions** per individual cells: extracts can be
14. collected into the same or different collection bottles
15. optional solvent controller permitting the use of **up to 4 solvents**
16. solvents can be mixed and introduced to the extraction cells in preset ratios /
17. **automatic filtration** of extracts prior to collection in the vial
18. built in **vapour sensor** to shut down if vapour levels are detected above accepted safety limits

**Evaporatoration module with solvent recovery module**
19. the evaporator shall use the combination of **heated block / not water bath /** and heated **nitrogen** to concentrate organic solvents
20. block shall be able to **reach 140°C**
21. the evaporator shall use the combination of heated block / not water bath / and heated
22. nitrogen to concentrate **water and aqueous solvents or buffers**
23. the evaporator shall be compatible with **40ml, 60ml and 250ml vials** of the extractor by interchanging only the block and manifold
24. ability to evaporate contents of up to six 40ml or six 60ml vials or two 250 ml bottles
25. system must contain a **solvent recovery module** to decrease an adverse impact to the environment and **cabinet**, which allows the system to be used in the laboratory without a hood

5) **Autosampler-bio compatible**

Instrument specification

1. Standard sample tray with cooling: 84 x 1.5 mL vials with 3 x 10 mL vials
2. Dispenser unit: 50 µL syringe standard
3. Injection volume: 1 to 5000 µL
4. Injection methods: nine methods in memory
5. Needle wash: integrated, programmable large reservoir
6. Vial detection: yes
7. Reproducibility: Full Loop: < 0.3% RSD, Partial Loop: < 0.5% RSD
8. Microliter Pickup: < 1.0% RSD
9. Carryover: < 0.05%
10. Compatible with Star software for LC/MSMS system 1200 L

6) **APCI interface to an existing VARIAN 1200 LCMSMS system**

Instrument specification

**LC flow range**: 100 µL/min to 2 mL/min

**Nebulizing gas**: 2 L/min max; 1.5 L/min typical

**Auxiliary gas flow rate**: 6 L/min max; 2 L/min typical

**Auxiliary gas temperature**: 550 ºC max; optimum is compound, mobile phase and flow dependent

**Drying gas flow rate**: 10 L/min max; 2 L/min typical

**Drying gas temperature**: 400°C max at 8 L/min; 150°C typical

**Corona current**: -50 to +20 µA
**Spray chamber temperature:** 65°C max

**Spray needle:** off-axis from the capillary axis; adjustable distance from spray plate

7) **Analytical Balance**

**Instrument specification**

Using for precise and accurate weighing of chemicals, standards, samples.

**PARAMETERS OF BALANCE:**

1. Maximum capacity 120 g
2. Readability 0,1 mg
3. Repeatability (sd) at maximum capacity 0,1 mg
4. Repeatability (sd) at 10 g 0,07 mg
5. Linearity 0,2 mg
6. Eccentric load at ½ maximum capacity 0,3 mg
7. Sensitivity offset 0,0004 %
8. Sensitivity temperature drift 0,00015 %/°C
9. Sensitivity stability 0,0002 %/a
10. Weighing time typical 4 s
11. Interface update rate 23/s
12. Balance dimensions (WxDxH) [mm] 263x453x322
13. Usable height of draft shield 235 mm
14. Weighing pan dimensions (WxD) [mm] 78x73
Annex No. 5

Description of the publications and books needed

Books, publications and journals focused on risk assessment in the field of residue pesticides (particularly toxicology in this field). The required resources for the hereinbefore specified literature and other scientific data sources purchase are in maximum amount of 5,000.- Euro. Publications are planned to be funded from national state budget.