TWINNING INTERIM QUARTERLY REPORT

No. 4

ANNEX

TABLE OF CONTENTS

Annex 1 Minutes Steering Committee with annexes

3rd Meeting of the Steering Committee

Minutes

Date: 19 December 2005 (12.30-14.00)
Place of meeting: Ministry of Health, Limbová 2, 837 52 Bratislava, room no. 152/3

Participants

- **Present:**
  Mr Geert van Etten – Dutch Project Leader (NSPOH)
  Ms Zuzana Škublová – Slovak Project Leader (MoH of SR) [chair]
  Ms Mária Avdičová – Co-ordinator component I (RPHA Banská Bystrica)
  Ms Jana Bosá – Co-ordinator component II (PHA SR Bratislava)
  Mr Milan Nikš – Co-ordinator component III (PHA SR Bratislava)
  Ms Soňa Gabčová – Task manager, Office of Government of SR
  Mr Miroslav Škvarka - CFCU at the Ministry of Finance of SR
  Ms Martina Galabová - CFCU at the Ministry of Finance of SR
  Ms Iveta Krbaťová – MoH of SR
  Ms Jana Ráčková – RTA Assistant

- **Absent:**
  Ms Anne Maria Aalders – new RTA (NSPOH)
  Ms Zuzana Krištúfková – Project Manager (PHA SR Bratislava)
  Ms Margaréta Sláčiková – Deputy Project Manager (PHA SR Bratislava)
  Ms Martina Šteliarová / Mr Steef van den Berg – Royal Netherlands Embassy
  Ms Jana Minarovičová - National Contact Point for Twinning, Office of the Government of SR
  Mr Peter Letanovský – MoH of SR [without notice]
  Ms Linda Winklerová – MoH of SR

Agenda

1. Opening
Ms Škublová as the chairperson officially opens the meeting.

2. Discussion on 3rd Quarterly report
The draft 3QR was prepared by Mr van Etten. All comments from Ms Škublová were already incorporated into this draft 3QR. There is no development with the new Act on Public Health (section 2 / Policy developments) in the reporting period. The law is still under the parliamentary process.

Ms Avdičová informed about component I. The questionnaire survey among physicians and laboratories were completed and considered as successful and very useful. The results were incorporated into the data flow. More details will be reported in the next QR.

Mr Nikš informed about component III. On his last meeting with the working group (see 3QR annex 4) an action plan for external quality assurance was approved. The development of this component does not exactly keep the original project plan. Activities were planned 2 years ago while the current situation requires different steps. Ms Škublová clarified that the description of original activities should be understood as a framework. Mr van Etten added the activities are described broader and in a general way and asked whether the steps in the

action plan will be covered by activities 3.3 & 3.4. Mr Nikš said yes and indicated completing of all planned steps (SOPs, pilot project) until summer 2006. Ms Škublová asked whether there exist any strict rule that as a first must be accreditation process and afterwards other activities. According to Mr Nikš they can go ahead even the laboratories are not accredited. Mr Nikš and Ms Bosá added they do not intend to let the external quality system to be accredited, just pilot laboratories.

Ms Škublová asked Ms Bosá about any developments / conclusions on possibility of a new expert on molecular microbiology which was discussed on 2nd Stc. Ms Bosá has opinion new expert is not needed at this stage. She asked Ms Waijboer (STE) to help her find someone but until now without response. Also she stressed the time pressure in last weeks – writing SOPs, application and other documentation for SNAS etc. During her last meeting with Ms Aalders (end October) she came to conclusion to wait for experts from SNAS and afterwards we should know whether a new expert is really needed or not. Assessment by an expert group from SNAS should take place at the end of March 2006. *See conclusions.* Ms Bosá informed about current reconstructions of laboratory part. She also informed about planned big event, "consultation days" which will be organized on national level by PHA SR at the end of February 2006.

Ms Škublová gave the floor to Ms Avdičová to inform about meetings with expert group for component I, short-term expert and selected company (SW development). Ms Avdičová briefly informed about the visit of STE Mr Otto last week and his contribution to discussions. Concrete agreements on details of the information system structure were made. They prepared plans containing definitive results from discussions. Each member of working group will prepare the terms of reference for specific disease. Ms Avdičová was interested in concrete time schedule agreed in the contract with selected company. Ms Škublová advised her ask for a copy contract either PM Ms Krištúfková or Ms Bosá as they were both provided with this contract.

Ms Avdičová evaluated additional internship of two SK-experts (Ms Hrubá, Ms Maslenová) visiting Dutch expert at RIVM as very successful. SK-experts had possibility to speak with Mr Bosman to make clear specific issues. During this mission they were offered a part of Dutch software for free. Ms Avdičová discussed this with STE Mr Otto and they both agree with this option. Ms Škublová had also discussion on this matter with Mr Hrubá after her arrival from the Netherlands and she considered this offer as positive where by the offered SW part could be joined to the new SW developed by selected company.

Conclusions:
- Ms Bosá will prepare a brief time table containing information on accreditation process (which has been meanwhile prepared and is attached to these Minutes).
- RTA Assistant will distribute final version of the 3rd Quarterly report until end of this week.

3. Discussion of an Action plan

Ms Škublová informed about the Action plan drafted by the new RTA Ms Aalders, filled in together with component coordinators and RTA assistant. The Action plan should give us a real view whether specific recommendations given by short-term experts within each taken activity was implemented or not. Ms Škublová explained the template, columns and content of an Action plan and invited participants for their comments to be incorporated once RTA starts work in the office.

Discussion on following recommendations took place:

Ms Škublová asked about recom. No 9. "In the new Law on Public Health it will be promoted that the National Register of communicable diseases will be seen as a health care facility". This register is really in

Banská Bystrica but whether it should be seen as an healthcare facility remains to be seen. Ms Avdičová reacted that from the legislative point of view (Law on Provision of Health Care) this register is prepared. Ms Škublová proposed future consultations with other organizations because apparently there are overlaps where different institutes should be responsible for this.

Ms Škublová asked about recom. No 11. "Question on data protection and ethnicity." Ms Avdičová informed about the meeting with representatives of Data Protection Office resulted into conclusion that they can not collect these data on ethnicity.

Mr van Etten asked about recom. No 14. "Do not tender for completely new software. Make an inventory of systems in use in different countries that fit the needs and routine in Slovakia and that can be easily adapted by Slovak experts." Ms Avdičová replied that they do not need such inventory because they have already studied Dutch, German and Czech systems.

Ms Škublová asked about recom. No 16. "Do not tender for an Early-Warning System! There is no software company who can understand what you want or has the epidemiologic or scientific knowledge." This approach is different from the originally planned development of the new SW. Ms Avdičová explained reasons why they after deeply analysis of both options decided to keep the original plan. Additionally, except Mr van Pelt, all other short-term experts recommended to develop a new SW that will exactly meet Slovak requirements and conditions.

Mr van Etten asked about recom. No 38. "Consider to bring the Virology NCRs at the NIPH under a single organisation with a virus isolation laboratory, headed by a classical virologist, a molecular laboratory for all NAT, headed by a molecular biologist and a serology laboratory, headed by a clinical immunologist. Within this organization, reference tasks can still be supervised by reference specialists." & No 39. "Reconsider to bring more PH reference activities under a single umbrella, whether or not to be concentrated at one single place, for example, hepatitis, candidate emerging viruses (zoonoses), viral STD (including HIV), food-related viruses etc." Ms Bosá considered these recommendations as expert's opinion. Its implementation is hardly possible because of small laboratories (no conditions) and still unknown organizational chart of PHA SR (unknown relations). This reason also creates other big troubles related to accreditation process. The whole issue depends on the new Act on Public Health which has not been adopted yet.

Ms Škublová raised a question about recom. No 43. "Development of electronic laboratory administration system." Ms Bosá clarified that the remark mentioned in the Action plan to this recommendation is not actual any more. The laboratory system for PHA SR is really needed. This system is already in Slovakia developed and has been commonly used for 15 years. Therefore it is the question of financing such system. Ms Bosá asked whether it is possible to buy the laboratory system by selected company. Unfortunately the answer is clear – not possible even in the case of not using all contracted amount for selected company. The spare money must be returned to EU budget. Ms Škublová suggested future discussion on this issue viewed as the necessity of the laboratory system for originally procured three SW applications.

Mr van Etten raised recom. No 61, 62 & 63 related to internal auditor course for some employees of RPHAs in Košice and Banská Bystrica. Ms Bosá informed that this is not actual because the course is financed by external sources as a part of accreditation process where SNAS is a provider of this course.

Conclusions:

- To take given information into account and to let Ms Aalders to upgrade the Action plan.

4. Any other business

Ms Škublová informed that Ms Aalders was officially appointed as the new RTA by approving the Addendum by Brussels in the first week of December.

Ms Škublová informed about the progress of the contracts from public procurement for:
1) Laboratory equipment supply - on 29 November a contract with company VITRUM was signed.
2) Hardware supply – company TEMPEST.
3) Software development (three SW applications) – company SOFTEC.
On 14 December first meeting with representatives of PHA SR and company Vitrum took place where the draft time schedule of delivery was made. On 7 December first meeting with company Tempest and Softec took place. Representatives of Softec company were also present at the working meeting during the mission of STE for activity 1.8. This company is also winner in tender for software development for National Data Centre for The Institute of Health Information and Statistics. Ms Škublová promised to suggest joined meeting for Ms Avdičová.

Ms Škublová informed about submission of the Side letter no. 4 last week. This side letter is related to installation of Ms Aalders as the new RTA. Although the SL partly uses saved money from RTA salary during his/her absence, Ms Škublová raised additional necessity of discussing the issue of spare money for future activities. *See conclusions.*

Ms Bosá opened an issue of postponement of activity 2.5 due to following reason. This activity is closely related to (above mentioned) "Consultation days" organized on national level at the end of February 2006. This event should be visited by around 100 specialists of whole Slovakia. Also members of working group for component II and III will participate and each heads of NRC will have a presentation followed by discussion and exchanging knowledge and experiences. Ms Bosá considered this event as a good opportunity for short-term experts coming for activity 2.5 to take part. Additionally she expressed her uncertainty of effectiveness to organise similar separate "training" within planned activity for Slovak experts in English language. Therefore she proposed to join this activity planned for January 2006 with the event in February. She also suggested rename activity 2.5 described as "Training of staff etc" into "Workshop etc". *See conclusions.*

Conclusions:
- Ms Škublová will find out with financial department at NSPOH the possibility of using saved money from RTA salary for future project activities.
- Ms Bosá will write down the reasoning of this change (is attached to these Minutes).

5. Date of next meeting

The tentative date of next meeting is agreed on 28 February 2006.

6. Closure

Ms Škublová officially thanks to all participants for their co-operation and contribution.

Annexes to the minutes

Timetable of the accreditation process

Public Health Authority in Košice

- Application form for re-accreditation has been approved by SNAS.
- An expert group for assessment has been set up.
- Contractual price for accreditation has been defined.
- Date for assessment on the place has been tentatively agreed on March 2006.
- A reconstruction of NRC laboratories is currently taking place and should be ended by end of January 2006.
- Laboratory equipment delivery is agreed by end of February 2006.

Public Health Authority in Banská Bystrica

- Application form for re-accreditation has been approved by SNAS.
- An expert group for assessment has been set up.
- Contractual price for accreditation has been defined.
- Date of accreditation: 20 December 2005.

Public Health Authority of the Slovak Republic in Bratislava

- Application form for re-accreditation has been approved by SNAS.
- An expert group for assessment has been set up.
- Contractual price for accreditation has been defined.
- Date for assessment on the place has been tentatively agreed on March 2006.
- Reconstruction of one part of NRC laboratories is currently taking place and should be ended by end of January 2006. Reconstruction of the second part of labs is planned to start in 2006.
- Laboratory equipment delivery is agreed according to sent timetable into three phases:
  1. by end of January 2006
  2. by end of February 2006
  3. after reconstruction of laboratory area

20th December 2005

RNDr. Jana Bosá
Coordinator Comp. II

Realization of activity 2.5 within the "Consultation days"

Activitiy 2.5 of the PHARE twinning project is described as follows: "Training of staff of 9 selected NRCs in quality control systems and progressive detection methods". The activity is focused on exchanging the information and knowledge gained by participants of internships to the Netherlands and Germany. The internships were aimed at implementation of the quality control system and possibilities of implementation of new detection methods in selected NRC labs.

"Consultation days" has been organized every year as a big meeting of microbiologists and epidemiologists from whole Slovakia. The meeting is focused on solving questions on labora-

tory diagnostics and surveillance of infectious diseases as well as other issues related to reference functioning.

Reasons why to join activity 2.5 with “Consultation days”:

- Opportunity of broader informing about functioning of the quality control system in the Netherlands and its implementation possibilities into NRC laboratories.
- Direct contact with representatives of specific laboratories while planning their participation on pilot project concerning external quality assurance.
- Communication in Slovak language with simultaneous interpreting for Dutch experts should simplify exchanging of information.
- Reduce time pressure.
- Meet all expected results within the twinning contract.
- Members of working group for component II fully support this idea.

All organizational issues of “Consultation days” will be ensured by appointed preparatory committee containing representatives of PHA SR with collaboration of RTA and RTA assistant.

20th December 2005 RNDr. Jana Bosá
Coordinator Comp. II

Additional explanation of combining activity 2.5 with “Consultation day”

- Participant of each study visit will inform about gained knowledge giving a presentation on behalf of each National Reference Centre. Presentations will put emphasise on new methods that are planned to be implemented into laboratory diagnostic, advantages and limits of these laboratory procedures in our conditions, comparison of Slovak and foreign NRC activities.
- Because of a broad attendance of the microbiology society from clinical laboratory practise, clinicians and researchers it would be possible to discuss, confront opinions and forward useful information to broader group of interested persons.
- In case of any interest in some diagnostic technique it would be possible to arrange future collaboration by organizing the training in our laboratories.
- Chance to inform epidemiologists working on regional level about possibilities of diagnosing and monitoring of virulence factors for each infectious agens.
- The benchmark of activity 2.5 will be fulfilled effectively rather by presentations and “brainstorming” discussions during “Consultation Day” than organizing separate training seminars for staff of selected 9 NRCs as originally planned in the project workplan.
- Short-term expert, Mr Galama will contribute to this one-day event by giving a presentation on certain topics according to programme of the “Consultation Day” which is now under preparation. In coming days there will be direct contact between component co-ordinator Dr Bosá with colleagues and Mr Galama in order to discuss his presentation.
- The second day of Mr Galama’s visit will contain discussions on several issues with working group, especially with Dr Tietzová, Head NRC for MMR. Detailed information of this visit could be seen in “Terms of reference” and “Tentative programme” for activity 2.5.

31st January, 2006 RNDr. Jana Bosá
Coordinator component II

Annex 2 Report Mr Otto – activity 1.8

Twinning Project

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

MISSION REPORT

EXPERT NAME Matthias Otto PhD DSc

COMPONENT 1

ACTIVITY NO. 1.8

DATES OF VISIT December 11 – 17, 2005

Activities according to the Work Plan
Activity 1.8 Development of a specification of the information system(s), including the mechanisms for generating, distributing, updating and evaluating information within the identified areas and taking SOP, QA/QC principles into account. *Defining the links between laboratory data from NRC's and CD database. Preparation of Terms of Reference for TA & training (Service contract).* *Specified requirements from component co-ordinator:*

Summary discussed items (bullets**)**

RIVM (preparatory meeting)

In order to prepare for activity 1.8, Dr. M. Otto (STE, Osnabrück) together with Dr. F. Hruba (RUVZ, Banska Bystrica) and Dr. D. Maslenova (RUVZ, Liptovsky Mikulas) visited on December 6 and 7 the RIVM at Bilthoven, Netherlands.

During this study visit Dr. A. Bosman and Mr. E. van Straten presented the Dutch reporting system of infectious diseases (ISIS/OSIRIS). Emphasis was put on:

- the web interface for data entry
- the workflow in reporting cases of infectious diseases (involving the local health office/GGD, the IGZ and the RIVM)
- the collection of laboratory results
- the presentation of the actual epidemiological status to health professionals and the general public

In addition, the concept of the Early Warning System was discussed. Dr. Bosman indicated, that in principle the RIVM would be willing to share their concept and software with their Slovak colleagues. This possibility which had been stressed earlier by two STEs (W. van Pelt, M. Otto) during previous missions should be kept in mind, too.

Activity 1.8 - Meetings and workshops

Activity 1.8 itself was focussed on contacts and discussions with SOFTEC Slovakia, the successful candidate in the tender for software development.

Meeting Dec. 12, 2005

On December 12, 2005 a meeting beween Dr. Avdicova, Dr. Hruba, Ing. Accipiter and the STE with 3 representatives of SOFTEC Slovakia (Ing. J. Mackay, Dr. L. Sesera, Mgr. M. Nemcova) took place.

Here, the present way of reporting infectious diseases at the local, regional and national level was discussed both from a conceptual and a technical (EPIS-System) point of view. Also, the data field structure of the paper-based "File of epidemiological investigation" (LEV) as well as of the "File of nosocomial infections" was analysed.

The following conclusions related to the forthcoming register of communicable diseases have been obtained:

- The data in the now outdated EPIS-System are of high quality. Thus they should be preserved and made available in the new system, e.g. for future analyses of long term trends.
- The envisaged architecture of a central data base accessed via a web module will overcome shortcomings of the present EPIS-System which relies on (numerous) distributed local data bases.
- The data fields in the forthcoming electronic register of communicable diseases should correspond as closely as possible to the data fields used in the paper-based blanks (e.g. name of responsible official, measures taken, contact, case management/version).
- A web-based flexible analysis and presentation of data according to different criteria, e.g. disease, aetiology, age and gender distribution as well as spatial (GIS) and temporal patterns is a top priority matter. To the general public, only aggregated data should be made available.

- The register should be flexible enough to accommodate new medical knowledge. Appropriately qualified operators should - up to a certain extent - be able to modify menues and/or static information.

- The system should enable a flexible data export to EU-networks.

Other issues which were discussed comprise a classification of cases into 3 categories (suspected/probable/confirmed case) and the handling of related cases (e.g. related by their aetiology). The identification of reporting subjects should be based on the National Register of Physicians and Hospitals (including hospital departments) etc.

Meeting Dec. 13, 2005

On december 13, 2005 a meeting between Dr. Z. Kristufkova, Dr. Bosa (UVZ, Bratislava), Dr. F. Hruba (RUVZ, Banska Bystrica), Dr. Hierweg, Dr. Sesera, Ing. Franzova (SOFTEC Slovakia) and Dr. M. Otto (STE, Osnabrück) at the Institute of Public Health Bratislava took place.

Issues discussed comprise the bulk reporting of influenza and flu-like diseases as well as the presently used ISHEM data base which was presented to SOFTEC. The basic functionalities of ISHEM comprise the processing of bulk influenza reports at the local, regional and national level, a check for completeness of reports and certain predefined graphic representations.

In addition to the basic requirements stated in the tender, the following conceptual and functional features were specified (see also SOFTEC protocol # 2):

- a modification of the data entry blank (separate entry of influenza and flu-like cases).
- a better way of calculating morbidity, taking the number of patients of a given reporting physician instead of the number of inhabitants of a given region into account
- a yearly update of the Physician´s Directory including data on the corresponding number of patients (data will be provided by UZIS Bratislava)
- identification of individual physicians to be based on the "physicians ID code" (instead of “ICO code”)
- the possibility to analyse the data on a daily, seasonal and yearly base

A problem yet to be solved is the difference between the national statistics on the age distribution on one hand and the age distribution requested by the European Union network(s) on the other hand.

Dr. Kristufkova presented her personal access to the European Influenza Surveillance Sceme (EISS) at www.eiss.org

In a separate meeting Dr. Bosa discussed the role of National Reference Centers (NRCs) to the SOFTEC-Representatives (see SOFTEC protocol # 3 for details).

Early Warning System

The web portal of the Early Warning System will comprise both early warning messages and scientific publications. Again, a more general part will be accessible to the general public, while a more detailed part will be made available to health professionals.

A system notifying/alerting key persons via e-mail or short messages will be developed. Also a discussion forum for epidemiologists will be created.

Incoming messages from the European Early Warning System will be stored and displayed in a way, that their priority text, commands and message history become visible. Message retrieval according to diseases and periods of time as well as a notification of new messages via e-mail will be implemented.

Finally, the problem of recognition and processing of epidemic cases of infectious diseases (most of them being of alimentary origin) has been discussed.

A "semaphor" or "traffic light" indicator will provide a quick overview on the actual status for a given disease – by comparing the number of *reported* cases to the number of cases being *expected to occur* during a certain time-frame. The UVZ SR will provide guidelines for the calculation.

Dec. 14, 2005

Preparation of the workshop to be held on the next day. The RIVM was contacted to obtain the permission for a live presentation of the Dutch reporting system .

Workshop Dec. 15, 2005

On December 15, 2005, a workshop on the menu-structure on the forthcoming register of infectious diseases took place at the RUVZ Banská Bystrica. Participants (for details see list) came form the Regional Public Health Offices at Banska Bystrica, Trencin, Liptovsky Mikulas, Bratislava, from the Institute of Public Health of the Slovak Republic Bratislava, and from SOFTEC and Kinderumwelt Ltd. Three work groups established in August 2005 were represented, i.e. work groups on zoonoses, STD and nosocomial infections.

-Presentation of the Dutch ISIS/OSIRIS System

By courtesy of RIVM, Dr. M. Avdicova and Dr. M. Otto obtained temporary access to the training area of the Dutch system. Thus is was possible to demonstrate its functionality on the live system including the report status (*draft*, *final*, *approved*) and the workflow (GGD, IGZ and RIVM). Also the web-based information on the status of communicable diseases in the Netherlands at the publicly accessible level was explored (Early Warning, trends, "traffic light indicator").

With respect to the storage and processing of data at the local (GGD) level, it was learned that a duplicate data entry may be necessary (information provided by RIVM).

-German SurvNet System

Here the functionality of the SurvNet System developed by the Robert Koch-Institute (RKI), Berlin and used by a majority of German "health offices" (Gesundheitsämter) was shown. SurvNet represents a system of distributed local data bases. Data from the individual health offices are being collected and checked for plausibility at the level of the individual federal state (Landesgesundheitsamt) and only then being transferred to the central data base at the RKI, Berlin. Both the contact management (contact persons, physicians, health care institutions etc) and the office module are well-elaborated. However, SurvNet is presently not available in a web-based manner.

SurvStat, the module for analysis and presentation of data, is available on the internet.
URL: http://www3.rki.de/SurvStat/

-EPIS Slovakia

An essential part of the workshop was devoted to a critical revision of the menue-structure of the EPIS-System presently used in the Slovak Republic. Numerous addendums, corrections and new specifications were suggested.

Also, the workflow between regional institutes of public health and laboratories including NRCs was discussed and agreed upon. The matching of information related to a given case (provided either by the RUVZ or a lab/NRC) will be based on the "birth number" (rodne cislo) or an equivalent. Each NRC will be able to "see" those cases exclusively which pertain to its own sphere of competence. Detailed patient's information will be visible to the RUVZ only.

Dec. 16, 2005

This workshop was continued on December 16, 2005. For details see also the protocols prepared by SOFTEC Slovakia (in Slovak language).

The document on the specification of the information system for the surveillance and control of CD is available as an Excel file ("EPIS_upraveny.xls"). Due to the multi-dimensional nature of this file, only front pages of the main menus have been attached. The file itself is available on request from Dr Avdicova.

During the debriefing meeting in the afternoon of Dec. 16, the STE and Dr Avdicova discussed recently published experiences on the surveillance of communicable diseases in Germany (Bundesgesundheitsblatt, September 2005).

Persons met **Name**	**Position**
Dr. Zuzana Kristufkova	Head of the Dept. of Control of Infectious diseases, Natl. PHA SR, Bratislava
Dr. Maria Avdicova	Head of the Dept. of Epidemiology, RPHA SR Banska Bystrica
Dr. Frantiska Hruba	Head of the Dept. of Informatics and Health Statistics, RPHA SR Banska Bystrica
Ing. Karol Accipiter	IT manager, RPHA SR Banska Bystrica
Dr. Darina Lopusna	Chief Hygienist of the Slovak Republic, Bratislava
Participants of the workshop (December 15, 2005)	see list
Participants of the workshop (December 16, 2005)	see list

Agreements including tentative date of next visit (bullets)

- Dutch system: it is advisable to seek information on the module used at the GGD for the local case management
- The (informal) offer of RIVM to share ISIS/OSIRIS software and know-how with their Slovak colleagues should be kept in mind.
- German system: if considered to be necessary, a contact to the SurvNet Developer Team can be established.
- Next visit: January 30 - February 3, 2006

Follow-up by RTA (bullets)

Remarks / Suggestions (bullets)

Evaluation (bullets) **Positive**	**Negative**
1 2 3	1 2 3

Date/signature of Expert	Date/signature of Component co-ordinator	Date/signature of Adviser

Annex 3 Report Mr Otto – activity 1.9

Twinning Project

Twinning No. SK03/IB/SO/01

Strengthening the Surveillance and Control of Communicable Diseases

MISSION REPORT

EXPERT NAME Matthias Otto PhD DSc

COMPONENT 1

ACTIVITY NO. 1.9

DATES OF VISIT Jan. 29 – Feb. 03, 2006

Activities according to the Work Plan
❑ Development of a technical framework, including recommendations on hardware (Technical specifications for Supply contract), software, data-format, issues of security, accessibility, access control, availability and technical management ❑ Specific requirements from component co-ordinator: • To check the analysis made by SOFTEC company. • To prepare proposal of analytical outputs from program according to example of German analysis.

Summary discussed items (bullets**)**

The technical framework and specifications on hardware, software, operating system, data format, security issues etc. as required in the tender had been specified in the contract No. 200300499503-0701-0005 between the Ministry of Finances (CFCU) of the Slovak Republic and SOFTEC s.r.o. Bratislava (see appendix 2 of this contract for details).
In agreement with the contract, SOFTEC prepared a report on the results of their analysis of

- functional requirements
- data flows
- collection, storage and evaluation of data
- requirements on performance, accessibility, security and management

of the forthcoming information system ("new EPIS") on communicable diseases (CD), which comprises 3 subsystems:

- register of CD
- bulk reporting of influenza and flu-like diseases
- Early warning system

On January 31, 2006, SOFTEC (L. Sesera, M. Nemcova) presented an introduction into the results of the analysis phase to M. Avdicova, F. Hruba, K. Accipiter and the STE. Both a hardcopy and an electronic version of their report were handed over. The steering committee was asked to critically read the report while paying special attention to chapters 4,7,12, 13 and appendix A. Comments and requests for modifications were requested till Feb. 03, 2006.

February 1, 2006: M. The members of the steering committee mentioned above agreed to individually read the report (165 pages) and to discuss all personal comments together on the following day. In view of the quite large number of remarks and requests for modifications, only a few topics of more general nature are mentioned here (for details see annex):

- re-definition of the purpose of the NRC information system within the new EPIS system
- re-definition of certain ROLES and PROCESSES in EPIS
- enlargement of case classifications ("possibe, probable, confirmed, not confirmed") by the category "carrier".
- acceptance also of *incomplete* records in certain circumstances (anonymous tests for STD´s)
- functional property of "database versioning" - for a retrospective analysis of an arbitrarily chosen earlier date (cf. SurvNet presentation in activity 1.7)

In the present phase several factors can be identified which will have a large impact on the overall succes of the project:

- internet connectivity - especially at RUVZ Banska Bystrica, but also at all other RUVZ locations
- involvement of a broader group of future users in the revision of the analysis report and later also in the pilot testing phase
- preparedness of the RUVZ´s to switch to the new EPIS
- requirements as to the internet bandwidth, computational capacity of the database server and staff skills with respect to non-standard analyses (see also SOFTEC report, p. 112-14)
- requirements as to staff skills with respect to possible changes in the structure of collected data in the future (special training needed).
- specification of the interface between laboratories of clinical mircobiology and the (new) EPIS.

Wth respect to server housing, internet connectivity and technical management the following items had been discussed:

- location, housing, power supply/UPS and access control
- air condition (temperature, dust)
- fire detection and – protection
- guidelines for operation, safety, updates, backup procedures, emergency training,
- automatic system surveillance (watchdog, notify system, control of bandwidth)

On request by M. Avdicova, a document (in Slovak language) describing the case management in Germany based on the "Journal module" of SurvNet@RKI was elaborated (prior to departure for this mission). In some GGD of the Netherlands a module called ORION-OSIRIS serves a similar purpose. This module was explored based on information available on the internet (www.wkm.nl) and the developer (WKM BV) was contacted.

Persons met **Name**	**Position**
Dr. Zuzana Kristufkova	Head of the Dept. of Control of Infectious diseases, Natl. PHA SR, Bratislava
Dr. Maria Avdicova	Head of the Dept. of Epidemiology, RPHA SR Banska Bystrica
Dr. Frantiska Hruba	Head of the Dept. of Informatics and Health Statistics, RPHA SR Banska Bystrica
Ing. Karol Accipiter	IT manager, RPHA SR Banska Bystrica
Ing. L. Sesera	SOFTEC Bratislava
Ing. M. Nemcova	SOFTEC Bratislava

Conclusions (bullets)

The SOFTEC report on the analysis of data flows and functional requirements for the new EPIS (version of January 27, 2006) is a comprehensive description both of the status quo and of the envisaged new information system with respect to its architecture, changes in workflow, functional requirements and examples of screens for typical applications. It also includes basic information on the technical realization, on data migration, security aspects and a risk analysis. The appendix A comprises a list of requested functionalities.

The report should be revised, e.g with respect. to some work flows, functionalities, ROLES and FUNCTIONS. The purpose of the NRC information system (p.46 -48) is not clear yet and should be redefined. All remarks will be supplied in an annex.

Recommendations (bullets)

- Involve a broad(er) group of future users in the revision of the analysis report and later also in the pilot testing phase
- In addition to criteria for the "lean client technology" (see SOFTEC Report, chapter 13.1, p.112), web design criteria from the viewpoint of computer workplace ergonomics should be observed, too (i.e. usability, accessibility, didactics, cf. www.w3c.org, www.afgis.de)
- A reliable internet connection of sufficient bandwidth is crucial for the success of the project !
- RUVZ Banska Bystrica: here the internet connectivity (minimum bandwidth 512 kBit/s, better 2 MBit/s) should be improved. Switch from radio-based connectivity to cable/dsl connectivity.
- All RUVZ´s should agree preferentially on one and the same Internet provider. This would facilitate the construction of a Virtual Private Network and thus enable also remote diagnosis and maintenance.
- With respect to the expected server housing at RUVZ Banska Bystrica, *location-specific* guidelines (in Slovak language) for access control, operation, safety, updates, backup procedures and emergency training should be developed, taking discussions with the STE and own experience into account.
- Start preparing a training *concept* (i.e. a train-the-trainer approach) for the future users of EPIS – in line with the progress of the project and in close collaboration with SOFTEC

Follow-up by RTA (bullets)

Remarks (bullets)

Document(s) on technical framework for the information system:

1. contract No. 200300499503-0701-0005 between the Ministry of Finances (CFCU) of the Slovak Republic and SOFTEC s.r.o. Bratislava, Appendix 2 , p. 8 and following pages, p. 20 – 21

2. document on the revision of SOFTEC Report on the Analysis (prepared on Feb. 03, 2006)

Evaluation (bullets) **Positive**	**Negative**
1 2 3	1 2 3

Date/signature of Expert February 03, 2006	Date/signature of Component co-ordinator February 03, 2006	Date/signature of Adviser February 03, 2006

Annex 4 Side letter No. 3

SIDE LETTER No. 3

TO TWINNING CONTRACT 2003-004-995-03-07/0001
"Strengthening the surveillance and control of Communicable Diseases"

Twinning No. SK/03/IB/SO/01

Both Twinning partners have agreed the following:

Art. 1 Objective

1. The objective of this Side letter is to notify reallocations in the "Budget for Action" (annex III) to the Twinning Contract 2003-004-995-03-07-0001.
2. To add two internships under activity 1.8.

Overall project budget remains as contracted.

Art. 2 Modification

The reallocations are mentioned in the revised budget (annex 1).

The modifications were made for the following reasons:

- In consultation between Dutch and Slovak consultants the conclusion was made that the gaining of specific knowledge on automated surveillance systems as it functions in the Netherlands is essential for obtaining the project results as described in the twinning contract under component I.
- It was jointly agreed by the Dutch Consultants and the Slovak counterpart that the gaining of such knowledge can only be obtained on the "spot", i.e. in the form of an internship at a highly specialised institute in the Netherlands.
- The Steering Committee at its meeting on 29 of September 2005 strongly supported this proposal and decided that a request would be made to the RIVM to facilitate this internship.
- RIVM (National institute for public health and the environment) is prepared to facilitate this two-day internship. The Slovak Delegation will consist of the following two persons: RNDr. Frantiska Hruba, PhD - Head Section of Informatics & Health Statistics, RPHA in Banska Bystrica and MUDr. Danica Maslenova MPH - Head Section of Epidemiology, RPHA in Liptovsky Mikulas.
- The two internships will take place from Sunday 4 December 2005 to Wednesday 7 December 2005.
- The trainees will receive a highly specialised training in accordance with Article 5.7.2 of the Twinning Manual.
- The institution involved in the internships charges a training fee.
- New budget lines 'fee internship', 'per diems for BC participants', 'local travel' and 'incidental costs' are therefore introduced under activity 1.8.
- After the internship afore mentioned participants will disseminate the generated knowledge to other relevant professionals in the Regional Institutes of public health.

A draft programme of the internships are enclosed with this letter.
The budgetary implications of the organisation of these internships are presented under activity 1.8 of the Notification of Reallocations No 3 enclosed with this letter. No other changes have been made in Notification of Reallocation No 3.

The budgetary changes in relation to the organisation of this internship are limited as the Dutch Ministry of Health will reimburse the costs for the international flight tickets. There will be no shift between budget items. The estimated costs of the other expenses (per diem, training fee, local travel and incidental costs) amount to € 2.560,00 and will be financed out of cost savings generated from the organisation of internships under activity 2.3 Not used savings remain within the original budget line.

The reallocations were made for a cumulated amount of less than 10% of the total budget for this Twinning project.

Art. 3 Confirmation of validity

All of the parts and dispositions of the initial Twinning Contract 2003-004-995-03-07/0001 and the approved side letters or addenda which are not modified here remain valid.

Read and approved for the parties of the Twinning Project:

Mr. Geert van Etten,
Project Leader

Ms. Zuzana Škublová
Project Leader

Annex: revised budget

Annex 5 Programme Internship - activity 1.8

Annex 2 to Side letter 3

Draft Programme of two-day internship on automated surveillance systems for two BC experts (activity 1.8)

Names participants:
1. RNDr. Frantiska Hruba, PhD - Head Section of Informatics & Health Statistics, RPHA in Banska Bystrica
2. MUDr. Danica Maslenova MPH - Head Section of Epidemiology, RPHA in Liptovsky Mikulas

Names facilitators:
Mr A. Bosman (RIVM)
Mr M. Otto (Kinderumwelt GmBH)

Date and Venue:
5 & 6 December 2005 at RIVM, Bilthoven

Programme

Day 1:

1. Analysis of Information System for surveillance of communicable diseases used in the Netherlands (process model, functional needs, actors, etc).
2. Detail description of each characteristics of collected data specific for each diagnose or group of diagnoses.
3. Detail description of anti epidemic measures within of each case and a system of their recording to the IS.

Day 2:

4. Connection between information on disease (or case) and measures.
5. Analytical outcomes (regular and on demand). System of reports generation, information dissemination.

Annex 6 Itinerary Internship – activity 1.8

Itinerary for the internship on automated surveillance systems activity 1.8 at the RIVM in Bilthoven the Netherlands

4 December 2005

Sun 4 Dec KL1846 Vienna Amsterdam 16.30 - 18.35

Buy a 2nd class one-way ticket to station Utrecht Centraal. This ticket costs EUR 7,10.
At Utrecht Centraal buy a ticket for the tram. This ticket is called 'strippenkaart' and costs EUR 6,50.
Take the tram (there is only one tram in Utrecht) and get out at stop 'Ziekenhuis Oudenrijn'
From there it is a short walk to the hotel.

Ibis Hotel Utrecht
Bizetlaan 1
3533 KC UTRECHT
NETHERLANDS
Tel.: 030-2910366
Fax: 030-2942066

Nico Brinkman (+31 (0) 51376948) will meet you at the hotel later that evening and will give you your per diem and money for train tickets.
Mathias Otto will also be staying in the IBIS Hotel.

5 December 2005 (RIVM, Bilthoven)

The National Institute for Public Health and the Environment (RIVM)
Address: Antonie van Leeuwenhoeklaan 9
Bilthoven
Tel: +31 (*0)30 274 91 11*

Arnold Bosman will be at the hotel at 07.00 am for a last discussion with Matthias Otto; you will have breakfast together. Right after he will bring you to the RIVM by car and will guide you through the programme at the RIVM.

In the afternoon the RIVM bus drives between RIVM and the station in Bilthoven between 16.00 and 17.30 hours.

6 December 2005 (RIVM, Bilthoven)

Take the tram to Utrecht Centraal. Buy a 2nd class train tickets to Bilthoven. This ticket costs EUR 3,30. Take the train to Bilthoven.

At station Bilthoven take the RIVM bus in the *Soestdijksestraatweg* near the Chinese restaurant It will bring you straight to RIVM.

In the afternoon the bus drives between RIVM and the station in Bilthoven between 16.00 and 17.30 hours.

7 December 2005

Buy a train ticket to Schiphol. This ticket costs EUR 7,10.
At Utrecht Centraal take the **05.10** train to Amsterdam Centraal. (change at Duivendrecht for the train to Schiphol which leaves at **05.52** and arrives at **06.05** at Schiphol.

Wed 7 Dec KL1839 Amsterdam Vienna 07.55 - 10.00

Please give all used train tickets to Jana Rackova!

Annex 7 Report Internship - activity 1.8

Study visit report

The National Institute for Public Health and the Environment (RIVM)
Antonie van Leeuwenhoeklaan 9
Bilthoven, The Netherlands

December 4-7, 2005

Participants
RNDr. Františka Hrubá, PhD - Head Section of Informatics & Health Statistics, RPHA in Banská Bystrica
MUDr. Danica Maslenová, MPH - Head Section of Epidemiology, RPHA in Liptovský Mikuláš

Aim
To study use of information technologies for support of infectious diseases surveillance.

Persons met
Mr Arnold Bosman (RIVM)
Mr Edward van Straten (RIVM)
Mr Matthias Otto (Kinderumwelt GmBH) – short-term expert

Discussed items
Information systems in the Netherlands, supporting:
- notification system for infectious diseases
- laboratory surveillance
- early warning system

Architecture, system of data collection, publication of information on web.
OSIRIS - architecture, metafiles, system management, roles, system of case authorization, issues connected with data warehouse.
ISID - reporting to general public, types of data presentation.

Information system in Slovakia
- system of data collection, notifiable diseases, regional and national responsibility
- current information system supporting surveillance and planned improvements

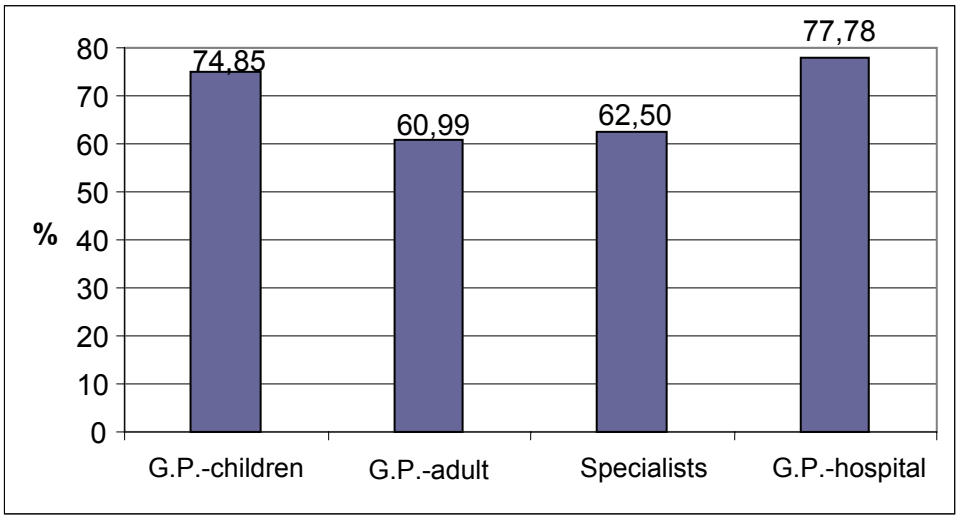
Conclusions
- OSIRIS is a very flexible system, able to be customized for any public health environment.
- Dr. Bosman mentioned an option to deliver the OSIRIS system to Slovak public health network, as the government institution.

Evaulation (positives, negatives)
- Even a short visit, it was helpful to clarify technical issues, which were not clear from the first study visit.
- We did not understand, how to continue with a possible use of the OSIRIS in the Slovak environment of the infectious diseases surveillance.

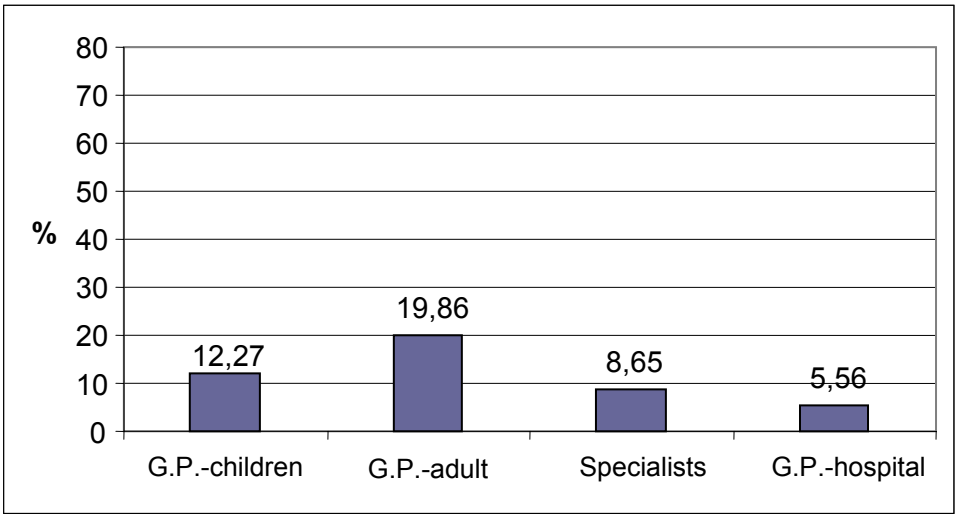
RNDr. Františka Hrubá, PhD. January 18, 2006
MUDr. Danica Maslenová, MPH

Annex 8 Graphs questionnaire survey

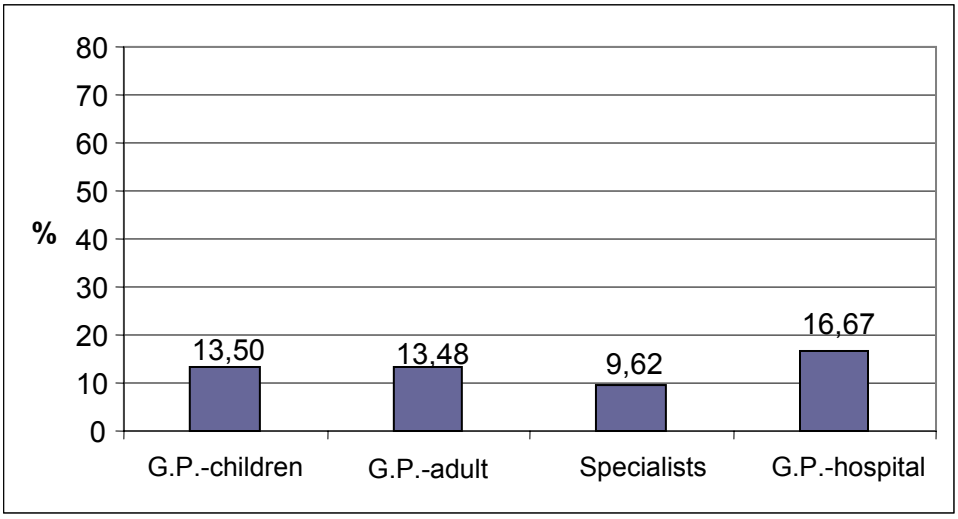
Reporting of infectious diseases – all according to valid legislation



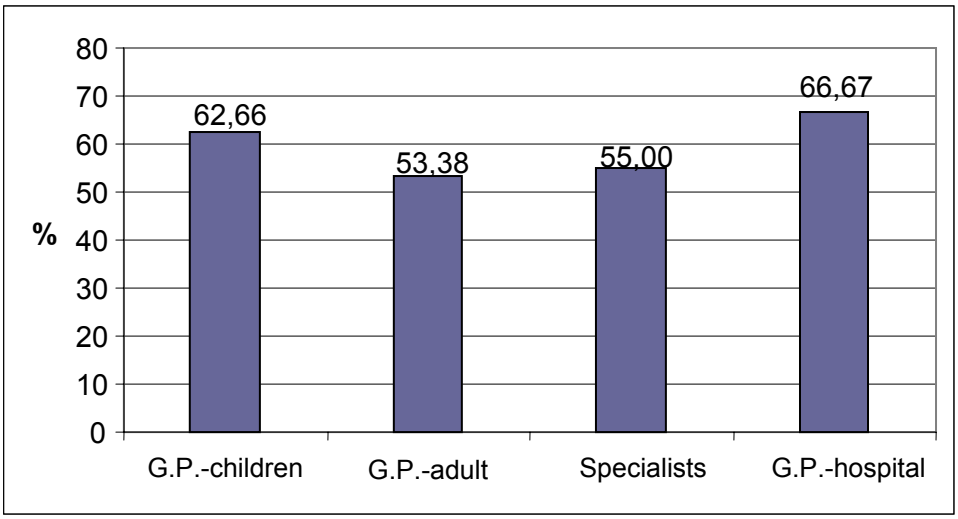
Reporting of infectious diseases – only clinical significant diseases



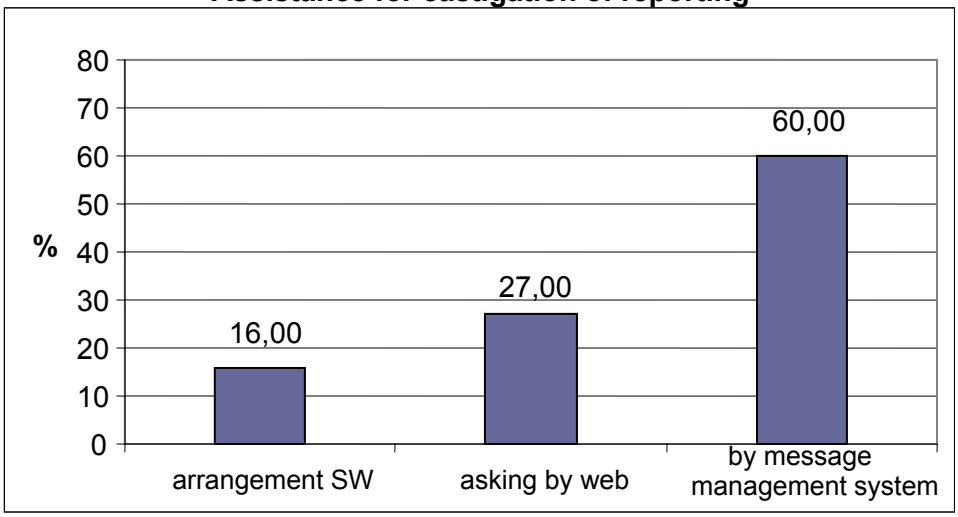
Reporting of infectious diseases systemless – occasionally



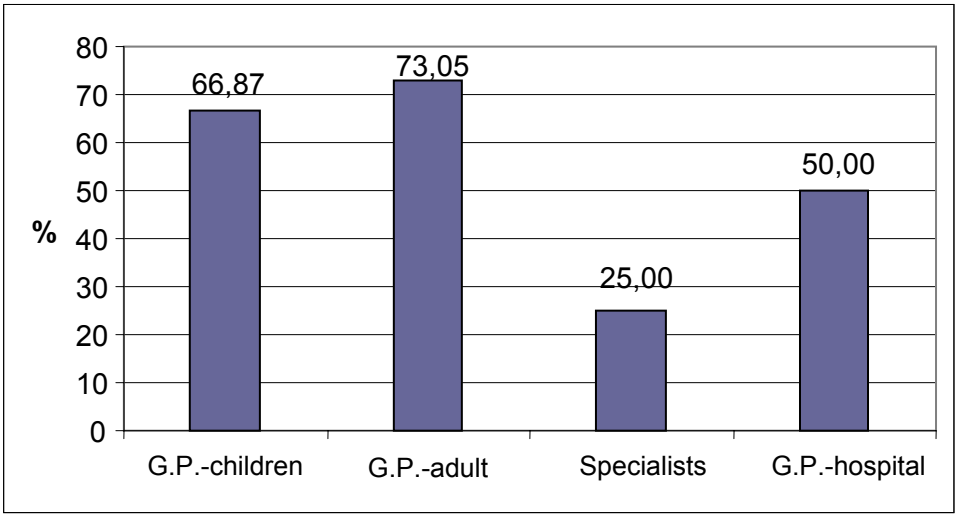
Connected to Internet

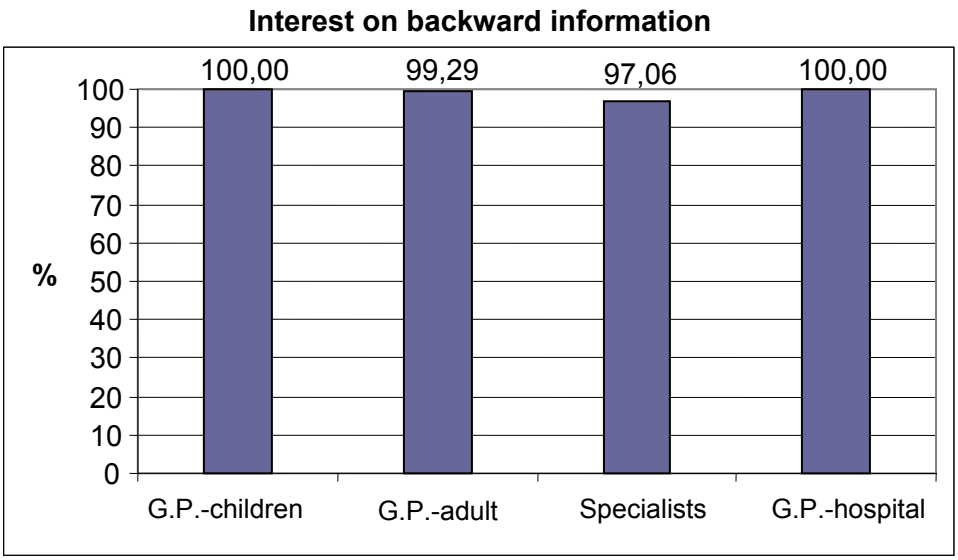


Assistance for castigation of reporting



Contemporary regular access to backward information




Interest on backward information
100,00
99,29
97,06
100,00
100
90
80
70
60
50
40
30
20
10
0
%
G.P.-children
G.P.-adult
Specialists
G.P.-hospital

Annex 9 Programme Study visit Mrs Gavačová

Phare Twinning Project in Slovakia

Twinning no. SK 03 IB SO 01
Strengthening the Surveillance and Control of Communicable Diseases in the Slovak Republic

Study Visit Programme

Slovakia to the Netherlands – November 2005

Contact person:	Tamara van Keulen Mobile: +31 (0) 6 49692342	Flight: Arrival in Amsterdam:
Transfer from Airport to NSPOH	Hotel Heidepark Jan Steenlaan 22/24 3723 BV BILTHOVEN	Tel.: +31 (0) 30 228 24 77

Participant:

Dr. Dagmar GAVAČOVÁ
Head of the National Reference Centre on Salmonella infections
Public Health Authority of the Slovak Republic
Trnavská cesta 52, 826 45 Bratislava, Slovak Republic
e-mail: gavacova@uvzsr.sk

Background from work plan

Activity 2.3
Two weeks Internships in corresponding accredited laboratories and institutes in the Netherlands or Germany of 4 selected Slovak employees of NRCs including for one employee an additional training of one week in quality assurance, EQAS

Issues of interest:

Training in diagnostic methods required for International Surveillance Network for Enteric Infections

- *Salmonella* spp: Serotyping
  PFGE(Pulsed- field gel electrophoresis)
  Genotyping methods

- *E.coli* : Serotyping
  Genotyping (virulence factors detection)

- EHEC/VTEC: Direct detection in stool samples
  Serotyping
  Verotoxin production testing by Vero-cell assay
  Virulence typing- by the DNA dot- blot hybridization technique
  PFGE

- *Campylobacter* spp.:Direct detection in stool samples
  Serotyping
  PFGE

- BSL3 Laboratory
  1. Laboratory design and facilities
  2. Laboratory equipment
  3. Laboratory protective personnel equipment
  4. Staff education
  5. Health and medical surveillance
  6. Training in laboratory procedures performed in BSL 3 lab.
     Detection of biological agents in environmental and biological samples-
     - Screening methods
     - Culture
     - RT- PCR diagnostics

15 Nov Tuesday	Contact person:	**Tamara van Keulen** Mobile: +31 (0) 6 49692342
		Travel to Amsterdam Schiphol airport **Tamara van Keulen** will meet you at the gate.
Travel to NSPOH		**Netherlands School of Public & Occupational Health** Tafelbergweg 51, 1000 CN Amsterdam *Tel. +31 (0)20566 4949*
		Distribution of per diem etc. by Carina van der Kloet Travel to hotel by Diederik Aarendonk Hotel Heidepark Jan Steenlaan 22/24 3723 BV BILTHOVEN Tel.: +31 (0) 30 228 24 77

16 Nov Wednesday	Contact person:	**Diederik Aarendonk** Mobile: +31 (0) 6 232309708

Travel by car to Lelystad		Animal Sciences Group, Wageningen UR Infectious Diseases Edelhertweg 15 8219 PH Lelystad The Netherlands Tel: + 31 320 238084
Confirmed	8.30 – 17.00	International workshop on Campylobacter Ms. Linda van der Graaf- van Bloois

17 Nov Thursday	Contact person:	**Tamara van Keulen** Mobile: +31 (0) 6 49692342
Walking to the RIVM.		RIVM (The National Institute for Public Health and the Environment) Antonie van Leeuwenhoeklaan 9 3721 MA Bilthoven *Tel.: +31 (0) 30 2749111* **Identification documents obligatory! (Passport)**
Confirmed	9.30 – 14.30	BSL 3 / 4 laboratories Ms. Evelien Kampert *Tel.: 31 (0) 30 2719909 (private)* *31 (0) 6 12338149 (mobile*)

18 Nov Friday	Contact person:	**Diederik Aarendonk** Mobile: +31 (0) 6 232309708
Travel by public transport to St Antonius Hospital		St. Antonius Ziekenhuis Koekoekslaan 1 Nieuwegein *Tel: 030-6099111*
	10.00 –14.00	Microbiological lab Quality control Dr. Paul Voorn *Tel : 030-6092624*

21 – 25 Nov Monday – Friday	Contact person:	**Diederik Aarendonk** Mobile: +31 (0) 6 232309708
Walking to the RIVM		RIVM (The National Institute for Public Health and the Environment) Antonie van Leeuwenhoeklaan 9 3721 MA Bilthoven *Tel.: +31 (0) 30 2749111* **Identification documents obligatory! (Passport)**
		Micro-biological lab

Confirmed	9.30-16.30	• *Salmonella* spp: Serotyping PFGE(Pulsed- field gel electrophoresis) Genotyping methods • *E.coli* : Serotyping Genotyping (virulence factors detection) • EHEC/VTEC: Direct detection in stool samples Serotyping Verotoxin production testing by Vero-cell assay Virulence typing- by the DNA dot- blot hybridization technique PFGE Dr. Wim Wannet

26 Nov Saturday	Contact person:	**Diederik Aarendonk** Mobile: +31 (0) 6 232309708 or **Tamara van Keulen** Mobile: +31 (0) 6 49692342
Travel by public transport to Schiphol airport		Flight nr: OS 372 AMS-VIE Departure: 10.30 Arrival: 12.25

Annex 10 Report Study visit Mrs Gavačová

Study visit report

November 15-26, 2005

Participant

Dr. Dagmar GAVAČOVÁ
Head of the National Reference Centre on Salmonellosis
Public Health Authority of the Slovak Republic
Trnavská cesta 52, 826 45 Bratislava, Slovak Republic
E-mail: gavacova@uvzsr.sk

Persons met and discussed items

15 November

Travelling by plane from Bratislava (Slovakia) to Amsterdam (The Netherlands).
Netherlands School of Public and Occupational Health in Amsterdam – introducing meetings.
Travelling from Amsterdam to Bilthoven and hotel accommodation.

16 November

Animal Science Group, Wageningen UR, Lelystad
Laboratory for molecular biology

Mrs Linda van der Graaf-van Bloois

- PFGE method – *Campylobacter* fetus.
- International Workshop on *Campylobacter* fetus typing – molecular biological methods used for detection of types and subtypes of serious pathogens at beef cattle stud.

17 November

RIVM (The National Institute of Public Health and Environment), Bilthoven
BSL3/4 laboratories

Mrs. Evelien Kampert

18 November

St. Antonius Ziekenhuis Hospital, Nieuwegein
Laboratory of clinical microbiology

Dr. Paul Voorn

21-25 November

RIVM (The National Institute of Public Health and Environment), Bilthoven
Micro-biological lab

21st *Dr. Wim Wannet*

- Introducing with workplace and to personnel.

Mr. Max Heck

- Starting with *S.*Typhimurium typing by PFGE (Pulsed-field gel electrophoresis).

22nd *Mrs. Anjo Verbruggen*

- *Salmonella* spp. serotyping – typing by agglutination in microtiter plates.

Ing. Kim von Zwaluw

- EHEC typing by PFGE.

Mr. Max Heck

- *S.*Typhimurium typing by PFGE.

23rd *Mrs. Henny Maas*
- *Salmonella* spp. serotyping – typing of problematic strains by tube agglutination method.

Ing. Kim von Zwaluw
- EHEC typing by PFGE.

Mr. Max Heck
- *S*.Typhimurium typing by PFGE.

24th *Mrs. Anjo Verbruggen*
- *Salmonella* spp. serotyping.

Ing. Kim von Zwaluw
- EHEC typing by PFGE.

Mr. Max Heck
- *Salmonella* Enteritidis phage-typing.

25th *Ing. Kim von Zwaluw*
- Evaluation of results of EHEC typing by PFGE.

Mr. Max Heck
- Evaluation of *Salmonella* Enteritidis phage-typing.

Finalization of serotyping unfortunately did not happen due to shortened working hours or vacation of employees performing this diagnostic process.

26 November
Travelling from Amsterdam (The Netherlands) to Bratislava (Slovakia) by taxi, plane, bus.

Organization of travel
On the day of arrival Ms. Tamara van Keulen from NSPOH accompanied me from Shiphol airport to NSPOH. Mr. Diederik Aarendonk, also from NSPOH, arranged my travel to Bilthoven and accompanied me to Lelystad and back on 16.11. He also arranged my transport to Niewegein on 18.11. and provided me with sufficient information about the best train connections from Bilthoven to Shiphol for my return flight. I really appreciate a big support of these two organizators from NSPOH to help me orientate, for their time and offered help in any urgent cases.

Conclusions
During my 12-days internship (instead of 14-days) I visited accredited laboratories and institutions of public health in the Netherlands. The aim of the internship was to study the laboratory practise and to implement new detection methods for surveillance of infectious diseases. On February I prepared issues of interest and I was expecting that I will get a feedback whether these topics will be possible to discuss or not. I was also asking for the contacts of experts I was supposed to meet in the Netherlands with the aim to consult the details in advance. I did not get the contacts therefore I assumed all proposed issues will be included. Also the programme sent before the study visit indicated exactly the same topics. Unfortunately, due to time and operating reasons it was not possible to realize the whole programme. Main reason is absence of the RTA whose employment for the project terminated in August 2005. New RTA has not started on this position until today.

Evaluation
Participation on the study visit enable to get overview about realization of detection methods used for surveillance of pathogens that are causing enteric infections.
Very valuable was the possibility to compare equipments and facilities of visited laboratories with laboratories at our institute (PHA SR) as well as getting knowledge on new diagnostic techniques and professional contacts. Didactic approach of individual specialist partners came up from their working busyness but could be considered as helpful. Longer stay at RIVM laboratories with previous familiarity with time schedule in individual detection tech-

niques, which should be in competence of RTA, would increase final contribution of my study visit even more.
During the visit of Dutch experts to our laboratories at PHA SR in April 2005, following thesis was expresses: diagnostic – *Salmonella* spp., EHEC and *Campylobacter* spp. typing should be processed by our laboratory. After my study visit I could say that RIVM laboratories are not processing the whole range of these detection methods despite very good material and technical equipments and higher number of involved staff.

MUDr. Dagmar Gavačová December 16, 2005

Annex 11 Standard Operating Procedures

ORGANISATION AND STRUCTURE OF PHA SK EQAS

AIMS OF PHA SR EQAS

The PHA SR EQAS (Public Health Authority of the Slovak Republic External Quality Assurance System) is intended to help to improve and to standardize selected diagnostic procedures in four defined fields of clinical microbiology and environmental microbiology in the Slovak Republic.
The four selected fields include antibiotic susceptibility testing of clinical bacterial isolates, detection, identification and subtyping of *Salmonella spp*., *Neisseria meningitidis* isolates and identification, typing and subtyping of *Influenza virus*. Corresponding laboratory procedures will be the scope of systematical PHA SR EQAS.
The PHA SR EQAS is organized as a traditional EQAS system with no sanctions for poor performance for participating laboratories. The scope of a long-term scheme is both the improvement of laboratory testing performance and the education. Obtaining of standardized data by routine clinical laboratories and a better reporting to reference laboratories of the Public Health Authority of the Slovak Republic is suggested.

ORGANISATION, FUNDING, COOPERATING INSTITUTIONS AND PARTICIPANTS OF PHA SR EQAS

The PHA SR EQAS is funded solely by the Public Health Authority of the Slovak Republic. To realize individual PHA SR EQAS steps, the Public Health Authority of the Slovak Republic cooperates on an official agreement basis with external accredited clinical microbiology laboratories (HPL sro., Bratislava, Slovakia), educational institutions (SZU, Bratislava) and scientific institutions (SAV, Bratislava, Kosice).
PHA SR EQAS participants are routine clinical microbiology and environmental microbiology laboratories in the Slovak Republic. Individual laboratories take part on the PHA SR EQAS anonymously and voluntarily (List of laboratories participating on PHA SR EQAS / ATB)..

PERFORMANCE OF UVZ EQAS

General procedures

The PHA SR EQAS system is organized according to four independent long-term programs specified for every field of selected laboratory procedures. The PHA SR EQAS unit is responsible for a general management of the whole program and is directed by a Head of Microbiology Center of PHA SR.

Specific procedures

The PHA SR EQAS operates in four different fields independently. The EQAS system for every field is organized periodically at defined intervals for a specified group of participant laboratories. A long-term program document for every field is followed (Antibiotic susceptibility testing, *Salmonella spp*., *Neisseria meningitidis* and *Influenza*).

In an individual PHA SR EQAS run, field-specialized steps related to a sample processing and intended quality assurance are followed. Here, the PHA SR EQAS unit cooperates with corresponding reference laboratories and with external specialized institutions (scheme of PHA SR EQAS).

Every step in the scheme is performed and documented according to a specific "SOP" (standard operating procedure document).

DOCUMENTATION

A complete documentation of every PHA SR EQAS run consisting of a specified documentation protocols according to SOPs is stored in two copies (PHA SR EQAS unit and corresponding reference laboratory).

Scheme of PHA SR EQAS

		PHA SR EQAS Unit			
		↓			
		Individual EQAS long-term program (ATB)			
		↓			
		EQAS process (run)			
		↓			
Cooperating institutions	↔	**Sample obtaining**	→	**Reference laboratory**	**SOP_EQAS-ATB-01**
Cooperating institutions	↔	**Sample characterization**	→	**Reference laboratory**	**SOP_EQAS-ATB-01**
		Sample selection	→	**Reference laboratory**	**SOP_EQAS-ATB-02**
		Definition of the question asked	→	**Reference laboratory**	**SOP_EQAS-ATB-02**
		Sample producing and aliquotting	→	**Reference laboratory**	**SOP_EQAS-ATB-03**
		Sample package	→	**Reference laboratory**	**SOP_EQAS-ATB-03**
Slovak Post	←	**Sample shipment**			**SOP_EQAS-ATB-03**
		Data collection	→	**Reference laboratory**	**SOP_EQAS-ATB-04**
		Preliminary report	→	**Reference laboratory**	**SOP_EQAS-ATB-04**
		Data analysis	→	**Reference laboratory**	**SOP_EQAS-ATB-05**
		Final report	→	**Reference laboratory**	**SOP_EQAS-ATB-05**

COLLECTION AND CHARACTERIZATION OF SAMPLES FOR UVZ SR EXTERNAL QUALITY ASSURANCE SYSTEM – SUSCEPTIBILITY TESTING.

DEFINITION

Samples for UVZ SR EQAS - susceptibility testing are obtained from clinical specimens submitted to routine clinical microbiology laboratories for routine testing. Samples are collected by cooperating clinical microbiology laboratories (see List of cooperating laboratories).
Bacterial isolates of interest (see attached List of resistance mechanisms) requested by Reference laboratory (typical as well as atypical, combined and unusual mechanism of resistance) are send to Reference laboratory for further identification. Every sample is given an NRC code and bacteria are stored for a required period incorporated to gelatin disks, or repeatedly subcultured (SOP-NRC-ATB-02).
Antibiotic profile and resistance mechanism of selected strains are retested in NRC (SOP-NRC-ATB-11-14) and send for independent verification to cooperating accredited clinical microbiology laboratory. If possible, resistance mechanisms are confirmed by genetic methods at collaborating scientific institution.
Strains with resistance mechanisms of interest are later selected for individual UVZ EQAS runs.

BACTERIAL SAMPLE - ACCEPTANCE AND REGISTRATION

Pure bacterial culture (sufficient amount of a fresh subculture inoculated on transport, or nenselective media) is send to the Reference laboratory. The sending has to be accompanied by data necessary to identify and document the sample origin:

- Institution
- Bacterial identification
- Date of isolation
- Assumed resistance mechanism
- Patient age and gender
- Clinical diagnosis
- Site of specimen collection

Each sample is given a NRC code consisting of a order registration number followed by slash and a year of acquisition (29/2005). Sample processing and registration is documented and signed by responsible technician. The sample is submitted to further testing (SOP-ATB-01-03)

DEFINITIVE SAMPLE CHARACTERIZATION

After confirmation of bacterial isolate identification and characterization of resistance mechanisms (also done by cooperating institutions) the isolate is put on a list of UVZ EQAS susceptibility test control sample. Examination protocols of each sample are stored separately. The sample is stored.

SAMPLE STORRAGE

Well characterized samples are stored for a required period of time incorporated to gelatin disks, or for shorter periods simply using a defined number of subcultures (SOP-EQAS-S-03).

RESISTANCE MECHANISMS

Actual list of resistance mechanisms/profiles supposed for further analysis is send to all laboratories potentially submitting samples:

Beta – lactamases in Gram – bacteria	**„TEM-1, -2, SHV -1 – low“**	Common beta-lactamases, low expression.
	„TEM-1, -2, SHV -1 – high“	Common beta-lactamases, high expression.
	„PSE-1, -4, OXA -1 “	Common beta-lactamases in *Pseudomonas aeruginosa*.
	„Class A, Amp C, hyp.!“	Derepressed chromosomal beta-lactamases
	„K. oxytoca high“	Derepressed chromosomal beta–lactamase in K. oxytoca
	“Plasmidic AmpC!“	Plasmidic Amp C beta-lactamases
	„ESBL“	Extended spectrum beta-lactamases.
Ps. aeruginosa	**„MexA-MexB-OprM+!“**	Efflux in Ps. aeruginosa
	„OprD-“	Porine defect OprD - carbapenem resistance
	„MexA,B-OprM+OprD-“	Efflux + porine defect in Ps. aeruginosa
	„metalobetalactamases“	Metalo-betalactamases
Gram+ cocci general	**„Amngl.PH(2'') – AC(6')!“**	Resistance to GEN, TOB, NET and AMI!
	„TEI / VAN unexpected!“	Unexpected results – TEI / VAN!
Staphylococcus spp.	**„PNC resist.!“**	Penicilin resistance
	„MRSA !!!“	Oxacillin resistant S. aureus
	„MRCoNS“	Oxacillin resistant coagulase-negative staphylococcus
	„Constitutive MLSB/c“	Constitutive resistance to macrolides, lincosamides, streptogram. B.
	„Inducible MLSB/i“	Inducible resistance to macrolides, lincosamides, streptogramin B.
	“VRSA/ hetero VRSA??“	Decreased vancomycine susceptibility
Enterococcus spp.	**„GEN High: HLR.!“**	High level resistance to GEN.
	„Constitutive MLSB/c“	Constitutive resistance to macrolides, lincosamides, streptogram. B.
	„VanA!“ ,“VanB!“	Glycopeptide resistance phenotypes.
Haemophillus spp.	**„Beta-lactamase“**	Beta-lactamase (inhibited by inhibitors)
	„Non-beta-lactamase“	Resistance to combination amoxicillin - clavulanate
Streptococcus spp.	**„Inducible MLSB/i“**	Inducible resistance to macrolides, lincosamides, streptogramin B.
	„Constitutive MLSB/c“	Constitutive resistance to macrolides, lincosamides, streptogram. B.

LITERATURE

Clinical Laboratory Standards Institute. Performance standards for antimicrobial susceptibility testing; fifteenth informational supplement. CLSI/NCCLS document M100-S15, Vol. 25, No. 1. CLSI, Wayne, Pa 2005.

Livermore DM, Winstanley TG, Shannon KP. (2001). Interpretative reading: recognizing the unusual and inferring resistance mechanisms from resistance phenotypes. *J Antimicrob Chemother. 48, Suppl 1:87-102*

Annex 12 Time schedule

Calendar Month (from/to)	2005 14/2 13/3	14/3 13/4	14/4 13/5	14/5 13/6	14/6 13/7	14/7 13/8	14/8 13/9	14/9 13/10	14/10 13/11	14/11 13/12	14/12 13/1	2006 14/1 13/2	14/2 13/3	14/3 13/4	14/4 13/5	14/5 13/6	14/6 13/7	14/7 13/8	14/8 13/9	14/9 13/10	14/10 13/11			
Project Month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**
Phase	**0**	**Phase 1**				**Phase 2**							**Phase 3**											
Inception period / "Kick-off"	RTA																							
Component 1																								
Activity 1.1		RTA																						
Activity 1.2		x																						
Activity 1.3			Otto (3 days)																					
Activity 1.4			Holvast (4 days)																					
Activity 1.5				van Pelt (5 days)																				
Activity 1.6					Otto (3 days)																			
Activity 1.7						Otto (5 days)																		
Activity 1.8							Otto (5 days)																	
Activity 1.9								Otto (5 days)																
Activity 1.10										LCI (Timen) (2 days)														
Activity 1.11													LCI (Timen) (2 days)											
Activity 1.12														RTA										
Activity 1.13															Otto (2 x 5 days)									
Activity 1.14																	RTA							
Activity 1.15																		RTA						
Component 2																								
Activity 2.1		RTA																						
Activity 2.2			Mulder, Galama, Waijboer (3, 4, 7 days)																					
Activity 2.3				RTA																				
Activity 2.4					Waijboer (3 days)																			
Activity 2.5								Mulder, **Galama**, Waijboer (2,2,3 days)																
Activity 2.6									Mulder, Galama, Waijboer (3,3,5 days)															
Activity 2.7												Waijboer (5 days)												
Activity 2.8												RTA												
Component 3																								
Activity 3.1		RTA																						
Activity 3.2			Waijboer (3 days)																					
Activity 3.3					Waijboer (3 days)																			
Activity 3.4								Waijboer (7 days)																

Annex 13 Addendum No. 1

ADDENDUM No. 1

TO TWINNING CONTRACT 2003-004-995-03-07/0001
"Strengthening the surveillance and control of Communicable Diseases"

Twinning No. SK/03/IB/SO/01

Ministry of Finance of the Slovak Republic
Central Finance and Contracting Unit (CFCU)
Represented by Ms. Silvia Czuczorová, CFCU Director/PAO
Štefanovičova 5
817 82 Bratislava 15
Slovak Republic

("the Contracting Authority"),

on the one part,

and

Ministry of Public Health, Welfare and Sport
Represented by Ms. A.M.P. van Bolhuis, Director of International Affairs of the Ministry of Public Health, Welfare and Sport
Parnassusplein 5
NL – 2511 VX Den Haag
Netherlands

("the Member State Partner")

on the other part**,**

have agreed as follows:

Art. 1 Objective

The objective of this Addendum is to approve Mrs. Anne Maria Aalders to be a Resident Twinning Adviser from the date of notification of Addendum No. 1. by the CFCU director.

Art. 2 Modification of Twinning Contract

The previous RTA, Mr. A.J.H. Korver was exceptionally approved for a limited period of maximum six (6) months from the day of the notification of the Twinning contract (14 November 2005).
Mr. A.J.H. Korver was approved as a substitute of originally selected RTA, Mr. R. Egger, who unfortunately died. Mr. A.J.H. Korver was not directly selected by the Slovak partner and he got only limited exception for his third assignment.
After termination of the contract with Mr. A.J.H. Korver, Slovak twinning partner requested new selection of RTA and Mrs. Anne Maria Aalders was selected.

Taking in account the expiration of the current RTA assignment (15 August 2005) together with result of the RTA selection, the signatories propose Mrs Anne Maria Aalders to be approved as a Resident Twinning Adviser.

In following article of the Twinning contract the text will be changed as follows:
Article 6.1 Human resources, the row in the table summarising the Member state human resources: Ms. Anne Maria Aalders will be included as well as her CV. (Annex 1 of this Addendum).

Mrs. Aalders contact details are:
Drs. A.M. Aalders
Binnen Bantammerstraat 7-1
1011 CH Amsterdam
The Netherlands
+31 (0)20 6381137
a.aalders@hetnet.nl

Art. 3 Confirmation of validity

All of the parts and dispositions of the initial Twinning Contract and the approved side letters which are not modified here remain valid.

Done at Bratislava in four originals in the English language, one original being for the Contracting Authority, one original for the Final Beneficiary, one original being for the Member State signatory and one original for the Mandated body of the Member State Partner.

For the Final Beneficiary:

Name: Ms. Zuzana Škublová

Title:

Signature:

Date:

For the mandated body of the Member State Partner:

Name:

Title:

Signature:

Date:

For the Member State Partner:

Name: Ms. A.M.P. van Bolhuis

Title:

Signature:

Date:

For the Contracting Authority:

Name: Ms. Silvia Czuczorová

Title:

Signature:

Date:

Annex 14 Financial report