DEMOCOPHES

NATIONAL REQUIREMENTS FOR LABORATORY

SLOVAKIA

Final version

1. Introduction

This document follows the requirements for laboratories defined in the EU study protocol. Within the Pilot Study a basic scenario will be followed measuring cadmium, cotinine and phthalates in urine and mercury in hair. In Slovakia, the NMU has already selected 2 laboratories.

The Regional Authority of Public Health in Banská Bystrica (RUVZ BB) will analyse mercury in hair and The Public Health Authority of Slovak Republic (UVZ SR) in Bratislava will analyse cotinine, cadmium and creatinine in urine (if they will be successful in ICI). Tendering was not necessary. Laboratory in Banská Bystrica has already participated in 1st and 2nd ICI round and it was in determination of mercury in hair successful. Laboratory in Bratislava has joined in 2nd ICI round for the first time. Based on the results of the 2nd round of COPHES ICI/2011 laboratories at UVZ SR have worked to increase the sensitivity of methods for the determination of cadmium and cotinine in urine (if the device allows the sensitivity of equipment – HPLC - cotinine in urine).

Laboratories have an accreditation according to the ISO/IEC 17025:2005. They are going to participate in 3rd ICI round.

Concerning the phthalates we have suggested the Institute of Chemistry under University Comensky in Slovakia to participate in 3rd ICI round. We are waiting for approval to join this laboratory within 3rd ICI round. Otherwise we will have to ask for collaboration one from the potential laboratories after ICI rounds organised by COPHES.

2. Selection criteria concerning the technical capability

The laboratory has to prove experience with the chemical analysis of the substances for which it is subscribing.

Laboratory has experience with a validated standard Operating Procedure (SOP) concerning the substances subscribing.
To prove this, the laboratory gives a general description of the SOPs concerning the substances subscribing for, used and validated in the laboratory, including all steps for sample preparation.

The validation includes the following:

- Accuracy (use of certified reference material or performing recovery experiments);
- Intra-assay and inter-series reproducibility (at least 2 concentrations, at least 6 replications);
- Detection / quantification;

If available the laboratory adds the results of previous participations in ICI and EQUAS, which were conducted with the same substance(s) or at least closely related substance(s) in the same matrix with the same analytical method. The laboratory also provides former internal quality control measurements.

The laboratories must participate in interlaboratory comparison investigations (ICI) and in EQUAS, which are organized by COPHES/DEMOCOPHES. They also must participate in web/telephone-conferences which are organized to discuss the results of ICIs, with the aim to harmonize analytical methods and to improve the comparability of HBM results.

Results from previous participations in EQUAS are available. These EQUAS have been performed with the addressed pollutants and closely related compounds -in the matrix that is going to be used in the Pilot Study and the analytical method that will be applied.
The laboratory will perform internal quality control measures. Past records of these measures as well as a concept for internal quality control measures during the run of the study will be provided by the laboratory.
The laboratory has appropriate experience in conducting chemical analyses for HBM-studies.
It also employs personnel which have been trained to perform appropriate analytical techniques. Copies of these records are available.

Participation in ICI and EQUAS during the project is guaranteed and ensured.

During the project in each series of analyses at least one control sample will be analysed. The minimum demand is that 5 % of the total numbers of samples have to be internal quality control samples. Control Material (CM) has to be used for this purpose. It is supplied by the offering institution. The results of such measurements have to be provided and added to every

delivery of data.
The laboratory will provide results within the time frame mentioned. Samples will be analysed in time and with the quality needed, and maintenance and disaster recovery procedures are in place for data quality and safety. Responsibility if things go wrong is also guaranteed.

3. Data reporting

Data transfer will be performed with the electronically provided data sheets (presumably in an Excel-format). With every delivery the results of internal and external quality control, including data from the parallel measurement of samples provided by the reference laboratory have to be delivered.
The laboratory will prepare a final report. In this report the analytical method will be described, the results summarized in the form of descriptive statistics (number of analysis, arithmetic mean, standard deviation, GM 95 percentile, minimum value, maximum value) and special events mentioned.