HBM4EU project

Specific QA/QC requirements within HBM4EU
Marta Esteban López
Argelia Castaño
1st HBM4EU Training School 2018
WP 9 Laboratory analysis and quality assurance

WP leader: Argelia Castaño & Marta Esteban.

Task 9.1. Inventory of best suited biomarkers, matrices and needs for new analytical methods
Catherine Thomsen, NIPH, Norway

Task 9.2. Network of Reference HBM laboratories for performing biomarker analysis, developing new methods and supporting the QA/QC program at EU level
Marta Esteban, ISCIII, Spain

Task 9.3. Developing new methods
Holger Koch, IPA, Germany

Task 9.4. Quality assurance
Thomas Göen, IPASUM, Germany

Task 9.5. Analytical phase
Katrin Vorkamp, AU, Denmark

Task 9.6. Helpdesk
Jana Hajslova, VSCHT, Czech Republic

The Quality Assurance Unit (QAU)
Core: ISCIII, IPA, IPASUM and VSCHT
Associated members: RIKILT, INRA, MU, UAntwerpen and ISS
WP 9 Laboratory analysis and quality assurance

WP 9 provides support for conducting HBM analyses and identifies the analytical needs

T 9.1  T 9.3  T 9.5  T 9.6
WP 9 Laboratory analysis and quality assurance

WP 9 connects EU laboratories and paves the way for harmonized chemical analysis
WP 9 Laboratory analysis and quality assurance

WP 9 ensures the quality and comparability of the analytical results

- Definition of the criteria for selecting candidate laboratories
- List of candidate laboratories to perform the analysis of HBM samples, to develop new methods and to support the QA/QC activities in HBM4EU
- Definition of the QA/QC program for HBM4EU
Analytical laboratories in HBM4EU

Selection of laboratories: step by step approach to guarantee the harmonization and the quality of the chemical analysis human samples.
The WP9 QA/QC Scheme in HBM4EU

ICI
Interlaboratory Comparison Investigation

First test for newcomers in HBM
objectify the skills in HBM-analytics
in the different countries

Comparability

Consensus value

COMPARABILITY

EQUAS
External Quality Assessment Scheme

Inclusion of reference labs (RL)

Accuracy

Assigned value
and tolerance ranges

The SAME value

Approx. of the TRUE value

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The WP9 QA/QC Scheme in HBM4EU

Standard Operating Procedures

• **HBM4EU-SOP-QA-001**: Organisation of Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS)

• **HBM4EU-SOP-QA-002**: Preparation of control materials for Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS)

• **HBM4EU-SOP-QA-003**: Evaluation of results from Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS)

• **HBM4EU-QA-004**: Reporting of results of Interlaboratory Comparison Investigations (ICI) and External Quality Assurance Schemes (EQUAS)

• **ICI / EQUAS REPORT**
The WP9 QA/QC Scheme in HBM4EU

- In parallel for the different groups of substances: 72 parameters
- 2 ICIs and 1 EQUAS in 2018
- 6 laboratories involved in the organization
Round 1 of the ICIs

**Phthalates**

**Matrix:** Urine

**Compounds:** MEP, MBzP, MiBP, MnBP, MCHP, MnPeP, MEHP, SOH-MEHP, 5oxo-MEHP, 5cx-MEPP, MnOP, OH-MiNP, cx-MiNP, OH-MiDP, cx-MiDP

**Organiser:** RIKILT

**Responsible of CM preparation:** RIKILT

**Responsible of CM testing:** IPA

1st round ongoing

**DINCH**

**Matrix:** Urine

**Compounds:** OH-MINCH, cx-MINCH

**Organiser:** RIKILT

**Responsible of CM preparation:** RIKILT

**Responsible of CM testing:** IPA

1st round ongoing
Round 1 of the ICIs

**Bisphenols**

**Matrix:** Urine

**Compounds:** BPA, BPF, BPS

**Organiser:** INRA

**Responsible of CM preparation:** INRA

**Responsible of CM testing:** INRA

1st round ongoing

**PFAS**

**Matrix:** Serum

**Compounds:** PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnDA, PFDa, PFBS, PFHxS, PFHpS, PFOS (sum of all isomers)

**Organiser:** IPASUM

**Responsible of CM preparation:** IPASUM

**Responsible of CM testing:** IPASUM

1st round finished
**Round 1 of the ICIs**

**PAHs**

**Matrix:** Urine

**Compounds:** 1-hydroxynaphthalene, 2-hydroxynaphthalene, 1,2-dihydroxynaphthalene, 2-FLUO, 3-FLUO, 9-FLUO, 1-hydroxyphenanthrene, 2-hydroxyphenanthrene, 3-hydroxyphenanthrene, 4-hydroxyphenanthrene, 9-hydroxyphenanthrene, 1-PYR, 3-hydroxybenzo(a)pyrene

**Organiser:** IPASUM

**Responsible of CM preparation:** IPASUM

**Responsible of CM testing:** VSCHT

**Flame retardants**

**Matrix:** Serum and urine

**Compounds:** BDE-47, BDE-153, BDE-209, α-HBCD, γ-HBCD, DPHP, BDCIPP, BCEP, BCIPP, TBBPA, Syn-DP, Anti-DP DBDPE, 2,4,6-Tribromophenol

**Organiser:** VSCHT

**Responsible of CM preparation:** VSCHT

**Responsible of CM testing:** VSCHT and IPASUM

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# Round 1 of the ICIs

## Aromatic amines

<table>
<thead>
<tr>
<th><strong>Matrix:</strong></th>
<th>Urine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compounds:</strong></td>
<td>MDA, MOCA, Aniline, p-aminophenol, N-acetyl-4-aminophenol, p-PDA, o-toluidine, 2,4-TDA, 2,6-TDA</td>
</tr>
<tr>
<td><strong>Organiser:</strong></td>
<td>External lab</td>
</tr>
<tr>
<td><strong>Responsible of CM preparation:</strong></td>
<td>External lab</td>
</tr>
<tr>
<td><strong>Responsible of CM testing:</strong></td>
<td>External lab</td>
</tr>
</tbody>
</table>

1st round in preparation

## Cadmium

<table>
<thead>
<tr>
<th><strong>Matrix:</strong></th>
<th>Blood and urine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Organiser:</strong></td>
<td>IPASUM</td>
</tr>
<tr>
<td><strong>Responsible of CM preparation:</strong></td>
<td>IPASUM</td>
</tr>
<tr>
<td><strong>Responsible of CM testing:</strong></td>
<td>IPASUM</td>
</tr>
</tbody>
</table>

1st round finished

## Chromium

<table>
<thead>
<tr>
<th><strong>Matrix:</strong></th>
<th>RBC, urine and plasma</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Organiser:</strong></td>
<td>IJS</td>
</tr>
<tr>
<td><strong>Responsible of CM preparation:</strong></td>
<td>IJS</td>
</tr>
<tr>
<td><strong>Responsible of CM testing:</strong></td>
<td>IJS</td>
</tr>
</tbody>
</table>

1st round in preparation
Example: Cadmium 1<sup>st</sup> round ICI 2018

- 23/02/2018 – Invitation to the candidate laboratories
- 03/04/2018 – Shipment of the samples
- 09/04/2018 – Samples received
- 01/05/2018 – Deadline for submitting the results
The value of these schemes: examples from DEMOCOPHES experience

• Capacity building was successful
  - recognizing the benefits of human biomonitoring
  - analytical know-how
• Only strict Quality assurance and Quality control will guarantee comparable and reliable results
• The analysis of the real samples analysis showed the necessity of strict criteria for lab selection and the importance of achieving LOQs, specially for children
The WP9 QA/QC Scheme in HBM4EU

Main Challenges

• High number of compounds (2\textsuperscript{nd} prioritization list will add more!)
• Time pressure for selecting the qualified laboratories to analyse the samples in HBM4EU and to obtain the results in the time-frame of the project
• Not enough capacity (laboratories available) to organise the ICI/EQUAS
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Marta Esteban López PhD works as scientific researcher at the National Centre for Environmental Health of the Instituto de Salud Carlos III. She has a University Degree in Biochemistry and obtained her PhD in Epidemiology and Public Health. In HBM4EU she is the leader of task 9.2 and coleader of WP9. She also participate actively in tasks of WP7 dealing with sampling and the preanalytical phase.