HBM4EU science and policy for a healthy future

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Criteria for selecting candidate laboratories to develop new analytical methods according to HBM4EU needs

Information extracted from Deliverable Report D 9.3:

Database of candidate laboratories for the

1st prioritisation round of substances

WP 9 - Laboratory analysis and quality assurance

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Entity	Name of person responsible	Short name of institution	Received [Date]
Coordinator	Marike Kolossa	UBA	13/09/2017
Grant Signatory	Argelia Castaño	ISCIII	04/09/2017
Pillar Leader	Argelia Castaño Greet Schoeters	ISCIII VITO	13/09/2017
Work Package Leader	Argelia Castaño and Marta Esteban	ISCIII	04/09/2017
Task leader	Marta Esteban	ISCIII	04/09/2017

Responsible author	Octavio Pérez Luzardo	E-mail	octavio.perez@ulpgc.es
Short name of institution	ULPGC	Phone	+ 34 928 451 424
Co-authors	Marta Esteban and Argelia Castaño		

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1 Authors and Acknowledgements

Lead authors

Octavio Pérez Luzardo, Universidad Las Palmas de Gran Canaria (ULPGC)

Marta Esteban López, Institute of Health Carlos III (ISCIII)

Argelia Castaño Calvo, Institute of Health Carlos III (ISCIII)

Contributors

Pillar 2 leader:

Argelia Castaño. Institute of Health Carlos III (ISCIII)

Partners in task 9.2:

- Juan José Ramos, Silvia Gómez, Susana Pedraza, Sara González, Helena García and Miguel Motas. Institute of Health Carlos III (ISCIII)
- Jean-Philippe Antignac. French National Institute for Agricultural Research (INRA)
- Ovnair Sepai. UK Department of Health - Public Health England (DH)
- Dagnė Janarauskienė and Rosita Balčienė. Lithuanian National Public Health Surveillance Laboratory (NPHSL)
- Jana Klanova. Masaryk University (MU)
- Katrin Vorkamp. Aarhus University (AU)

Task leaders in WP9:

- Marta Esteban López. Institute of Health Carlos III (ISCIII)
- Cathrine Thomsen, Norwegian Institute of Public Health (NIPH)
- Holger Koch. Institute for Prevention and Occupational Medicine of the German Social Accident Insurance (IPA)
- Thomas Göen, Friedrich-Alexander-Universität Erlangen-Nürnberg (IPASUM)
- Thomas Lundh. University of Lund (ULUND)
- Jana Hajslova. University of Chemistry and Technology (VSCHT)

Partners in WP9:

- Enrique Cerquier and Line S. Haug. Norwegian Institute of Public Health (NIPH)
- Monika Kasper-Sonnenberg. Institute for Prevention and Occupational Medicine of the German Social Accident Insurance (IPA)
- Adrian Covaci, University of Antwerp (UAntwerp)
- Löic Rambaud. Santé publique France (ANSP)
- Hans Mol. RIKILT Wageningen UR (RIKILT)

Chemical group leaders (CGLs):

- Marike Kolossa, Ulrike Doyle, Till Weber. Umweltbundesamt (UBA)
- Robert Barouki. Institut National de la Sante et de la Recherche Medicale (INSERM)
- Maria Uhl. Umweltbundesamt GMBH (EAA)
- Jana Klanova. Masaryk University (MU)
- Milena Horvat. Institut Jozef Stefan (JSI)
- Alessandro Alimonti. Istituto Superiore Di Sanita (ISS)
- Greet Schoeters. Vlaamse Instelling Voor Technologisch Onderzoek N.V. (VITO)
- Tiina Santonen. Finnish Institute for Occupational Health (FIOH)
- Lisbeth Knudsen. University of Copenhagen (UCPH)

2 Introduction

The objective of the task 9.2 was to elaborate a list of candidate laboratories for the substances selecteded in the 1st HBM4EU round of prioritisation for:

- Performing chemical analysis of biomarkers
- Developing new analytical methods
- Supporting Quality Assurance/Quality Control (QA/QC) program in WP9

These candidate laboratories could take part in the activities of HBM4EU after their subsequent successful participation in the Interlaboratory Comparisin Investigations (ICIs) and External Quality Assurance Scheme (EQUAS) (biomarker analysis) or after being selected according to the criteria defined by experts (new analytical methods and QA/QC support).

3 Criteria definition

The first draft of the criteria for selecting the candidate laboratories was discussed within the QAU (23/03/2017). After that, the QAU associated members and other WP9 partners were included in the discussions.

The QAU members decided to define a primary criterion for each section as a direct exclusion criterion. This was presented and approved by the Management Board. Then, the data received would be evaluated according to the scoring defined for each of the criteria and consequently, obtaining the final score for each laboratory (Table 1-3). The evaluation of data for each section and group would be evaluated separately. Regarding the section covering analysis of the different biomarkers, data for each group of chemicals would be considered separately.

Criteria for selecting laboratories to develop new analytical methods according to the needs identified in HBM4EU.

KNOW – HOW	Exclusive	1st level	2nd level	Scoring system
Experience in developing new methods in biological matrices	X			
Relevance of the peer-reviewed publications provided (impact factor and number of citations)		x		Taking as 100% the maximum of the answers received: 5: 100-50% 3: <50%
Experience in developing methods in the target matrix/biomarker		x		5: experience in matrix and biomarker 3: experience in matrix or biomarker
Application of their developed methods at large scale studies		x		5: >1000 samples 3: 250 - 1000 samples 1: <250 samples
QA/QC AND BIOSAFETY				
If not accredited, existence of a QA/QC system in the laboratory covering the control of the equipments, reagents and control material, traceability of the samples, data protection and biosafety practices and facilities (chemical fume hoods, biological safety cabinets, chemical hygiene plan, SOP for chemical handling, etc.)			x	3: if yes in all options 1: if yes in control + other
Existence of a system for method validation		x		5
Number of accredited methods after their development			x	Taking as 100% the maximum of the answers received: 3: 100-50% 1: <50
CAPACITY				
Level of permanent resources dedicated to method development activities (staff, equipments, funding)			x	3: ≥50% permanent 1: <50% permanent
Access to high exposure material		x		5
Capacity for synthesising and labelling molecules (or possible access to) as control material for distribution at low scale			x	3