

ESBIO Workpackage 2: „Harmonized Approach Pilot Project“

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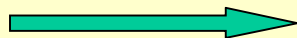


HBM in Europe

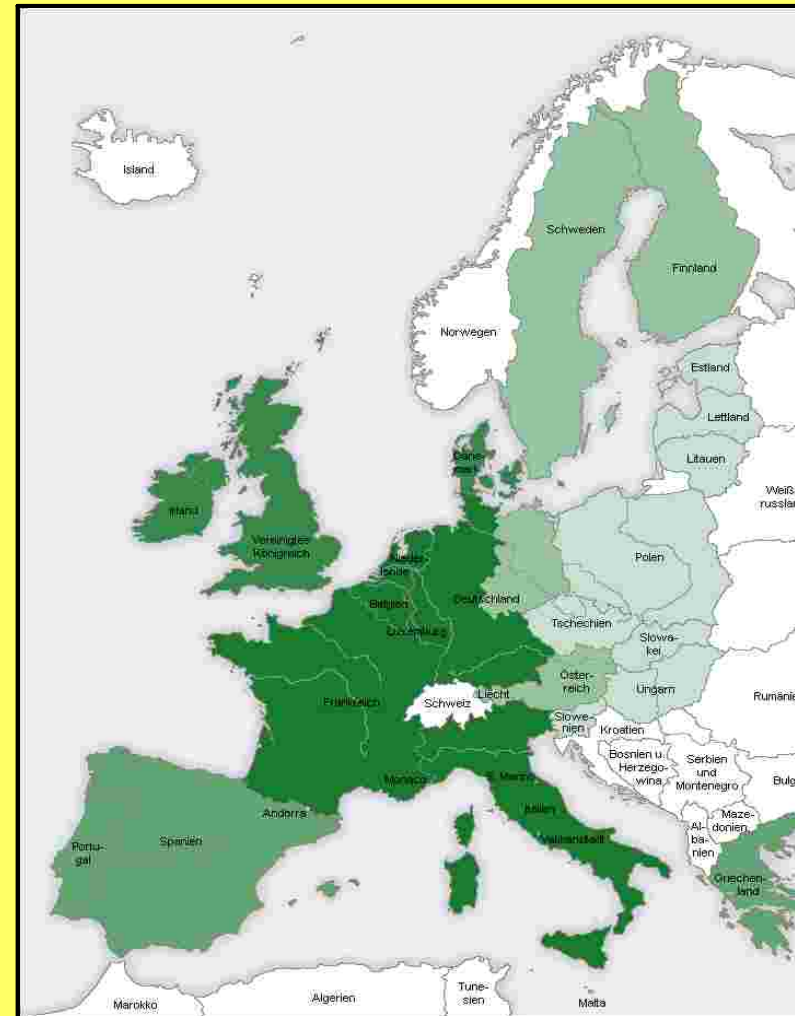
Starting point

HBM Studies in some countries

- different chemicals
- different methods
- different objectives
- different population samples
- different study designs
- different questionnaires



- no comparable data
- insufficient knowledge



Overall Objective of the Pilot Study

Test hypothesis that HBM can be performed in a coherent and harmonized approach

- develop protocols, strategies, scientific tools**
- produce reliable and comparable data**
- use resources effectively**

Work Package 2:

1. Study Population
2. Study Design
3. Selection of Participants, Sample
4. Recruitment
5. Field Work
6. Questionnaires
7. Chemical Analysis
8. Harmonisation of Data Treatment and Evaluation
9. Quality Control

WP2: 1. Study Population

Topic	
	▶ Choice of population segment regarding age
	▶ Choice of member states
	▶ Choice of population segment regarding exposure
	▶ Exclusion criteria
	▶ Choice of vulnerable population segment
	▶ Miscellaneous
	▶
	▶

WP2: 1. Study Population

Topic	Alternatives
Choice of vulnerable population segment	▶ Newborns
	▶ Babies
	▶ Toddlers
	▶ Preschool children
	▶ Schoolchildren
	▶ Mothers, pregnant women
	▶ Women in childbearing age
	▶ Seniors

Selection Criteria for Pollutants

- Scientific justification
- Biomarkers/ Metabolites
- Chemical analyses (standard/ alternatively)
- Expected LoQs

Proposal for Pollutants/ Biomarkers in regard to EU Human Biomonitoring Project

- Pollutants / Biomarkers [in media] selected

Szenario 1

“Basic”

- Lead in blood
- Cadmium in urine
- Mercury in hair
- Cotinine in urine

Szenario 2

“Shopping list”

1. Metabolites of PAHs in urine
2. Phthalate Metabolites in urine
3. Perfluorinated und polybrominated Chemicals in blood
4. Polybrominated flame retardents in blood
5. Organochlorine Compounds in blood
6. Metabolites of Organophosphates in urine
7. Metabolites of Pyrethroids in urine

Sample Size Estimates

- statistical calculation on the basis of the variance of data – specific for each pollutant (variance, power, significance level)
- according to population density
- endorsed by IUPAC/ Clinical Chemistry Division (N= 120)

Major decisions

- Mothers 22- 45 years
- Children 6- 11 years (ethical issue: blood!)
- Natural- rural- urban- industrial area
- Information on non- responders
- Written consent

Draft Questionnaires

1. Inclusion/exclusion questionnaire
2. Basic questionnaire
 - (1) In-house and ambient environment questions
 - (2) Dietary habits and food frequency questions
 - (3) Socio-demographic questions
 - (4) Health-related questions
3. Specimen sampling-documentation

Quality Assurance Considerations for the Questionnaires

Quality factors:

- Bias
- Missing entries
- Plausibility

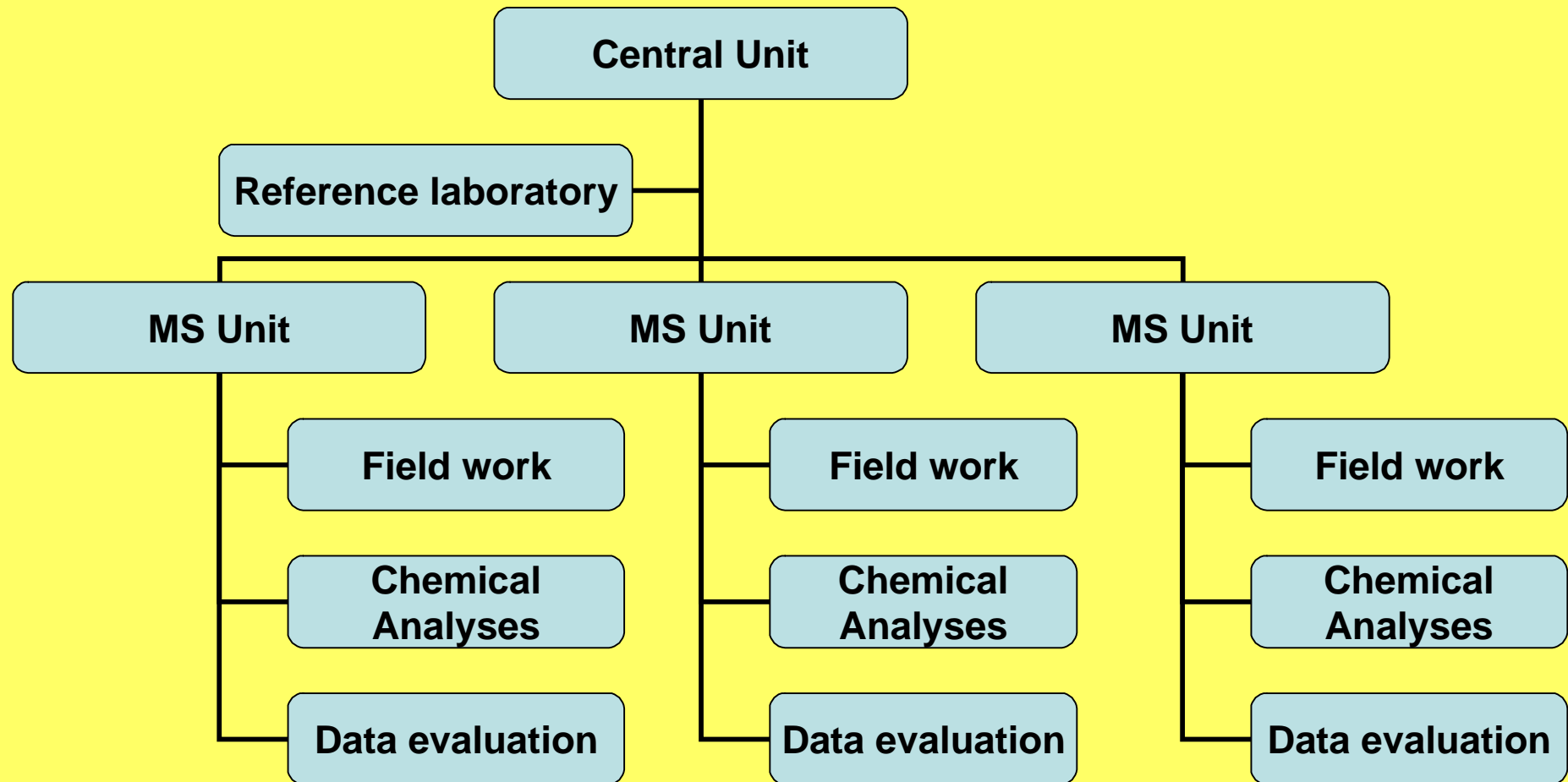
Quality criteria:

- Validity: external control; verification of data provided
- Reliability: reproducibility of data
(same questionnaire & collective after period of time)

Proposal for a harmonised way of collection, analysis and data management

- Chemical analysis
 - sample preparation
 - analytical methods
 - quality control
- Data management
 - checking data
 - merging data
 - anonymise data
 - generate a data base
- Data treatment
 - recruitment, response, compliance
 - statistical analysis of exposure
 - reporting of results

Organisation of QS: Reference laboratory



Del.	Title of deliverable
D2.1	Proposals for objectives of EU HBM approach and for pilot project including a justification of recommended priorities
D2.2	Proposal for pollutants and biomarkers including a justification of recommendations
D2.3.1	Protocol for [design] population sampling, recruitment and biological sampling
D2.3.2	Questionnaires for the Pilot Project
D2.4	Protocol for harmonised way of collecting and analysing selected pollutants and for data management

and what else did we do?

- learn much from other HBM-projects and scientists in Europe
- develop co-operations within the EU HBM community
- experience the pleasure to be part of a group of scientists coming from all parts of Europe
- a lot of technical stuff to realize our vision of the future Europe

