Report on an Action Plan and Options for Action for “biomonitoring of Children”

in the framework of the European Environment and Health Strategy (COM(2003)338 final)

TWG Biomonitoring of Children
Dr. Ludwine Casteleyn
The subgroup is assisted by Reinhard Joas and Sonja Bauer from BIPRO as a technical consultants and by Birgit Van Tongelen from the European Commission, DG Environment.
Human biomonitoring is an excellent tool to better integrate the two fields, environment and health. One of its big advantages is that within the chain it is much closer to health effects than environmental monitoring.
Monitoring activities in children, using biomarkers, that focus on environmental exposures, diseases and/or disorders and genetic susceptibility, and their potential relationships.

Biomonitoring of children includes the prenatal period up to an age of 18 years and follow-up activities for monitored children into adulthood extend the information to be collected to the child’s parents current and past exposure.
Various biomonitoring studies in European countries

- Total number of questionnaires received: 97
- Reported budget with 47 questionnaires: about 57 million euro
- About 480,000 children are covered (basis 90 questionnaires)
- 42 covered heavy metals,
- 25 projects examined asthma or allergies
- 19 projects covered dioxin/PCB exposure,
- 4 covered endocrine disrupters

... generally not carried out using the same methodological approach.
A more harmonised biomonitoring approach

Comparability would contribute to the EU Strategy for E & H by:

- Providing data on **distribution of exposure and related health impact** across Europe
  - definition of **reference values**
  - detection of **spatial differences** in exposure (populations/regions at risk)
  - detection of **temporal differences** in exposure

- Providing policy makers with better information on **control measures** to be taken
  - identification of **priorities** in exposure reduction strategies
  - allowing **follow up** of the efficiency of reduction strategies,
  - allowing a **geographically differentiated E&H policy**
A more harmonised biomonitoring approach

- Enable a **more effective use of resources** by shared development of tools and strategies.

- Enable **more meaningful results** of national surveys as the number of study subjects involved becomes larger.
  
  This would strengthen any observed correlation between exposure and health effects, which ultimately can point at potential causal relationships.

- Allow for **a more equal distribution of efforts** amongst European countries and a better respecting of the equal right of each European citizen on healthy environments.
Carrying out large surveys that include human biomonitoring presents challenging logistical problems and generally cannot be done without having medical staff available.

If it comes to a multi-national activity, the logistical problems and problems of coordination become even more pronounced than for national surveys.
Problems

- Differences in threats to health
- Different levels of analytical capacities
- Differences in political and health priorities
- Cultural differences,
- And perhaps also different perceptions of ethics

May render a common biomonitoring survey carried out simultaneously in several European countries difficult to achieve.
Integration of local, regional and national initiative in a wider European perspective needs above all:

- sound and harmonised study design
- adequate biomarkers: well validated, less invasive, effect biomarkers, ….
- reliable tools for sampling and analysis with consistent/comparable protocols
- harmonised data treatment
- adequate quality control
Action Plan

Approach: Step-by-Step Strategy

I  Develop guidelines for a harmonised EU approach for biomonitoring

II  Start an European wide pilot project

III  Develop tools to translate results into a response system
I. DEVELOP GUIDELINES

Design and protocol for surveys
- Population sampling strategy
- Objectives of monitoring
- Endpoints to be monitored

Sampling strategy and analysis
- Sampling strategy: single/pooled samples, repeated sampling, appropriate media (blood, urine, hair, breast milk, ..)
- Sampling methods and processing
- Analytical methods (validation, quality assurance, ..)

Data treatment
- Statistical analysis, storage of data, ...

Dissemination and information of results

Ethical rules and practices, social and legal aspects
II. START EU WIDE PILOT PROJECT

- “Learning by doing” tool
- Test and validate common harmonised approaches for all steps
- Facilitate the establishment of collaboration networks and the sharing of methodologies
- Promote the idea of harmonisation in biomonitoring.
- Identify possible problems linked with such harmonisation
II. START EU WIDE PILOT PROJECT

In view of not complicating the study by major analytical problems it is proposed to select a pollutant:

- for which there is already sufficient analytical experience.
- for which the exposure and health relevance is well known

Possible candidates: lead and mercury

in line with a WHO proposal to ensure regular biomonitoring of lead (amongst other hazardous chemicals) in at risk children.
III. Develop tools to translate results into a response system

- Develop **scenarios for translation of biomonitoring data into a response system**. Such scenarios require:
  - integration of biological monitoring data with environmental monitoring and health data
  - the development of
    - **reference values** to which biomarker results from different areas or time periods can be compared
    - **health based action levels** that can help indicate when measures need to be taken in order to reduce body burden

**Child-specific**

for most exposure- and effect biomarkers NO health based values exist
III. Develop tools to translate results into a response system

- In order to translate the results of biomonitoring into effective policy measures, effective communication is needed.

- Effective communication needs participation and exchange between the different stakeholders (general public, study participants, general practitioners, regulators, scientists, public interest NGO’s, industry, others) and will promote public awareness.

- A *communication plan* is an essential part of a biomonitoring programme and should be a part of the study design.
HOW?

Establish specific working group(s)

- **Bringing together existing expertise and experiences**
  - From MS already carrying out surveillance programmes
  - From occupational health field
  - From research field

- **Aim: to develop**
  - Harmonised technical procedures
  - Protocol for carrying out a pilot project
  - Tools allowing for translation of biomarker results into intervention strategies

- In coordination with Commission and MS
Other options for actions

1. Evaluation by experts of the various levels of scientific evidence for links between exposure and diseases or disorders that can be deduced from existing biomonitoring studies

2. Inventory of biomonitoring activities in Europe, possibly starting from the information from the baseline report
3. Proposal for a surveillance programme addressing exposure to heavy metals (lead and mercury) dioxins and dioxin-like compounds, based on an integrated biomonitoring system and focused on mother-newborn pairs by using, as much as possible, less invasive and cost effective methods.

4. Guidelines for necessary training, education and skill of health practitioners on environmental influences on health in children
Other options for actions

5. Priority list of factors for which only scarce information on biomonitoring data is available in EU

5. Selection criteria for biomonitoring pesticides in EU

6. Specific actions to include the AC in the common European system of biomonitoring of children

7. Identification of children at increased risk with recommendations for biomonitoring
Additional options for actions

Relating to exposure assessment:

9. Geographical mapping of pesticides, based on mandatory farm level record keeping, to be supplied annually to the competent authorities and accessible to the public

Related to exposure reduction:

10. The adoption of a legislation on pesticide dependency reduction in Europe

Related to health data

11. Childhood cancer and spontaneous abortion registers
Response Rates in GerES IV Pilot Study
(3 out of 4 Sampling Points, Summer 2001)

B. Seifert, K. Becker, C. Schulz, C. Krause
Federal Environmental Agency, Berlin, Germany
Response Rates in GerES IV Pilot Study

- Lower than in earlier GerES with adults
- Lowest with teenagers (14 and 17 years)
- Most frequent reason (49 %): no time
- Reduced RR goes along with
  - lower level of education of mother
  - mother working full-time
  - mother being single
- More frequently, non-responders are
  - single child, child of immigrants,
    and child of smoking parents
Research needs

Perception of environmental biomonitoring studies by participants: why do they consider to participate or to refuse participation, what do participants expect from these studies, how can we address their concerns?

Communication Strategies: develop and validate possibilities for appropriate communication of biomonitoring studies to different target groups and stakeholders
ETHICS

Informed consent: authenticity of consent
- Consent of both parents and children?
  - What is the age of being knowledgeable/competent for self determination?
- Who should ask for consent?
- How informed is a consent? (Who should give the information and how, written, video, oral, updates regularly - How to inform children from different ages ?)
- How to treat “given consent” in long term follow up studies?

Withdrawal from the study: individual versus societal right
- Withdrawal possible at any time?
- Destruction of samples and/or data after withdrawal of participants from the study?

Right to know & right not to know
- Communication of results when link with health risk is not clear
- Communication of individual results or aggregated data?

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Research needs

Research on socio-ethical and legal constraints

1. Environmental biomonitoring studies are regulated as clinical trials with applications to Ethical Committees and Data Protection Agencies. Existing Studies and programmes differ in strategies for communication, for recruitment and withdrawal of participants, for the content of informed consent to both children and parents.

2. Harmonisation of these rules may promote data sharing and may be a prerequisite for performance of international studies and programmes.

3. It is increasingly recognized that medical ethics, originated and developed for clinical situations, may require modification for public health or community needs, taking into account the “public interest” of the outcome of biomonitoring surveys.
Comments welcome!

ludwine.casteleyn@lin.vlaanderen.be
Reinhard Joas: Bipromuc@t-online.de