

Report from ESBIO workshop on ethics and communication in Copenhagen 11-13.3.2007

Almost 50 participants from most European countries and US attended the workshop and represented stakeholders of industry, regulators, academia and animal welfare.

The workshop provided two days of debate on identifying major items for guidelines for ethical issues and communication in human biomonitoring. Summaries of selected contributions to the workshop is enclosed. Some presentations will be submitted for publication and other presentations include key references. This report will be available on the ESBIO website when contributors have agreed. The workshop will also provide input to a separate supplement issue of the web based journal Environmental Health.

Welcome to EEA and presentation of EEA and biomonitoring

Dorota Jarosinska, European Environmental Agency, Copenhagen

EEA is

- Independent provider of **timely, targeted, relevant** and **reliable** information for policy making and to the public ... to support sustainable development and to help achieve ... improvement in Europe's environment
- **Networking** organisation – a European Environmental Information and Observation Network (EIONET) and other partners
- **Reporting** on the state and trends of Europe's environment – analyses and assessments
- **Providing access** to environmental information to different users

For the ethics of biomonitoring and children reference is made to: *Resnik & Wing, Children's Environmental Exposure Research Study – the ethical concerns and lessons learnt Am J Public Health, 2007* with the following recommendations

-Seek community consultation and participation

-Make participants aware of all the risks associated with the research, including hazards at the home and uncertainties about the risks of agents under investigation

-Take steps to ensure that studies do not have unfair representation of the poor or ethnic minorities

-Avoid even the appearance of a financial conflict of interest

-Make it clear to all parties that studies will not intentionally expose participants to hazardous environmental agents

Recent collaborations of EEA:

- Environment and health report (JRC and EEA) State of the Environment and outlook, 2005
- Environment and Health indicators in cooperation with WHO and DG Sanco
- Methodological approaches to estimate environmental burden of disease
- Evaluating evidence for action (association or causation - BH criteria)
- 'Late lessons' – precautionary principle in decision making

The objectives and results from ESBIO WP4 related to ethical issues was presented by

Lisbeth E. Knudsen, Institute of Public Health, Denmark

The objectives of work package 4 of ESBIO are to identify and analyse major ethical problems related to individualised biomonitoring. The processes of information of study persons and stakeholders should be described and analysed as well as the informed consent, data protection and dissemination. Specific attention should also be devoted to use of information obtained in common databases and adhering regulations in force and foreseen. WP4 performed a survey on the general ethical procedures related to individualised human biomonitoring (HBM) through questionnaires for

stakeholders within biomonitoring forwarded to ESBIO members for supplementary information. A Danish template was used and inputs were received from Germany, Belgium, United Kingdom, Sweden, France Luxembourg, Italy, Estonia, Czech Republic, Slovakia, Portugal and Cyprus.

Besides this questionnaire the legal situation in a number of countries regarding Ethics committees and data protection was extracted from existing data in Privirial database. Tables with information about country specific regulation were developed and sent for approval to key persons in each country of Germany, United Kingdom, France, Sweden, Portugal, Poland, Netherlands, Spain, Lithuania, Estonia and Ireland.

The key issues identified were

- a study protocol has to be developed at an early stage describing rationale, justification of study, calculation of minimum number of study persons needed for sufficient power of study, recruitment of study persons
- the informed consent must also be developed at an initial stage and information material to be sent for approval of ethics committees a.o. before initiation of studies
- the biobanking issues must be resolved by specification of sample characteristics, duration and purpose of storage of samples
- the use of incentives for participation must be considered with special concerns regarding children
- a strategy for information about study results including all stakeholders must be developed, including right not to know
- follow up strategies must be developed
- harmonised approaches to steps of recruitment, information, consent, data protection, biobanking, dissemination and data/sample transfer between countries and institutions should be considered eg in future directives/guidelines for human environmental biomonitoring in Europe (and worldwide).

Marie Pedersen, Franco Merlo, Lisbeth E. Knudsen. (2007) Ethical issues related to biomonitoring studies on children. *Int J Hyg Environ Health*. 2007 May; 210(3-4):479-82.

At a stakeholder meeting in Brussels organised by the DG environment of EU, stakeholders in human biomonitoring from industry, government, research and NGOs gave opinions on organisation of biomonitoring studies including children. Enrolment could either be through direct approaches to parents or advertisements. Repeated measurements were fully acceptable by all and the majority accepted all samplings of blood, urine, scalp hair and questionnaire. Study persons should be informed about study results or request results. Data should be protected by coding and made available for governments and research after anonymisation. Reimbursement of expenses related to participation should be organised while different views were expressed regarding incentives as gifts and payment. National differences in regulation should be respected while harmonisation was considered a necessity for future HBM activities.

Knudsen LE et al Results from European surveys of Ethical issues related to biomonitoring studies on children. *Environ Health*. Special issue – in preparation

Research on ethics in ECNIS and NewGeneris: A bottom up approach.

Birgit Dumez and Ludwine Casteleyn, University of Leuven

Current research projects using human biomarkers in their search for better knowledge on the interaction between environment and human health are facing sensitive ethical issues. Researchers may be put in situations in which it is unclear how to act in accordance with all necessary legal requirements on ethical aspects of research. As a consequence, scientific opportunities and

important developments of which many individuals will benefit, may be missed. Sound scientific research in the field of environment and health may benefit from a "rethinking" of current theoretical frameworks and procedures issuing from clinical medicine, putting emphasis on decisional autonomy and the protection of the individual and to a much lesser degree taking into account the concept of "public interest". The protection of individuals participating in studies in the field of environmental health calls, e.g., new communication strategies from recruitment to debriefing, at individual as well as at societal levels. Research on the socio ethical aspects on HBM within ECNIS and Newgeneris is situated at the interface of science, ethics and law and should be considered in the context of one final goal: contributing to guidelines for a harmonized socio-ethical and legal approach of human biomonitoring activities in the EU, including procedures for effective and appropriate communication both at the individual and at the collective level, resulting in a European research atmosphere in which scientific research related to development and use of human biomarkers is promoted, and in which a simultaneous protection of the rights and dignity of the study subjects is guaranteed. A harmonized socio-ethical and legal approach not only increases the possibilities for comparison between data generated but may also allow for more equality in the protection of the rights of each citizen of the European Union.

Experiences and guidelines will be collected and elaborated from the two EU projects taking the following into account:

Respect for human dignity: the guiding principle in social relations is equality in moral status of individuals, which includes that people will not be discriminated against in any way for reasons which are not justifiable in a democratic society.

Social justice: striving for equality in distribution of burdens and benefits among all members of society, by structural measures of social protection.

Solidarity: the expression of willingness to contribute to and develop a societal dynamics aiming at developing social justice, and aiming at avoiding social exclusion of any individual or group of persons.

Democratic participation: the pluralistic process of societal decision-making in parliament or bodies of governance empowered and controlled by parliament, issuing in adopting or putting in practice regulations or frameworks for regulations by elected or democratically appointed representatives, who are bound in their choices by democratic constitutional principles, which include tolerance and striving for the right balance between the rights and duties of every individual, between individual freedom and social coercion, such that respect for human dignity, social justice and solidarity are not compromised but promoted.

Reference is given to Research on the socio-ethical impact of biomarker use and the communication processes in ECNIS NoE and NewGeneris IP, B. Dumez, K. Van Damme and L. Casteleyn; Int. J. Hygiene and Environmental Health, Vol 210, issues 3-4, May 2007, p. 263.

Birgit Dumez, Karel Van Damme, Ludwine Casteleyn (2008). Research on ethics in ECNIS and NewGeneris: a bottom up approach. Environ Health. Special issue – in preparation.

Ovnair Sepai, Clare Collier, Birgit van Tongeleen, Ludwine Casteleyn. Stakeholders opinion: Human biomonitoring data interpretation and ethics, obstacles or surmountable challenges. Environ Health. Special issue – in preparation.

The seven deadly sins in environmental epidemiology and biomonitoring

Philippe Grandjean, University of Southern Denmark

Precautionary virtues needed to counterbalance the deadly sins in environmental health

- The limitations to epidemiologic evidence
- Conclusions being provisional and temporary
- The impact of uncertainties

- Worst-case scenario, not just null hypothesis
- Facilitating application of the “Precautionary Principle” in decision-making: In situations of potentially serious or irreversible threats to health or to the environment, the need to act to reduce potential hazards before there is strong proof of harm, should take into account likely costs and benefits of action and inaction

Ethical issues in human biomonitoring – a view from science studies

Susanne Bauer Medical Museion, University of Copenhagen

Biomarkers constitute a direct measure of multiple environmental exposures and are increasingly used in epidemiological studies. Monitored in large populations, they often add to or replace previous environmental indicators. Measuring environmental exposure within the human body shifts the site of monitoring from air, soil and water towards a screening study populations. What are the ethical and social implications of this shift?

Biomarkers can indicate exposure, susceptibility or disease and are interpreted within an array of risk factors including “genetic predisposition, lifestyle, culture, socio-economic factors, geographical location, climate and exposure to environmental stresses”. The linkage of biological samples together with the storage of individual data (biobanking) raises a host of ethical issues with regard to participation, consent, risk communication etc..

Epidemiological studies can be understood as complex assemblages that comprise extensive information networks and data flows stabilised for knowledge generation. Their products – population-based risk estimates – represent tools of governance; at the same time they enrol citizens into a mode of risk management, drawing on epidemiological assessments. What kind of biological citizenship do they enact - both as to the researchers, study participants and the general public? In what ways do sampling, data organisation practices, biomarkers and choices of indicators co-shape how we conceptualise the environment, health and disease?

Susanne Bauer. Societal issues in human biomonitoring – a view from science studies. (2008). *Environ Health*. Special issue – in preparation.

Applying Traditional Bioethical Principles to Human Biomonitoring

*Myron Harrison, Exxon Mobil Corporation Safety, Health and Environment
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Addressing bioethical concerns is routinely identified as one of the challenges in the field of human biomonitoring (ECETOC, EU commission and NAS). Similar issues have been raised with the emergence of genetic biomarkers where reasonable consensus has been reached regarding responsible uses (WHO, EMEA, ELSI FDA?)

Application of "traditional bioethical principles" to the interpretation and use of human biomonitoring data is one approach.

- Autonomy - Also known as the “respect for humans” principle; people understand their own best interests
- Beneficence - “do good” for people; the corollary is nonmaleficence -- “do no harm”
- Justice - fair distribution of benefits and costs (including risks to health) across stakeholders
- Secondary Principles
 - Utility - achieve the most good for the greatest number of people
 - Fidelity - consistency; don’t be arbitrary
 - Veracity - truth, scientific integrity; “bad science” always results in “bad ethics”
 - Confidentiality - protect the individual’s right to privacy

This however requires considerations related to circumstances eg workplace vs community cohorts and individualized vs population data.

The application of bioethical principles to human research is highly developed and codified (Common Rule, Helsinki Principles, other codes or statutes) Protections such as informed consent, written protocols and publishing are widely practiced under the purview of IRB's and REC's Increasing emphasis on the scientific validity of the research – especially population based investigations Individuals desire for communication of personal results can create bioethical dilemmas (autonomy vs. beneficence); is there a precedent in genetic research? IRB's and REC's need to be adopted by researchers in the private sector

The U.S. Center for Disease Control's National Exposure Report is a good example of how biomonitoring information can be generated and communicated with high scientific and ethical standards

- individual test results are not given unless the concentration is markedly above population means (very rare)
- the CDC states accurately that the data cannot be used to make statements about increased health risks for populations

Some advocacy groups have been less responsible in their communications (arguably, violating principles of beneficence and veracity)

Even responsible communications regarding biomarkers for exposure may in the future create social harms if stigmatization results for certain groups

Biomonitoring for chemicals of interest may have a role to play in product stewardship

- testing the validity of exposure estimation for specific products or emissions
- the need will vary with degree of hazard and public perception

While human biomonitoring for absorption will rarely be necessary, responsible behavior requires a systematic assessment of the potential for human absorption of chemical products and emissions failure to do this will increasingly be viewed as an ethical violation of the principles of autonomy, nonmaleficence, justice, and veracity

In summary:

Bioethical principles are widely used as a normative framework in areas of human research and medical care; increasing formalization in public health

Using unidentified, population-based biomonitoring information for risk assessment or population surveillance raises fewer bioethical concerns than personally identified biomonitoring information such as employed in health screening

Ensuring that scientific and technical issues are accurately presented (veracity) is essential in all deliberations

Companies should proactively apply normative bioethical principles when considering the disposition of products and byproducts in the environment and humans

There is a need for more engagement by scholars on the bioethical issues raised by the use of biomarkers of exposure

A key point is that there is not a single generic bioethical analysis applicable to the use of human biomonitoring data, but that each specific use requires a separate deliberation.

Myron Harrison. Applying bioethical principles to human biomonitoring. (2008). Environ Health. Special issue – in preparation.

Issues of biobanking related to HBM

Lisbeth E .Knudsen, Institute of Public Health, University of Copenhagen

Biobanks: The biological samples, plus related databases, allowing a certain level of accessibility, availability and exchange for scientific studies.

Very sensitive information: Racial origin, political opinions, religious or other beliefs, health, sexual life, criminal convictions, trade union membership

Less sensitive information: Personal finances, family relations, education, employment relations

Ordinary information: Gender, address, telephone number

Recommendations:

-Common guidelines for protocols including sampling and storage of data and samples

(Information, Consent, Data-protection)

-Transparency in sampling and results?

-Collaboration (e.g. like ILSI transgenic mice)

-Public databases

-Special concern with vulnerable groups (children, elderly, diseased)

Knudsen LE et al. Issues of biobanking and human biomonitoring. (2008). Environ Health. Special issue – in preparation

Monitoring research – a sociological study of research subjects participation in HBM

Uffe Lind, Institute of Public Health, University of Copenhagen

Purpose: To gain sociological knowledge about why and how research subjects participate in the production of medical knowledge and technologies in relation to HBM.

Method: 20 in-depth semi-structured interviews with research subjects participating in placenta perfusion project at University of Copenhagen. Interviews are recorded and transcribed. Interviews are analysed according to an interactions method.

Results: Results regarding the themes trust in science, reasons for participation and ways informing will be presented:

Trust in science: Research subjects have general trust in science as such and are pro-science

Reasons for participation: Research subjects feel obliged to participate but they are also genuinely interested in the project. They ask for the results. They stress the importance of being asked (informed consent) and the importance of proper information. They want to know what the research is about. The easiness of participating is important.

Ways of informing: Information must be short and precise. The purpose of the project is important. It should also be clear what the nature of the results is and what the participation involves.

Discussion: Results from the analysis may lead to different ways of understanding practices of medical ethics and the role of research subjects in the production of medical knowledge and technologies.

U. Lind, LE. Knudsen, T. Mose (2007) Participation in environmental health research by placenta donation - a perception study Environmental Health 6:36

Special ethical issues in environmental health

Domenico Franco Merlo

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Environmental health research is expected to be scientifically justified, with sound research questions and valid study protocols of sufficient statistical power. Regardless of which human population is included in field studies (e.g., general population, working population, children, elderly, vulnerable sub-groups, etc.) their conduct must guarantee well acknowledged ethical principles. These principles, along with codes of conduct, are aimed at protecting study participants from research-related undesired effects and guarantee research integrity. A central role is attributed to the need for informing potential participants (i.e., recruited subjects who may be enrolled in a study), obtaining their written informed consent to participate, and making them aware of their right to refuse to participate at any time and for any reason. Data protection is also required and communication of study findings must respect participant's willingness to know or not know. Special ethical aspects arise when children (including newborns) are enrolled in field studies. Given their lack of autonomy up to a certain age there is a need for obtaining their assent together with the permission from their parents or guardians to enrol them in any research. In addition, their consent may be withdrawn when they grow older. This is specifically relevant for studies including biological markers and/or storing biological samples that might be analysed years later to tackle research objectives that were specified and communicated to participants at the time of recruitment or that may be formulated after consent was obtained. Integrity is central to environmental health research searching for causal relations. It requires open communication and trust and any violation (i.e., research misconduct) may endanger the societal trust in the research community as well as jeopardize participation rates in field projects.

Franco Merlo, Lisbeth E. Knudsen, Kamilla Bargiel-Matusiewicz, Lezlaw Niebroj, Kirsi Vähäkangas (2007): Ethics in studies with children and environmental health J. Med Ethics (in press).

Franco Merlo, Kirsi Vahakangas, Lisbeth E. Knudsen (2008). Scientific integrity: a critical issue in environmental health research. Environ Health. Special Issue – in preparation.

Ethical and psychological aspects of sampling for biomonitoring: experiences in R Croatia

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Due to differences in social systems, Western and Central Europe differed in the biomonitoring practice of populations occupationally or environmentally exposed to xenobiotics. The practice of ethics committees in socialist countries varied, as it started from different concepts and quality levels. Harmonization on the European level seen in the last decade has resulted in standardized procedures to obtain individual consent to participate in a biomonitoring study as well as in standardised ethics committee procedures. In Croatia, biomonitoring was a routine part of occupational medicine and was also often applied for the evaluation of environmental exposure, such as analyses of breast milk, urine or saliva. Genotoxicological methods have been used as a part of biomonitoring studies for almost 30 years now.

Individual voluntary decisions (not) to participate in cytogenetic tests for occupational exposure to carcinogens involve a complex interaction of personal ethical and religious values and apprehension of test results. Traditionally, Croats have been taught to put common benefit before personal, even if it sometimes takes a wilful sacrifice, which has certainly been beneficial for collaboration with potential study participants. The critical requirement, however, is that the biomonitoring study

interviewer is highly qualified and able to adjust to potential participants, whatever their education, social status or age.

Ethical issues experienced in HBM within Portuguese health surveillance and research projects

*M. Fátima Reis¹, *, Susana Segurado¹, Ana Brantes¹, Helena Teresinha Simões³, M. Melim⁴, J. Pereira Miguel*

In keeping with the fundamental practice of transparency in the discussion and resolution of ethical conflicts raised by research, we present a summary of ethical issues raised during Portuguese biomonitoring in health surveillance and research and describe if and how they have been solved.

Projects include the biomonitoring in the general population as well as in pregnant women and children, of dioxin-like compounds and heavy metals in tissues including blood and scalp and pubic hair; monitoring of blood lead and dioxin-like compounds and linkage to incidence of miscarriage; correlation of blood lead levels in pregnant women to sub-normal foetal development; and monitoring of persistent organic pollutants and dioxin-like compounds in breast-milk. The frequent involvement of both children and pregnant women, although intended to protect these particularly vulnerable sub-groups, raises important questions about autonomy – an individual's right to be fully informed and free to decide to participate – as children (born or unborn) are legally unable to provide informed consent. In an attempt to mitigate the harm-benefit ratio, current research efforts include alternative less invasive biomarkers. Recruitment has been successful, among eligible participants, in spite of rewards or incentives rarely being offered. The notable exception has been the difficulty in obtaining guardians' consent to children's participation, particularly for blood sampling. Surveys are currently conducted under contract as independent biomonitoring actions and as such, must be explicitly disclosed as a potential conflict of interests, relying on researchers' objectivity and impartiality and a supervisory committee's appraisal for its ethical resolution. Communication of results to participants is in general only practised when a health issue is present and corrective action possible. Communication of pollutants in breast-milk is especially carefully approached so mothers do not stop breast-feeding for fear of risks to children, thereby forgoing its proven greater benefits. No national legislation currently accounts for the surveillance component of biomonitoring as distinct from research, so ethical issues including those presented here are frequently left to involved professionals' or ethics committees' best judgement.

Paper in progress

Fátima M Reis, Susanne Segurado, Ana Brantes, Helena Teresinha Simões, M. Melim, V Galdes, J Pereira Miguel. Ethics issues experienced in HBM within Portuguese health surveillance and research projects. (2008). *Environ Health. Special issue* – in preparation.

Activity of Biomedical Ethics Committees and Data Protection issues in Poland

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The detail regulations concerning functioning of Bioethical Commissions in Poland are on the basis of Ordinance of the Ministry of Health and Welfare on 11 May 1999. All regulations complain most important guidelines such as: the Helsinki Declaration, The Rules of Good Clinical Practice, EU Directives and legal regulations binding in Poland, mainly Act of medical doctor profession and the dentist profession on 5 December of 1996, as well as Act of Pharmaceutical Law on 6 October 2001.

Bioethical Committees are the collegial body independent in its opinion whose task is to guarantee the rights, safety and welfare of subjects of medical research. The Committee guards the respect for the dignity of human being as the superior value to scientific aims of research.

In Poland there are 54 Bioethical Committees; where 20 are appointed at the Medical Universities, 19 at the R &D Medical Institutes and 24 are at the Regional Medical Councils.

At the Ministry of Health is one Bioethics Appeals Commission.

In the frame of the Human Biomonitoring Programme, the application for bioethical evaluation will be submitted to the Bioethical Committee at the Nofer Institute of Occupational in Lodz.

Data protection legislation in Poland according to the Act of the Protection of Personal Data on 29 August 1997, last amended in 2006 complains EU regulations. The Act contains also detailed provisions regarding the duties of the Inspector General for Data Protection. In presentation there are some data of activity of the Bureau of the Inspector General for Personal Data Protection in 2005 and 2006.

Danuta Ligocka. Activity of Biomedical Ethics Committees and data protections issues in Poland. (2008). Environ Health. Special issue – in preparation.

Interpreting and communicating HBM results

Roel Smolders, Greet Schoeters, Vito Belgium

Environmental health sciences focus on the link between the presence of contaminants in the environment and their relationship with possible adverse health effects. Human biomonitoring (HBM) has recently gained much attention as a tool to evaluate exposure to and effects of environmental pollution by measurements in human tissue or fluid samples. HBM directly measures the amount of a chemical substance in a person's body, taking into account often poorly understood processes such as bioaccumulation, excretion, metabolism and the integrative uptake variability through different pathways, rather than each individual exposure source. Hence, these data can be much more relevant for risk assessment than extrapolations from chemical concentrations in soil, air, and water.

However, important challenges remain in the field of interpreting and communicating the results of HBM studies to scientists, policy makers and the general audience. It is increasingly recognized that the chemical-analytical capacity to measure contaminants in human tissue often exceeds the ability to evaluate whether and how this may cause a health risk or to evaluate its sources and pathways of exposure. Putting HBM data into a relevant and scientifically sound context is a necessary requirement to fully exploit this powerful tool for environmental health research.

This presentation will in first instance outline the main questions that need to be addressed in a framework that aims at translating HBM data into risk management and policy making options. Secondly, we will report from last December's "Stakeholder Workshop on Data Interpretation and Ethics" in Brussels, where several of these questions and related issues were discussed in breakout sessions. Finally, we will briefly focus on the work that is taking place in WP3 of the ESBIO project on these matters.

Roel Smolders. Translating biomonitoring data into risk management and policy implementation options for European network on human biomonitoring. (2008). Environ Health. Special issue – in preparation.

Knowledge for action: joint reflection on environment & health-data

Hans Keune (Research Department for Technology, Energy & Environment (STEM), University of Antwerp), Gudrun Koppen (Flemish Institute for Technological Research (VITO)), Karen Van Campenhout (Environment & Health, Flemish Government, Department of Environment, Nature and Energy)

In Flanders (Belgium) the Centre for Health and Environment started a biomonitoring campaign end 2001. Main purpose of this project, funded by the Flemish government, is to investigate the relation between environmental pollution and human health by measuring pollutants and health effects in (more than 4000) Flemish inhabitants. The big question is: what should be done with this vast amount of information? Together with medical and environmental scientific experts and policymakers, social scientists worked on the preparation of an action-plan for interpretation and policy measures. At first this was thought of as a merely scientific quest: with the right group of experts the interpretation with regard to policy priorities will follow automatically. While trying to build bridges towards policy interpretation though the limitations of an exclusively scientific endeavour clearly showed: no scientist or group of scientists dared claiming to possess the necessary and overarching knowledge for answering difficult questions, questions e.g. on policy priorities when also other than (medical and environmental) scientific factors had to be taken into account (economics, social preferences, feasibility of policy measures). The social scientists therefore introduced the formation of a jury that will judge relevant data and knowledge in order to give advice to the government. The jury will be made up of experts, stakeholders and (other) citizens. For the jury we developed a multi criteria analysis. The action-plan was accorded by both the Centre for health and Environment and policy representatives, and was adopted by the government.

Hans Keune, Bert Morrens, Ilse Loots. Risk communication and human biomonitoring: which practical lessons from the Belgian experience are of use for the EU-perspective. (2008). Environ Health. Special issue – in preparation.

The Flemish action plan used to deal with regionally elevated serum pp'-DDE in two Flemish areas

Gudrun Koppen (Environmental Toxicology, Flemish Institute of Technological Research , VITO), Hans Keune (Faculty of Political and Social Sciences, Department of Sociology, University of Antwerp), Karen Van Campenhout (Environment & Health, Flemish Government, Department of Environment, Nature and Energy)

Key words: Action plan, Biomonitoring, DDT, DDE, policy interpretation

P,p'-DDE is a metabolite of the pesticide DDT, which was banned in Belgium in 1974. However, in the Flemish Human Biomonitoring campaign, p,p'-DDE was found in measurable concentrations in all 4400 analysed samples of cord plasma or serum of youngsters, and elderly people. Each of the age groups were examined totally independently in three consecutive parts of the campaign running from 2002 tot 2006.

The levels in two Flemish regions (rural area in the W, and Albert canal area in the N-E of Flanders) appeared always significantly higher (30 to 80 %) than the Flemish reference value calculated based on all study participants across Flanders (i.e. reference mean of 110, 94 and 423

ng/g fat in cord plasma and serum of adolescents and elderly, respectively). However, the levels in all Flemish regions, were comparable to recently measured values in other European countries. Furthermore, the estimated uptake of DDT was calculated to be 1000 to 100 times below the provisional tolerable daily intake (PTDI) suggested by JECFA (2001). Nevertheless, because of the high consistency of elevated DDE levels in the two regions among all age groups, and since DDT contamination should be eliminated according to the Stockholm Convention on Persistent Organic Pollutants (2001)⁵, it was considered a case to be coped with in the Flemish 'action plan'.

Further desk research of existing data, pointed out that, in both regions, more local and/or own cultivated products were consumed. For each of the age groups the mean p,p'-DDE concentration appeared to be 24 to 44% higher for people consuming local food (apart from the influence of the covariates: age, BMI and sex). DDT is rarely found in nutrition sold at the Belgian market. However, data from a limited random sampling of chicken eggs from private free ranged chicken, in the area under investigation (but also some other regions), indicated that at some places these eggs had concentrations far above the acceptable concentration for consumption (500 ng sum DDT/g fat). It was assumed that use of DDT could be more traditional in both regions. Also, the ratio of DDT/ p,p'-DDE was significantly higher in adults of both regions compared to the reference value of Flanders, indicating more recent use, than in other regions. Furthermore, over the past years, higher concentrations of DDT were measured in the soil and sediment of rivers in the rural area (Leie and Boven-Schelde). High DDT levels were also observed in eels from this river basin. From the N-E of Flanders (Albert canal area), there were no data (available) indicating environmental contamination with DDT. There was no known dump or any production of DDT or related compounds in non of the regions.

Communicating human biomonitoring results – interference with public health recommendations

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Analysing breastmilk- promoting, protecting and supporting breastfeeding?

Last year during the debate on REACH legislation a report was presented in the European parliament called toxic inheritance - more than 300 pollutants in breastmilk. This is a shocking reality and I will try to present the biomonitoring results of breastmilk in a wider context. The results presented are the mirror of the chemical substances accumulated over the lifespan in the bodies of both men and women.

These substances in our bodies may have an effect on male or female reproductive cells; they are present in the womb in the direct environment of the fragile developing foetus and are present in breastmilk. Repeated biomonitoring of breastmilk or other body fluids shows that effective legislation for phasing out or reduction of chemicals has had results.

Analyses of breastmilk show important components, active in building up the immune system, in gastro intestinal maturation, in immune defence and have anti viral and anti bacterial activity. Some of those are: secretory IgA, lactoferrin, lysozyme, cytokines, epithelial growth factors, antioxidants and leucocytes.

Through cohort studies researchers ended up with the conclusion that:

- Little if any adverse health effects have been associated with breast-feeding.(Feeley) - There is evidence that breast feeding counteracts the adverse developmental effects of PCBs and dioxins

⁵ aiming reduction and eventual elimination of 12 particularly toxic POPs (www.pops.int).

(Boersma) (Vreugdenhil). - The effect of prenatal exposure to p,p`DDE causing delay in mental and psychomotor development was counterbalanced by long-term breastfeeding.(Ribas-Fito) Breastfeeding strengthens the infant's developing immune system and decreases the incidence or the severity of infectious diseases. Breastfeeding is associated with slightly enhanced performance on test of cognitive development. These studies have been done in our western environment with the actual pollution levels.

Based on the strong scientific evidence of the benefits of breastfeeding the American Academy of Pediatrics, WHO and UNICEF and other organisations of health professionals recommend exclusive breastfeeding for the first 6 months of life and continued breastfeeding up to two years and beyond.

Therefore caution should be used when presenting the results of biomonitoring of breastmilk. The results should be an incitation to have strong legislation on chemicals and review the use of chemical substances turning up in breastmilk, but the results should not be used to undermine the confidence in breastmilk as the optimal food for infants and young children

Similar caution in communication should be used when communicating levels of chemicals in fish versus the positive health effects of fish, or about residues of pesticides in fruit and vegetables while promoting five portions of fruit or vegetables a day.

Maryse Lehnert-Arendt (2008). Communicating human biomonitoring results to ensure policy coherence with public health recommendations - Analysing breastmilk whilst protecting, promoting and supporting breastfeeding. Environ Health. Special Issue – in preparation.

Conclusions – what to do next in WP4

Protocols need to be developed covering common issues

-Hypotheses to be tested regarding HBM exposures in populations and differences related to environmental exposures – background levels, spot exposures, vulnerable populations

-Methods to be used

-Selection and recruitment of study persons (special issue with children – directly via family or through schools), sampling (which media and how much) and processing and storage of samples, analysis

-Results and results interpretation

-Information strategy prior, while and after study

-Informed consent

- Information about study
- Procedures (sampling, questionnaire, monitoring, follow-up, data protection)
- Sign to participation in separate parts
- Agree to store samples and biobanking/future uses
- Agree to use samples for purposes of environmental health studies
- Agree to share results with other researchers, policy makers

-Biobanking

-Reporting

-Data protection

-Data sharing

-Follow-up

Research questions: Biological citizenship, concepts of environmental health, of biomonitoring, expectations towards policy makers