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)

Produced by the Technical Working Group on
Integrated Monitoring

subgroup
Biomonitoring of children

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This report reflects the opinions of the members of the Working Group and it highlights the different opinions contained within the group where appropriate. It should not be considered as an official statement of the position of the European Commission.

Further information relating to this work is available on the project website:

www.brussels-conference.org

or from the Technical Secretariat:

Dr. Reinhard Joas

BiPRO GmbH
Grauertstr. 12
81545 Munich
Germany
Telephone +49 89 18979050
Facsimile +49 89 18979052
Email: Reinhard.joas@bipro.de

This Report is prepared by the subgroup "Biomonitoring of Children" that has been set up by the European Commission in the framework of the "Environment & Health Strategy" (COM(2003)338final).

The subgroup is chaired by Ludwine Casteleyn and co-chaired by Lisbeth E. Knudsen and Carlo Sala.

The members of the subgroup are:

Bloemen Louis	Cefic – Dow Europe
Brits Ethel	Flemish centre of E&H, Belgium
Boogaard Peter	CONCAWE (oil companies' European organisation for envt, health and safety), Belgium
Canna Michaelidou Stella	State General Laboratory, Ministry of Health, Cyprus
Casteleyn Ludwine	Ministry of the Flemisch Community, Environment, Nature, Land and Water Management Administration (AMINAL)
Fréry Nadine	INVS, National Institute of Public Health Surveillance, France
Fucic Aleksandra	Institute for Medical Research and Occupational health, Croatia
Harrison Paul	Institute for Env & Health, UK
Jakubowski Marek	Institute Occupational. Medicine, WHO Collaborating Centre, Poland
Knudsen Lisbeth E.	University of Copenhagen, Denmark
Lehners Maryse	IBFAN, INT. BABY FOOD ACTION NETWORK, Luxembourg
Lorente Christine	Instiut de Vaille Sanitaire, France
Ramet José	Secretary of Paediatric section of EU Medical Specialists AZ VUB PICU Belgium
Reis Maria de Fatima Calado Varela	Instituto d Medicina Preventiva, Portugal
Sala Carlo	ARPA Lombardia, Italiy
Seifert Bernd	Federal Environmental Agency, Germany
Schoeters Greet	Flemish centre of E&H, Belgium
Steenhout Anne	ULB, Belgium
Tusscher Gavin W Ten	Emma Children's Hospital Academic Medical Centre, University Amsterdam, Netherlands
Wattiez Catherine	PAN (Pesticides Action Network)
Wijnen Joop van	EUROCITIES

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.

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1 Executive summary

Monitoring of the quality of the environmental media, air, water and soil, has a long tradition in European countries and there is ample legislation dealing with it. However, if it comes to assess human exposure to environmental pollutants and potential health effects of such pollutants, monitoring environmental quality is only one first step in the chain that reaches from source emissions to health effects. A step that is leading closer to evaluating human health effects is human biological monitoring (HBM). In HBM, the concentration of a pollutant - or its metabolite(s) - is determined in a biological sample, generally blood or urine. In a similar way, other types of biomarkers can help assess the reaction of the human body to environmental pollutants. Biomonitoring is therefore an essential aspect for a strategy that is intended to bring together health and the environment.

An overview of existing biomonitoring activities of children being undertaken in the Member States and Acceding Countries was made for the baseline report. Although incomplete and not fully evaluated, the inventory allowed to conclude that within the EU a substantial amount of biomarker data on children are collected and that significant resources are devoted to these efforts.

The various biomonitoring studies that are run in the different European countries are generally not carried out using the same methodological approach. More harmonised biomonitoring *survey programmes* would (i) lead to generate broader information on the data on the content in the human body of, or the response of the human body to chemical, physical or biological environmental agents, (ii) allow for better detection of spatial and - if studies are carried out repeatedly - temporal differences in exposure of the European population, (iii) provide insight into the contribution of different environmental compartments (e.g. air, water, food) and emission sources to body burden, and (iv) provide policy makers with better information on control measures to be taken. To study the cause-effect framework and to document the level of scientific evidence of a cause-effect link properly defined research studies are needed. Therefore *research projects* should be 'grafted' on the surveillance framework where possible.

However, there are also some limitations in biomonitoring. Carrying out large surveys that include human biomonitoring presents challenging logistical problems. If it comes to a multi-national activity, the logistical problems and problems of coordination become even more pronounced than for national surveys. Besides these problems, the difficulties linked with the availability of human samples have also to be taken into account.

For the creation of an EU harmonised biomonitoring programme the biomonitoring group suggests a step by step procedure. Specific experts groups should be established. The aim of these groups should be to develop harmonised technical procedures, a protocol for carrying out a pilot project, guidelines for ethical social and legal issues, and communication programs for health professionals, teachers and social workers. This procedure should start from existing experiences and ongoing projects. In addition tools should be developed allowing for translation of biomarker results into intervention strategies and integration with environmental monitoring data and health data. Furthermore effective communication with policy makers and the public should be developed. Several issues need also to be addressed in research projects (e.g. the development of less invasive methods, best ways of providing information to and obtaining consent from study persons, as well as interpretation and

validation of measurements with biomarkers). This constitutes the first and essential phase of an action programme for an EU harmonised approach.

Also further actions and recommendations were already pointed out by several members of the group. They relate to possibilities for immediate action e.g. starting from already available material or to actions to be implemented in an EU harmonised activity, pending on the success of the earlier steps.

To foster implementation and increase the European added value, synergism with other international activities like WHO, Healthy Environments for Children Alliance at managerial and technical level should be promoted.

The present report has been prepared by the Technical Working Group "Biomonitoring of Children". In preparing this proposal for an action plan, the working group for biomonitoring identified several options. These were further developed in small groups throughout the process, both at the meetings and by exchange of written information via the fiches with options for actions. Due to the limited time available all these options were not discussed in a plenary meeting or commented by all members of the group. Although being preliminary material, reflecting thus the different items of interest, but not to be seen as consensus documents, these options are listed in annex. Where appropriate, reference is made to these options in the different chapters.

2 Introduction

Monitoring of the quality of the environmental media, air, water and soil, has a long tradition in European countries and there is ample legislation dealing with how and where to monitor and what levels should not be exceeded. However, if it comes to assess human exposure to environmental pollutants and potential health effects of such pollutants, monitoring environmental quality is only one first step in the chain that reaches from source emissions to health effects. A step that is leading closer to evaluating human health effects is human biological monitoring (HBM).

For quite a long time HBM has been widely used in the work place environment to assess the extent of internal exposure to dangerous substances. Over the last two or three decades it has become more and more accepted in the field of environmental health as a good step forward on the way towards assessing health effects. In HBM, the concentration of a pollutant - or its metabolite(s) - is determined in a biological sample, generally blood or urine. In a similar way, other types of biomarkers (see below for definition) can help assess the reaction of the human body to environmental pollutants.

For the time being, the various biomonitoring studies that are run in the different European countries are generally not carried out using the same methodological approach. Thus, it is difficult to compare the data generated by these studies. It would be of great benefit for European scientists, policy-makers and citizens if such comparability were achieved. In the recently published European Commission's Communication concerning a European Strategy for Environment and Health[1], the need has been emphasised to assess the links between environment and health and give strategic answers. A more harmonised biomonitoring approach would help achieve this. In particular, it would (a) lead to generate broader information on the content in the human body of environmental pollutants, (b) allow for better detection of spatial and - if studies are carried out repeatedly - temporal differences in exposure of the European population, and (c) provide policy makers with better information on control measures [2]to be taken.

The present report has been prepared by the Technical Working Group "Biomonitoring of Children". A first short chapter gives a definition of biomonitoring and its objectives, addresses the outcome of a survey on current and past European biomonitoring studies that was carried out by the Working Group, and discusses briefly the contribution of biomonitoring to the objectives of the E&H strategy. The following chapters of the report discuss an action plan for European biomonitoring, identify the research needs, and assess the impact of the proposed action plan.

In preparing this proposal for an action plan, the working group for biomonitoring identified several options. These were further developed in small groups throughout the process, both at the meetings and by exchange of written information via the fiches with options for actions. Due to the limited time available all these options were not discussed in a plenary meeting or commented by all members of the group. Although being preliminary material, reflecting thus the different items of interest, but not be seen as consensus documents, these options are listed in annex. Where appropriate, reference is made to these options in the different chapters.

[1] COM (2003) 338 final, Section 6.2.1, a)
[2] e.g. measures to reduce exposure and source directed measures

3 General aspects

Definition of biomonitoring (in children)

Biomonitoring (in children) is defined for the purpose of this report as monitoring activities (in children), using biomarkers, that focus on environmental exposures, diseases and/or disorders and genetic susceptibility, and their potential relationships. The term "biomarker" comprises biomarkers of exposure, biomarkers of effects and biomarkers of susceptibility[3]. Biomonitoring of children includes the prenatal period up to an age of 18 years. It may be complemented by follow-up activities for monitored children into adulthood. Depending on the aims of a study and given the importance of prenatal exposure it may be useful to extend the information to be collected to the child's parents current and past exposure

Objective of biomonitoring

In general, the objective of biomonitoring is to increase knowledge on the relation between human health and the environment and to use this knowledge to improve environmental health. Distinction is made between (1) activities that aim at periodical measurements in order to produce information on the prevalence of exposure to environmental agents and the related public health impact with a view to developing and evaluating policies that protect health, e.g. detecting positive outcomes of control measures (***survey projects***) and (2) activities that aim at improvement of knowledge on causal links between environmental factors and health by hypothesis generation and testing (***research projects***). In general, the number of study persons in research programmes is smaller due to the exploratory character of the studies, the focused character of these studies, the need to collect information on potential confounding factors and the limitations of available resources. This very often limits the power of the research studies. In contrast, surveillance programmes more commonly are designed with a high number of participants.

Overview of existing activities

An overview of existing biomonitoring activities being undertaken in the Member States and Acceding Countries was made for the baseline report. Although the response to our call was encouraging (more than 100 studies reported), gaps in information clearly remained (for some countries there was insufficient or no information at all) and no straightforward assessment or assumption could be made due tot the limited representativeness of the data collected.

However, although incomplete and not fully evaluated, the inventory allowed to conclude that within the EU a substantial amount of biomarker data on children are collected and that significant resources are devoted to these efforts. Many of the biomonitoring activities reported data on links between *environmental* factors and *health data.* Several studies address both *children* and their *parents* (particularly their mothers, therefore integrating *prenatal* and *postnatal* exposure) and simultaneously address markers of *exposure, effect and susceptibility.* Overall, it is highlighted that similar aspects are addressed in biomonitoring programmes in nearly all countries. Exposures to heavy metals, PCBs and dioxins are the subject of many studies that were reported. Endpoints such as asthma,

[3] See the baseline report, annex I – definitions and examples

allergy and neurodevelopmental disorders, as well as exposures to genotoxic agents are also covered in some studies[4], and multidisciplinarity is typical of many activities. In a few cases bio specimen banks (archives of biological materials/samples) have been established to allow for follow-up analysis[5].

It should be stressed that these activities provide useful information that may be of relevance for policymakers. A further evaluation is suggested of the extent to which information already available from existing biomonitoring studies can be used for immediate actions to reduce exposure and prevent adverse effects. Also a further and systematic inventorisation of biomonitoring activities in Europe, possibly starting from the information in the baseline report, was considered useful as a step in the creation of an information exchange platform and for the initiation of common activities.[6]

Contribution of biomonitoring to the objectives of the E&H strategy

In contrast to the analysis of the quality of the environment as such through air, water and soil monitoring programmes, biomonitoring provides a unique possibility to characterise environmental exposure and possibly its early effect on human health. It represents the link between the influence of the environment on the human body and health outcomes. The biomarker of exposure is more directly linked to the adverse health effects that one attempts to prevent than any environmental measurement. Therefore it may offer a better estimate of the risk than ambient monitoring and in this way, it is an essential aspect for a strategy that is intended to bring together health and the environment.

The ultimate objective of the E&H strategy is to develop a response system with a view to reduce the disease burden caused by environmental factors in the EU, to identify and prevent new health threats caused by environmental factors and to strengthen EU capacity for policymaking in this area with a special focus on children[7]. **Biomonitoring survey programmes** contribute to this goal i) by generating (representative) data on the content in the human body of, or the response of the human body to chemical, physical or biological environmental agents; ii) by documenting spatial and temporal differences in population exposure; iii) by getting insight into the contribution of different environmental compartments (e.g., air, water, food) and emission sources to body burden; and iv) by providing policy makers with information if and what measures[8] need to be taken and to what extent measures that have been taken have proven to be successful.

[4] but no data on radiation

[5] Basic data of questionnaires obtained so far (18-02-04):

- Total numbers of questionnaires received: 100
- Reported budget with 49 questionnaires: about 57 million euro
- average budget per project: 1,2 million euro
- about 440 000 children are covered (basis 97 questionnaires)
- average duration of a project 4,9 years
- 44 heavy metals, 15 projects covered dioxin/PCB exposure, , 5 endocrine disrupters
- 27 projects covered asthma or allergies.

[6] see chapter 4.4

[7] COM (2003) 338 final - p.5

[8] e.g. measures to reduce exposure and source directed measures

To study the cause-effect framework and to document the level of scientific evidence of a cause-effect link properly defined research studies are needed. Therefore **(biomonitoring) research** projects should be 'grafted' on the surveillance framework where possible, allowing reduction in costs by using already existing infrastructure.

Strengths and Limitations of biomonitoring

Human biomonitoring results integrate the contribution of the different routes of exposure and take into consideration the differences between individuals with regard to uptake, which are due to differences in hygiene, breathing characteristics etc. Thus, they give a complete picture of the body burden. When metabolites are measured, inter-individual differences in metabolism of the compounds are also implied.

Human biomonitoring is an excellent tool to better integrate the two fields, environment and health. As has been pointed out above, one of its big advantages is that – although not providing information on health effects a priori – within the "source emissions-environmental concentrations-exposure-human biomonitoring-health effects" chain it is much closer to health effects than environmental monitoring.

However, there are also some limitations in biomonitoring. Carrying out larg surveys that include human biomonitoring presents challenging logistical problems and generally cannot be done without having medical staff available (at least if blood samples are taken). If it comes to a multi-national activity, the logistical problems and problems of coordination become even more pronounced than for national surveys.

Besides these problems, the difficulties linked with the availability of human samples have also to be taken into account. The collection of samples is not possible without the agreement of the study subjects and samples may therefore not be easily obtained in all cases. With regard to blood samples of young children, it must also be borne in mind that the quantity of blood that can be taken under ethical and medical considerations is restricted and may not be sufficient for the analysis of all pollutants of interest. Pooling of samples before analysis could be helpful to address this problem. However, such pooling necessarily results in a loss of information about the individual's body burden.

4 Proposals for a European action plan for biomonitoring in children

Environmental issues are global, interdependent and transboundary, and environmental health policies are to a large extent defined at European level. Member states are requested to provide relevant data to European organisations. A European environmental policy will be supported by better data comparability and accessibility within and between countries.

Coordination of biomonitoring activities through Europe may contribute to this and allow for a better integration of information by bringing together available knowledge and actively promoting exchange of experiences between teams and countries and enable a more effective use of resources by shared development of tools and strategies. Another advantage of such harmonised approach could be that the results of national surveys may become more meaningful 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

Actions for EU harmonisation may be foreseen at different levels. The group proposes a step by step procedure. A first step could be to **bring together existing expertise and experiences in the member states with a view of harmonising their way of proceeding through the use of comparable protocols and harmonised data treatment**. Establishing a working group comprising mainly experts from those Member States which have already carried out surveillance programmes or are currently doing so (see information gathered in the baseline report), would be a good way to undertake this task. Additional expertise could be obtained from the occupational health field and the research field and lead to a European information exchange platform.

Before deciding on how to carry out a full scale Europe-wide biomonitoring project, the feasibility of such project should be studied in a **pilot project** that should test out the common harmonised approaches as developed in the working group mentioned above.

Research allowing to provide better conditions for biomonitoring programme (development of less invasive biomarkers, development of strategies for communication by professionals, set the appropriate legal conditions, etc) and allowing for a more appropriate use of results of biomonitoring programme (research into dose effect relationships, combined effects, development of biological standards, developing scenario's for policy, …) is needed for the further development of biomonitoring programmes in the EU, be it at a national scale or at a harmonised European level. Part of the guidelines to be developed in view of a harmonised EU approach would benefit from research studies. Therefore, such research will constitute an important incentive for the **promotion of biomonitoring programmes** in the EU.

It has to be acknowledged that 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. However, the results of a common biomonitoring programme of the European countries could contribute to detect areas or population groups subject to elevated exposure and - by envisaging appropriate control measures - to better environmental equity. This is far in the future because a biomonitoring activity does not lead automatically to health protection. In order to allow information from biomonitoring programmes to be useful in reducing the disease burden and to identify and prevent new health threats caused by environmental factors,

appropriate tools should be developed for translation of results into intervention strategies and for effective communication with policymakers and the public.

In a biomonitoring programme **cost-efficiency** should also be considered. A cost-efficient system should cover major health endpoints that might be related to environmental factors. It is clear that such programme would gain from **flexibility.** To the extent possible it should take into account new information, which may become available (e.g. new non-invasive techniques, new markers with increased specificity and sensitivity, newly detected threats to health).

In conclusion, for the creation of an EU harmonised biomonitoring programme the biomonitoring group suggests a step by step procedure. Specific experts groups should be established. The aim of these groups should be to develop harmonised technical procedures, a protocol for carrying out a pilot project, guidelines for ethical social and legal issues, and communication programs for health professionals, teachers and social workers. This procedure should start from existing experiences and ongoing projects. In addition tools should be developed allowing for translation of biomarker results into intervention strategies and integration with environmental monitoring data and health data. Furthermore effective communication with policy makers and the public should be developed.Several issues need also to be addressed in research projects (e.g. the development of less invasive methods, best ways of providing information to and obtaining consent from study persons, as well as interpretation and validation of measurements with biomarkers). This constitutes the first and essential phase of an action programme for an EU harmonised approach.

However, also further actions and recommendations were pointed out by several members. They relate to possibilities for immediate action or to actions to be implemented in a EU harmonised activity, pending on the success of the earlier steps.

Although group members are experts in the field of biomonitoring, this action plan does not intend to give answers to all problems associated with biomonitoring surveys and research. Given the short time frame, it was felt more appropriate to summarise the main questions and problems and propose an action plan that allows tackling these problems at a European scale, using as broad an expertise as available and in a time schedule that allows solutions to be well-considered. For the same reason the group has refrained from focussing on and highlighting of own research projects and results.

4.1 Guidelines for a harmonised EU approach for biomonitoring starting from existing expertise and experiences

Various biomonitoring studies that are run in the different European countries are generally not carried out using the same methodological approach. Thus, it is difficult to compare the data generated by these studies. It would be of great benefit for European scientists, policy-makers and citizens if such comparability were achieved.

Also the baseline report pointed at various difficulties that ongoing activities are facing. They relate a.o. to the recruitment of the study population (participation), the biomarkers addressed, the logistics of conducting biomonitoring including the need for staff and continuous funding, biosafety issues, the need for a stronger collaboration among disciplines, the need for adequate communication of results and reporting to the relevant authorities, and to the authorisation of studies.

A long term EU biomonitoring programme can only be achieved if these problems are also tackled at a European level. Therefore a multidisciplinary European working group should be established bringing together experts in the field.

Valuable experience is already available in member states carrying out surveillance programmes (see information gathered in the baseline report) and in various European research groups[9]. Lessons can also be learned from other fields such as occupational health using biomarkers in their preventive activities[10]. Synergism with other international activities like WHO, Healthy Environments for Children Alliance should be pursued. Published guidelines for Good Epidemiological Practices can be considered as a guiding document.

The working group should develop technical guidelines for common use with the aim of harmonising. The guidelines should address the following issues related to initiation, performance and follow up of actual monitoring activities

Design and protocol for study

- Objectives of biomonitoring activities[11]
- Endpoints to be studied (which substances/metabolites and/or related effects)
- Population sampling strategy (age, location, socio-economic characteristics, statistical and geographical representativity, information for consent)
- Possibilities where small pilot studies might be done before conducting a full scale study.

[9] See option 7: the German strategy of biomonitoring surveys may, among others, provide input for successful harmonisation of monitoring programmes within Europe
See option 14: previous and ongoing research programmes will provide information on successful applications of monitoring activities e.g. through information exchange platforms, expert working groups

[10] See option 1: experiences from occupational health biomonitoring programmes and studies may be useful: the same procedures may be applied, at however different exposure levels, and the same institutions may be involved.

[11] See option 5: possible aims for biomonitoring

Sampling strategy and analysis

Sampling strategies (single/pooled samples, repeated sampling, appropriate media (blood, urine, hair, breast milk, etc), type and amount of sample, reference/background/ exposed vs. non exposed)[12]

- Sampling methods (reproducibility, quality assurance)
- Sample processing, preanalytical processing and storage (e.g. to avoid contamination and assure stability, storage containers)[13]
- Analytical methods (sensitivity, specificity, quality assurance, validation, reference material)

Data treatment

- Statistical analysis (frequency distributions, tests used, confidence intervals)
- Reporting of results (units, reference units, variability)
- Storage of data

Dissemination and communication of results[14, 15]

- Dissemination of results (individual or group-wise, by medical persons or other professionals)
- Communication

Ethical rules and practices, social and legal aspects [16]

- Storage of data (data protection)
- Sample banking (informed consent, ability to opt out)

Action:

It is recommended that a group of experts develops the mentioned guidelines in coordination with the Commission and with Member States.

[12] see option 8 on procedures for sampling and analysis in surveillance programmes that are focussed on less invasive biomarkers and option 15 b on research in breast milk
[13] see option 15 b
[14] see option 4 on developing guidelines for appropriate communication of biomonitoring studies and also the baseline report
[15] see also under chapter 4.3. for development of tools and indicators by which aggregated concrete information can be provided to decision makers and the public
[16] see further under option 3 on establishing a European Standard on how social, ethical and legal questions need to be taken into account in biomonitoring studies and surveys; see also the baseline report

4.2 An European wide pilot project

At present, there is no standard procedure to carry out biomonitoring on large population groups. This makes it difficult to compare data generated in different European countries. Also, the extent to which biomonitoring plays a role in the various countries varies widely, and so does the experience gained so far. Before deciding on how to carry out a full scale Europe-wide biomonitoring project, the feasibility of such project should be studied in a pilot project.

In this pilot study common harmonised approaches (see chapter 4.1) should be tested and validated for all steps, from study design, selection of study parameters, sampling and analysis, until statistical data treatment. The pilot study is seen as a "learning by doing" tool. It should facilitate the establishment of collaboration networks and the sharing of methodologies, and help promote the idea of harmonisation in biomonitoring. The pilot study is also essential to develop the necessary tools for harmonisation between European countries, and to identify possible problems linked with such harmonisation.

While one of the essential goals of such pilot study would be to test methodological issues, the results would also give a first impression of the comparability of biomonitoring data in Europe for the pollutant that will become the object of the study. 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. The exposure and health relevance should also be considered. Possible candidates for this are lead and mercury. This choice would be in line with a WHO proposal to ensure regular biomonitoring of lead (amongst other hazardous chemicals) in at risk children.

Action:

It is recommended that a group of experts be convened to discuss in more depth the design of such pilot study, decide on the appropriate size of the study and the study parameters and develop a detailed workplan proposal.

4.3 Tools for translation of results into a response system

Biomonitoring should provide policy makers with information on spatial and temporal heterogeneities with regard to exposure and environmental health risks within the population. If biomonitoring programmes are integrated with toxicological and ecotoxicological data and environmental monitoring (including emissions), in a multidisciplinary setting the identification of risk factors may become possible. Also knowledge of the cause-effect chain linking environmental exposure to health may increase. Policy makers may develop hereby efficient control strategies for protecting public health. On the other hand the instrument may allow for evaluating trends in time and the efficacy of environmental measures in reducing internal dose and protecting public health. To this effect an integrated evaluation scheme is needed to integrate all the information. The level of integration with environmental monitoring programmes is crucial. An integrated monitoring program may be based on a selected set of environment and health indicators which should be followed up in time and space.

Procedures on how to link actions with the biomarker results should be developed. A framework should be designed that describes scenarios for use of the biomonitoring data and convert them into a policy programme. Reference values[17] should be defined to which biomarker results from different areas or time periods can be compared. 'Health based' action levels could help indicate when measures need to be taken in order to reduce body burden. Examples for establishing these levels are the German HBM (Human BioMonitoring values)[18]. The measures may include looking for further information on health data or environmental data and searching for additional information on potential exposure routes (e.g. by environmental modelling) to increase awareness, to identify and reduce pollution sources, if needed by amendment of legislation on a European or MS level. However, for most exposure- and effect biomarkers no health based limit values exist. An environmental health care system could aim for reducing levels in toxicants in highly exposed populations based on hazard identification, potential health risk and the precautionary principle.

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. A communication programme should clearly specify the goals and the limitations of the study, what is expected from the participants, how they

[17] Reference values indicate the upper margin of the current background exposure of the general population to a given environmental toxin at a given time. They can be used to identify subjects with an increased level of exposure (in relation to background exposure) to a given environmental toxin. However, they do not represent health-related criteria for the evaluation of human biological monitoring data (Ewers et al, Int Arch Occup Environ Health (1999) 72: 255-260).

[18] HBM values are derived from toxicological and epidemiological studies and intend to represent health–based biological exposure limits. However, they are currently available for only few well defined environmental toxins and may preferably be used in situations with clearly defined exposure. They refer to only one agent and do not take into account synergistic effects or complex exposure situations (see also – research need for more validated biomarkers).

can contribute, when and how the results will be communicated and interpreted, and indicate possible follow up[19].

Action:

It is recommended that a group of experts in close coordination with the Commission and with Member States develops frameworks that describe scenarios for translation of biomonitoring data into a response system. Such scenarios require integration of biological monitoring data with environmental monitoring, the development of reference values and action levels.

Also appropriate communication strategies allowing for adequate responses to results of biomonitoring programmes should be developed, in collaboration with stakeholders on local, regional, national and European level.

[19] See options 10 and 12

4.4 Other recommendations

As said before, the group felt that for the creation of an EU harmonised biomonitoring activity a step by step procedure is needed allowing to develop the necessary guidelines for a common European approach and testing of the feasibility in a pilot project. Developing the guidelines should start from existing experiences and ongoing projects. Several issues may also be addressed in research projects. This constitutes the first and essential phase of an action programme for an EU harmonised approach.

Also other options for action were identified by the group and further developed by group members. Due to the limited time available they were not discussed in a plenary meeting or commented by all members of the group.

They relate to possibilities for immediate action or to actions to be implemented in an EU harmonised activity, pending on the success of the earlier steps.

1. As mentioned above, some group members asked for a further evaluation, as objective as possible, by a group of experts with different background, of the various levels of scientific evidence depicting links between exposure to xenobiotics and diseases or disorders that can be deduced from existing biomonitoring and epidemiological studies. This information may be used for actions to reduce exposure and prevent public health damages[20]. Given the general and broad character of this proposal it is recommended that such evaluation should start with a selection of pollutants following a prioritisation scheme.

2. Also a further and systematic inventorisation of biomonitoring activities in Europe, possibly starting from the information from the baseline report, was considered useful for the formation of a platform for exchange of information and for common initiatives [21]

3. A proposal was made 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[22].

4. Children at increased risk were identified with recommendations for biomonitoring[23]

5. Currently little attention is paid to environmental influences on health in children by medical schools and by training programmes for General Practitioners and Paediatricians. Guidelines for necessary training, education and skill of health practitioners should be promoted[24].

[20] See option 2 and 6
[21] See option 17
[22] see option 10 b
[23] see option 11
[24] see option 12 and baseline report

6. A priority list of factors was proposed for which only scarce information on biomonitoring data is available in Europe and selection criteria were developed for biomonitoring pesticides in Europe[25].

7. Specific actions to include the AC in the common European system of biomonitoring of children were identified[26].

[25] see option 13
[26] see option 16

4.5 Additional options

Some proposals were not by all members of the group seen as directly linked to an action plan for a biomonitoring programme. As a consequence they were listed as options with relevance to a global environment and health strategy, but not included in the proposed action plan for biomonitoring.

Relating to exposure assessment:

- Geographical mapping, at resolution level of administrative entities, of pesticides, based on mandatory farm level record keeping of PPP use, to be supplied annually to the competent authorities and accessible to the public

Related to exposure reduction:

- The adoption of a legislation on pesticide dependency reduction in Europe
- The definition, in the context of the review of Directive 91/414/EEC on Plant Protection Products authorisation, of exclusion criteria from Annex I (positive list of active substances of pesticides agreed at EU level) of substances having PBT or CMR or vPvB or endocrine disrupting properties

Related to health data

- Supporting of developing of child cancer registers and spontanous abortion register.

5 Research Needs

Integration of monitoring activities into a European biomonitoring program raises the need for concerted actions and for more basic research

Concerted actions may relate to:

1. data sharing, necessitating common protocols regarding study design, analysis, data analysis, data management and protection, dissemination of results and ethical issues

2. elaboration of a European ethical standard in relation to studies with children

3. common design and protocols for e.g. mother/child cohorts with biological and prospective information collection

4. collection of information on biomonitoring activities in Europe starting from the preliminary information gathered in the baseline report and by collaboration with other initiatives (WHO, US)

More basic research concentrating on mechanistic research relates to:

1. Age differences in environmental exposures (e.g. including validation of biomarkers for children, taking into account differences between age groups)

2. Age differences in metabolism of environmental agents (e.g. including Specific Physiologically Based Pharmokinetic (PBPK) models for children)

3. Age differences in DNA damage and repair of selected environmental agents

Within each category the stated needs are to some extent overlapping and the level of details is varying. The proposals are considered elaborated within the European area with participation from several countries and research groups.

5.1 Collection and analysis of available information within the European area concerning biomonitoring

- Experiences from occupational health[27]
- Lessons from reported and ongoing EU research programs[28]
- Results and experiences from performed biomonitoring surveys[29]

with a view of:

- validation of biomarkers (incl. predictive value towards disease)
- collection of data regarding exposures and background levels studied in biomonitoring[30]
- collection of data regarding known risk factors identified from biomarker studies and susceptibility factors

5.2 Development of <u>new</u> methods for biomonitoring

- Define procedures for sampling and analysis in surveillance programs that are focussed on less invasive methods (dioxins and ear wax, heavy metals in hair (scalp, pubic) and nails, deciduous teeth, exhaled breath) [31]
- Development of more specific biomarkers related to mode of action based on novel genomics and proteomics techniques
- Research in breast milk and lactation as a widely used indicator (relevance, representativity)[32]
- Research in use of placenta as an indicator tissue
- Research in use of miscarriages and abortive tissue as an indicator tissue
- Development of sensitive and specific analytical methods
- Development and validation of effect biomarkers, e.g. covering mechanisms of endocrine disruption
- Development of biomarkers/measures of programming/imprinting in early life and adverse reactions later in life – mother/child cohorts.

5.3 Establish relationships of biomarker outcome with emission and imission data

- Methods for more accurate and timely exposure characterisation (e.g. modelling of imission, emission)
- Linking human effect monitoring with ecological effect monitoring

[27] see option 1
[28] see option 14
[29] see option 2
[30] see option 2
[31] see option 8

5.4 Ethical, social and legal issues related to biomonitoring

- Research on socio-ethical and legal constraints and possible solutions[33]
- Research on 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?

5.5 Information strategies

- Develop and validate possibilities for appropriate communication of biomonitoring studies to different target groups and stakeholders[34]

5.6 Research in problems associated with use of cord blood (ethical, stem cells, disruption of the birth environment)

Since cord blood present a special tissue with special legal and ethical concerns specific standards for use of this tissue should be developed. Bio banking of such sampling should be analysed and discussed within the frame of environmental health studies. Such issues relate to 5.2, 5.4 and 5.5.

[32] see option 15 b
[33] fiche 3
[34] fiche 4

6 Impact assessment

For the assessment of impacts the following categories have to be analysed:

- financial impacts
- environmental impacts
- health impacts
- social impacts

It is obvious that the working group could not provide a detailed impact assessment for more than 20 options within the given time and resources frame.

For the financial impacts the following costs have been considered:

- costs for European working groups (mainly personnel for a defined time frame, estimate: 5 working groups with 5 to 25 members, for a period of 3 years)
- costs for European pilot project (financial resources and personal resources for a defined time frame, rough estimate: financial budget below 10 million Euro for a 4 year period)
- costs to cover research needs (mainly financial resources, estimation: above 100 million euro to cover all described activities)

Options with a continuous need for financial or personal resources are not included in the action plan.

Having in mind the financial efforts for Member States activities in biomonitoring, the possibilities to save resources by avoiding double work and sharing experiences, it is expected that in the short run the savings will amount to the same order of magnitude as the expenses. Further justification and additional data can be prepared within an additional time frame for the working group. In the long run it is expected that in some aspects biomonitoring on a European scale might substitute some activities in classical environmental monitoring and thus might enable additional savings of costs.

It is expected that there will be no immediate consequences for the environment. However it is expected that with the proposed action plan a more targeted biomonitoring will be possible on a European scale. And this instrument will enable a better targeted policy-making and thus improve the environmental situation.

The same causality is expected with respect to health consequences.

It is however recognised that it is not possible to evaluate health costs that could result from delaying exposure reduction actions to certain xenobiotics. The health costs of taking no precautionary action now can be important (see EEA report “Late lessons from early warnings - The precautionary principle 1896-2000”).

Significant social impacts are not expected. Increased awareness of the relationships between environmental exposures and health is anticipated.

7 Links to and inputs from other working group (preliminary)

Links to and input from the "environment" groups heavy metals, endocrine disrupters and dioxins and PCBs are seen with respect to the recommended pilot projects. As explained under 4.2. there are certain advantages if an European wide pilot project starts with well known pollutants like lead or mercury. Biomonitoring with respect to dioxins and PCBs has to face difficulties a.o. due to the high costs of the corresponding analyses. For biomonitoring with respect to endocrine disrupters validated markers are under research. It might be necessary to focus on this field as soon as results of such research are available.

Several members of the biomonitoring group support the developing of child cancer registers and spontaneous abortion registers[35].

The biomonitoring group also endorses the recommendation of the TWG on childhood cancer regarding data protection and confidentiality of patient records and access to necessary data.

The biomonitoring recognises close links to the work of the indicators group. The following options of the indicators group will be further discussed with respect to the proposed action plan for a harmonised biomonitoring:

- Establish a harmonised E&H indicator set
- Develop indicators for vulnerable groups and vulnerable periods in life
- Develop methods to monitor and evaluate effects of combined exposures
- Develop mechanisms for sharing experiences and improving integrated assessments
- Biobanks for assessment of long-term effects and multicausality
- Indicators for policy performance
- Develop tools for awareness raising and improved communication to the public.

The research needs of the biomonitoring group have been reported to the TWG research. The biomonitoring group has addressed its hopes that a high priority will be attributed to these research needs.

[35] See option A4

8 Time Schedule

The group felt that for the creation of a EU harmonised biomonitoring activity a step by step procedure is needed allowing in a first step to develop the necessary guidelines for a common European approach and testing the feasibility in a pilot project. Also tools for translation of results into a response system should be developed. This constitutes the first and essential phase of an action programme for an EU harmonised approach.

This first phase could start as soon as possible and may be expected to take 2 to 3 years time.

Part of the guidelines to be developed in view of a harmonised EU approach would benefit from research studies (e.g. research on development of less invasive biomarkers, development of strategies for communication by professionals, set the appropriate legal conditions, etc) and allowing for a more appropriate use of results of biomonitoring programme (research into dose effect relationships, combined effects, development of biological standards, developing scenario's for policy, etc) that should therefore be initiated as soon as possible in close collaboration with the expert working groups.

Other proposals for immediate action are:

- a further evaluation of existing biomonitoring and epidemiological studies to assess their possible contribution for actions to reduce exposure and prevent public health damages. Given the general and broad character of this proposal it is recommended that such evaluation should start with a selection of pollutants following a prioritisation scheme.
- a further and systematic inventorisation of biomonitoring activities in Europe, possibly starting from the information from the baseline report, was considered useful for the formation of a platform for exchange of information and for common initiatives.
- the development of guidelines for necessary training, education and skill of health practitioners

By giving priorities to the recommendations of the biomonitoring group it is possible, that an added value for policy making by a harmonised European Biomonitoring can be realised within the Action Plan 2004-2010.

9 Annex: Fiches

In preparing this proposal for an action plan, the working group for biomonitoring discussed several issues both at their meetings and by exchange of written information via fiches with options for actions, following as much as possible the reporting format proposed by the European Commission. Although being preliminary material, reflecting the different items of interest, but not to be seen as consensus documents, these fiches are listed in the following annex.

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Option 1: Learn and proceed from existing experiences from occupational health with regard to analytical methodology (including quality control) and interpretation.
Institutions already engaged in biomonitoring of exposure under occupational conditions can also be involved in biomonitoring of children.

Option 1	
	Preliminary statement: The most valuable data for interpretation of results of biomonitoring of occupational exposure are health-based values obtained from dose/effect relationship. Only to a limited number of substances (e.g. Pb, Cd, Hg, MetHb-inducers, AchE inhibitors, fluorides) extent these data are truly health-based and allow prediction of effects directly based on biomonitoring results as they were obtained as result of epidemiological studies in occupational settings. Most other data have been extrapolated from the corresponding occupational exposure limits on the basis of correlation between air concentrations and the corresponding level of substance or its metabolites in biological media such as urine, blood or expired air. However, biological exposure limits thus derived are based on studies under occupational conditions, i.e. healthy, selected persons, or on human volunteer studies, i.e. mainly young males. On average, the general population is expected to be more sensitive than workers (e.g. Cd) and for children the situation may even be more difficult as critical effects may differ from those in adults (e.g. Pb, methylmercury) and children may be more sensitive than adults. Therefore occupational recommendations cannot be simply extrapolated to the general population of specific subgroups thereof, such as children.
Option for action:	
	Learn and proceed from existing experiences from occupational health with regard to analytical methodology (including quality control) and interpretation. **Institutions already engaged in biomonitoring of exposure under occupational conditions can also be involved in biomonitoring of children.**
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	- Guidance has been developed for conducting biomonitoring studies by several organisations (e.g. Deutsche Forschungsgemeinschaft, World Health Organisation)

Option 1	
	- A quality assurance, encompass the range of concentrations of toxic substances and/or metabolites suitable for occupational exposure as well as environmental exposures is available from the Institute of Occupational, Social and Environmental Medicine, University Erlangen-Nürnberg, Germany). At the environmental level this system includes a.o. As, Cd, Cr, Hg, Ni, Pt, 1-hydroxypyrene, pentachlorophenol, pyrethroids, chlorophenols, cotinine, nicotine and several organochlorines. - For a very limited number of substances (Pb, methylmercury) health-based relationship between internal exposure of children and early adverse health effects is available. These relationships were obtained as result of meta-analysis of numerous epidemiological studies carried out in the general environment
What is the problem (qualitatively and quantitatively where possible)?:	
	There is a knowledge gap with regard to low-dose/effect relations which impedes making scientifically sound decisions on (perceived) environmental pollution, contamination of the food-chain etc. Isolated studies are difficult to compare because of lack of harmonisation in analytical approaches and quality controls essential for trace analysis.
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparability – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
	Will produce comparable information on (low-level) exposure, which is useful for both ecological and health assessments
Main stakeholders affected by the option and how they are affected:	
	Member States and especially NAS can identify institutions experienced in performing biological monitoring in occupational conditions which can be involved in biomonitoring of children
	Health Research Institutions will need to apply harmonised analytical methods and established quality

Option 1	
	assurance as far as available and developed them for critical substances where lacking.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	
Health	In general, to obtain more reliable and comparable data at the European level on the environmental drivers of health issues allowing preventive policy to be science-based.

Option 2a: Further collection of biomonitoring data to establish a European Database

Collection of information about ongoing biomonitoring studies with children was initiated within the frame of the TWG biomonitoring of Children. An overview of existing monitoring activities being undertaken in the Member States and Acceding Countries was made for the baseline report. Although the response to our call was encouraging (more than 100 studies reported), gaps in information clearly remained (no information from eg Hungary and very sparse information from eg UK) and no straightforward assessment or assumption could be made on the level of representativeness of the data collected.

Although incomplete and not fully evaluated, the inventory allowed to conclude that within the EU a substantial amount of biomarker data on children are collected and that significant resources are devoted to these efforts. Many of the biomonitoring activities reported data on links between *environmental* factors and *health data.* Several studies address both *children* and their *parents* (particularly their mothers, therefore integrating *prenatal* and *postnatal* exposure) and simultaneously address markers of *exposure, effect and susceptibility.* Overall, it is highlighted that similar aspects are addressed in biomonitoring programmes in nearly all countries. Exposures to heavy metals, PCBs and dioxins are the subject of many studies that were reported. Endpoints such as asthma, allergy and neurodevelopmental disorders, as well as exposures to genotoxic agents are also covered in some studies, and multidisciplinarity is typical of many activities. In a few cases bio banks (archives of biological materials/samples) have been established to allow for follow-up analysis. It should be stressed that these activities provide useful information that may be of relevance for policymakers. Group members suggested an evaluation by independent experts of the extent to which information already available from existing biomonitoring studies can be used for immediate actions to reduce exposure and improve public health..

Realisation of a database is connected with employment of permanent staff which has to maintain database and «committee» which at least every year up to date database with new reports. The elementary problem which is obvious from collected projects is that only very few agents are covered. That means radiation, electromagentic fields (mobiles), microwaves (radar station), metals and pesticides for example are almost or completely missing. For these agents is necessary to consult «extra European data» in order to act as effective as possible in a short time.

There is no biomonitoring of children living in vicinity of waste disposals, nuclear plants, chemical industry complexes or rural population, children at labor. No data on influence of infections and malnutrition. As for adult population remains the same problem of complex exposures.

There is practicaly no genotoxicological monitoring of children.

Option 2b: Further collection of biomonitoring data to establish a European Database

Option 2b	
Option for action	
	Further collection of biomonitoring data to establish a European Database Define requirements on a European Database (including quality criteria) Define possible users and rules for confidentiality Explore the added value of including international data (link to e.g. WHO, USA, Far East) Check how far already collected questionnaires can serve as a basis Start a pilotproject which consequences for policymaking can be derived from such a database Investigate which data are missing to get a representative basis (at least for some biomarkers)
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparability – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
	The establishment of a European database forms a strong platform for common incentives regarding data sharing and harmonised methodology. Comparative analysis may increase the understanding about dose response relationships. Also the European diverse exposure may be described improving the knowledge about environmental exposures and the awareness. Data sharing and combination for pooled analysis is already part of the research agenda in selected areas and may be widened
Alternative ways of achieving the same contribution :	
	National contributions could be collected by a EU Commission board or a WHO initiative in line with the ongoing CEHAPE organising 'a collection of case studies'. However in all cases requiring frequent updates

Option 2b	
Main stakeholders affected by the option :	
The EU Commission	Will obtain a priority tool for further monitoring. Should develop criteria for inclusion of information
The Member States	Will obtain a tool for comparisons within regions. Must identify relevant national contributions
Research institutions	Will meet demands on data reporting and harmonisation of data collection, dissemination and protection
Research participants	Will provide data for a wider perspective than just national study
Benefits, advantages:	
Health	Tool for prevention in areas with high levels
Environmental	More knowledge about population exposures in different regions
Economic	Tool for prioritisation of efforts to diminish exposures etc
Social	More knowledge available on exposures and needs for protection/not need for protection from comparisons
Costs, disadvantages	
Health	Irrelevant measures may be initiated from a global scope, not focused on actual regional problems
Environmental	Same as above
Economic	Same as above
social	Stignatisation of selected populations e.g highly exposed compared to other study groups
Timing (specific if possible)	
	May be initiated now from the existing collection of data

Option 3: Establish a European Standard on how Social, Ethical and Legal Questions need to be taken into account in biomonitoring studies and surveys

Option 3	
Option for action:	
	Establish a European Standard on how Social, Ethical and Legal Questions need to be taken into account in biomonitoring studies and surveys
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	There is no specific national or European regulation for environmental biomonitoring studies, they are regulated as clinical trial studies. with applications to ethical committees and Data Protection Agencies Existing studies and programs differ in strategies for communication, for recruitment and withdrawal of participants, for the content of informed consents to both children and participants.
What is the problem (qualitatively and quantitatively where possible)?:	
	<u>Different MS have different systems, which invalidate comparisons and data exchange as well as data protection</u> <u>Harmonisation of the following issues may promote data sharing</u> <u>Informed consent:</u> • Ask consent to both parents and children? • How to inform children from different ages ? • How informed is a consent? (Who should give the information and how, written, video, oral, updates regularly etc) • What is the age of being knowledgeable/competent/mature for self determination? • How to treat "given consent" in long term follow up studies? • Learn more about children' s perception ? <u>Withdrawal from the study:</u> individual versus societal right • Withdrawal possible at any time? • Destruction of samples and/or data after withdrawal of participants from the study? <u>Recruitment of participants:</u> • How to involve participants in a study, how keep them motivated and involved? <u>Communication of results:</u>

Option 3	
	• Individual results or aggregated data? (dependency on interpretation of results in relation to health risk?) • How to provide back ground information? • How to organise community participation ? • Identify the most appropriate format of a European Standard (do´s and don't´s) How to protect anonymity and make maximal use of samples and data? How to cope with different European cultures ?
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparability – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
	EU citizens will be uniformly protected – ethically and legally. Uniform regulations and ethical codes may be a prerequisite for performance of internationally harmonised studies Taking into consideration the "collective advantage" of the outcome of biomonitoring surveys, different agreements on ethics may be applied than those used for clinical treatment studies. Objectives will be : maximise the use of human samples improve exchange of data and samples with respect of anonymity This option will contribute to uniform research protocols, preferably resting upon collection of practices used today in Europe. Such collections could take the form of a European research program
Main stakeholders affected by the option and how they are affected:	

Option 3	
Policy makers	Develop regulation adapted to the specific goals and characteristics of an environmental biomonitoring study
	Define aims and constraints of the study, receive policy supporting information (priority setting, evaluation of measures) , provide financial support, stimulate public involvement, are prepared to take results of the studies into account in their environmental policy
General public	Obtain appropriate legal protection, A harmonised ethical code may provide the same ethical protection for people involved in environmental biomonitorings studies all over Europe
	Recruited to participate in the studies, donate biological samples and fill in questionnaires, receive information on aims, results , risk factors and eventual measures
Social scientists, ethicists, health professionals	Become more sensitive for the perception of the public, put more emphasis on interaction with participants, have the possibility to carry out surveys according to internationally accepted ethical , legal and social rules
	Study design and quality assurance Communication with policy makers, health professionals and public Develop international collaborations
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	Better exploitation of data and biological material
Health	Comparable approach within medical society
Environmental	More data/information accessible
Social, familial	May promote interest in environmental issues and health on the individual and on group level
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	
Health	
environmental	
Social	Some personally non-beneficial results may stigmatise individuals and families
Other	

Option 3	
Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.	
Is further analysis needed?:	
What would be the work programme?:	
	Collection of practices today and formulation of a best practice for research projects and for surveillance studies. May be initiated as a research program with workshops and international cooperation. Lessons may be learned from clinical medicine and clinical trials.

Option 4: Develop guidelines for appropriate communication of biomonitoring studies

Option 4	
Option for action:	
	Develop guidelines for appropriate communication of biomonitoring studies
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	Amongst current biomonitoring studies, there can be found a wide variety of methods used and audiences addressed by the communication of these studies and their results. The range goes from excellent to non-existing.
What is the problem (qualitatively and quantitatively where possible)?:	
	Biomonitoring studies of children involve children, parents, communities, politicians, scientists. It is important that all these parties are informed adequately and timely. This because of ethical reasons with regards to the study subjects and their parents, as well as strategic reasons, to allow parties involved to come to an informed and timely position in the study, its results and the implications of the results.
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparability – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
Main stakeholders affected by the option and how they are affected:	
	Main stakeholders are: the children, their parents, local general practitioners, the funding institution, authorities involved in enforcing regulations

Option 4	
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	Effective communication will increase study effectivity, study participation, prevents often disproportionate effort to clear up misunderstandings or faulty expectations.
Health	Effective communication will reduce stress in community involved
environmental	N a
Social	
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Initial costs could be higher when communication specialists are involved. However ROI will be high.

Option 5: Set up a selection of possible aims for biomonitoring

Option 5	
Option for action:	
	Set up a selection of possible aims for biomonitoring 1. To generate (representative) data on the content in the human body, or the response of the human body to chemical, physical or biological environmental toxicants: biological samples are analysed that have been obtained from subjects that have been selected to be representative for the whole population or a populations with specific exposures (eg citizens, rural population, fish eaters…). Methodologies needed: Methods to select a proper study population including ethical considerations; Procedures to collect and analyse biological samples; Procedures on statistical data treatment Useful extent of harmonisation: Agreement on rules for study design and on common analytical procedures 2. To document spatial and temporal differences in exposure of the EU population Methodologies needed: Agreement on data treatment and data reporting. Repeated cross-sectional studies. Useful extent of harmonisation: Conduct of studies at the same time and repetition at equal time intervals would be ideal, but unlikely to be achievable. 3. To provide policy makers with information if and what environmental measures need to be taken and to what extent measures that have been taken have proven to be successful. Methodologies needed: Develop quality standards to be followed in terms of biomonitoring data collection and processing. Useful extent of harmonisation: Application of quality standards. 4. To improve linkage of environmental exposures to health outcome: biological markers can detect alterations in molecular processes that are known or believed to occur on the continuum between exposure and disease. Mechanistically relevant biomarkers can for example provide information on the molecular dose of an environmental factor (dose markers), the resultant preclinical biological effect (effect marker) and specific genetic or acquired factors that modify the effect of exposure (susceptibility markers).

Option 5	
	Methodologies needed: Develop quality standards to be followed in terms of biomonitoring data collection and processing. Integration of biomonitoring with environmental monitoring and health effect studies (eg. Questionnaires) Useful extent of harmonisation: Application of quality standards.
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?: isolated activities in different countries,	
What is the problem (qualitatively and quantitatively where possible)?: data are not comparable due to lack of harmonised procedures and study design	
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
	1) to the European Integrated Environment & Health Monitoring and Response System : • Provide comparable knowledge on the presence of environmental toxicants in a representative population in each of the countries included in a biomonitoring program (aim 1 &2) • Quantification of dose distribution in the population allows identification of highly exposed groups (aim 1 &2) • Enhance standardisation and exchange of results by developing common procedures and databases (aim 1&2&3&4) 2) to improve public health with respect to environmental risk factors • Allows follow up of the efficacity of environmental measures for children which are sensitive targets among the human population (children) (aim 2&3) • May indicate geographic areas that warrant specific environmental measures (aim 1&2) • Allows to set priorities for environmental measures based on endpoints that are relevant for human health (internal

Option 5	
	dose) (aim 2&3) 3) to the research agenda • Measures uptake of pollutants from external media (aim 4) • Measures internal dose which is the best metric to predict environmental health risks (aim 1&2&3&4) • Improves study power of epidemiological studies by decreasing exposure misclassification, (aim 4) • Reconstructs past exposures and monitors the effect of interventions in surveillance programs (aims 2&3&4). • Determines mechanistic pathways of environmental pollutants (aims4) • Cohorts can accomodate ad hoc research projects on biomarkers , environmental health risks, molecular toxicology (aims 1&2&4) 4) to raise awareness, to educate • comparative data on the environmental health status in different participating countries may make the policy makers and the public more alert (aim 1&2) • recruitment of a representative population in a biomonitoring program needs an intensive communication and information program (aim 1&2&3&4)
Main stakeholders affected by the option and how they are affected:	
Policy makers	Define aims and constraints of the study, receive policy supporting information (priority setting, evaluation of measures) , provide financial support, stimulate public involvement, are prepared to take results of the studies into account in their environmental policy
scientists	Study design and quality assurance Communication with policy makers, health professionals and public Develop international collaborations
public	Recruited to participate in the studies, donate biological samples and fill in questionnaires, receive information on aims, results , risk factors and eventual measures

Option 6: A comprehensive evaluation – by independent experts – of the levels of scientific evidence between exposure to pollutants and diseases or disorders that can be deduced from existing epidemiological , biomonitoring and food contamination studies including but not limited to those collected in Phase I of the TWGs work.

Option 6	
Option for action:	
	A comprehensive evaluation – by independent experts – of the levels of scientific evidence between exposure to pollutants and diseases or disorders that can be deduced from existing epidemiological , biomonitoring and food contamination studies including but not limited to those collected in Phase I of the TWGs work.
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	The « integration of information to provide a strategic overview » is foreseen in the Environment and Health Strategy (art 5.1.) . Although several TWGs attempted to provide this overview, it is very incomplete due to time constraints and the voluntary nature of expert participation.
What is the problem (qualitatively and quantitatively where possible)?:	
	Such an evaluation of various level of scientific evidence is key in order to highlight levels of evidence that are sufficient to contribute to the elaboration of priority legislative action of exposure reduction. Without this evaluation, additional research might, in some cases result in only differing the actions needed to prevent diseases or disorders.
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to contract independent experts to carry on this exercise.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	less social security and research costs , better efficiency of workers as a result of subsequent preventive action.
Health	disease and disorders prevention actions can be more quickly implemented
environmental	

Option 6	
Social	
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	intellectual costs

Option 7: Evaluate to which extent the German strategy of biomonitoring surveys can be applied on an European scale

Option 7	
Option for action:	
	Evaluate to which extent the German strategy of biomonitoring surveys can be applied on an European scale
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparability – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
	The German Environmental Surveys are representative large-scale population studies carried out repeatedly at several-year intervals. They are aimed at getting a representative picture of the internal exposure of the general population of a specified age group. These surveys are demanding at several levels, especially at the level of - selecting the study population properly, - running the field work to collect biological samples (e.g., blood, urine) and perform other experimental work in the field, - analysing a multitude of chemical and biological parameters in the samples collected, - guaranteeing that appropriate quality control be carried out during the various steps of the survey, - carrying out appropriate statistical treatment of the data obtained, - reporting of the results.

Option 7	
	While it is clear that such surveys are extremely useful to answer a number of questions not only at the national level, but also at the European level, it may not be possible for a number of reasons to apply the German strategy directly in all EU Member States. For example, different levels of analytical capacities, political priorities, cultural differences, and perhaps also different perceptions of ethical rules to be followed preclude such direct application. However, it would be beneficial, especially in view of a better comparability of biomonitoring data collected in Europe, to evaluate to what extent other countries would be ready and able to carry out work in the same way, thus harmonising the way of proceeding in Europe. This could be done, for example, by investigating if harmonised protocols based on the German experience can be set up and applied in practice and to what extent. Establishing a working group comprising mainly experts from those Member States which have already carried out large-scale population studies or are currently doing so (see information gathered in the baseline report), would be a good way to undertake this task. This task could be best undertaken in conjunction with work on starting a European biomonitoring pilot project.
Alternative ways of achieving the same contribution :	
	It would be difficult to achieve the same degree of harmonisation in Europe if countries continue to go their own way independently. The long-lasting experience available in Germany makes the procedures applied there an excellent starting point
Main stakeholders affected by the option :	
The EU Commission	
The Member States	
Research institutions	
Research participants	
Benefits, advantages:	
Health	
Environmental	
Economic	Duplication of a time-consuming “learning by doing” process will be is avoided. This will save resources.
Social	
Costs, disadvantages	
Health	Using a system that has been installed for many years will speed up the process of gaining new health-relevant

Option 7	
	information in other countries.
Environmental	
Economic	
social	
Timing (specific if possible)	May be initiated now from the existing collection of data

Option 8: Define procedures for sampling and analysis in surveillance programs thar are focused on less invasive methods

Option 8	
Option for action:	
	Define procedures for sampling and analysis in surveillance programs thar are focused on less invasive methods Methods of biomonitoring by genotoxicological methods should use buccal epithelium, urothelial cells, deciduous teeth, hair, nails, urine or umbilical cord blood . With listed samples it is possible to detect action of both chemical or physical agents. Advantages of these methods are that the sampling method is not invasive. Additional method which could be used for genotoxicity studies is in vivo micronucleus assay. Method requests 40 mikrlit of blood and could be used as such even for newborns. The method is not time consuming and do not request classical cytogenetic lab, just fluorescent microscope. Limitation is that method is applicatible in a case of recent acute overexposure or in a case od continuous exposure. Similar to in vivo micronucleus assay the method of measuring deletions on chromosome Y which requests 100 mikrol of blood is very informative although covers only male part of population. The method is routinly used in diagnostics laboratories , it is not expansive and time consuming. Huge limitation of these methods is they do not give information on stable genome damage which can be connected with increased risk for development of neoplasia. The method which has such potency , fluorescent in situ hybridization (FISH), needs 2 or 3 ml of blood. FISH can detect genome damage accumulated during life from fetal period and which will remain during all life as a genetical burden.
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
What is the problem (qualitatively and quantitatively where possible)?:	

Option 8	
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparibility – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to …
	Member States will need to …
	Health Research Institutions will need to …
	… etc
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	
Health	
environmental	…
Social	
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	
Health	None
environmental	Ecological data will become less specific, due to compromise
Social	
Other	

Option 8
Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.
Is further analysis needed?:
What would be the work programme?:

Additional input /a

Umbilical and cord-blood sampling is invasive and possibly detrimental to the long-term health of children. Instead of promoting these forms of sampling, it is probably better to promote sampling of placentas themselves. This would involve more work (extraction of the determinants out of placental tissue) but is potentially just as reliable as cord and umbilical blood, without the risk of causing long-term (relative) aplasias.

Additional input /b

Input for the option on non-invasive tests particularly for monitoring in relation to air pollution and asthma and allergy in children

In the field of lung inflammation/damage, new non-invasive tests are being developed which may be applicable to young children .

Analysis of exhaled breath has enormous potential as an easy, non invasive means of monitoring lung burden and inflammation in the airway , particularly in children.

In the gasfase of exhaled breath pollutants such as metals and volatile organic compounds can be measured . The concentrations being related to the lung burden.

Also markers for airway inflammation can be measured such as NO and aliphatic hydrocarbons derived from free radical peroxidation of polyunsaturated fatty acids. The liquid phase of exhaled breath (exhaled breath condensate), contains biological molecules such as pro-inflammatory cytokines and oxidative stress markers. Exhaled breath condensate is a fluid obtained by freezing exhaled air . Both the gas phase and the liquid phase can be easily collected under spontaneous breathing conditions. Samples can be collected from children under field conditions and thus on an epidemiological scale.

Option 9: Identify actions that could start immediately on a European level

Option 9	
Option for action	
	Identify actions that could start immediately on a European level
	The fine particles (PM 2.5 or finest) penetrate in the gas exchange region of the lung and are strongly associated with cardiovascular and respiratory effects. The mainly percentage of metals, PAHs, endotoxins and other organic compounds, are contained or adsorbed in fine particles and are associated with other specific health effects. **Exposure assessment is the first step for human biomonitoring and epidemiological studies.** **Epidemiological studies on controlled children exposure by indoor and outdoor sources and trough lung function indicators or other health indicators can represent one of possible priorities.** The goals of epidemiological studies are: - To use new methods for research on particles, both for toxicologic and epidemiologic studies - Estimate the effects of short term exposure on mortality, with the approach of Ostro. - To use cohort mortality studies approach (Kunzli, Pope, ecc.) to estimate the risk for a long exposure (10-15 years) to fine particulate matter (PM 2.5) in the principal urban towns in Europe, to identify a wide range of adverse health effects in children population associated with current ambient air pollution levels, ranging from mortality to subtle subclinical effects. - A new modelling criteria to measure and estimate young population exposure to different concentration on particulate matter, but taking attention for fine particular (PM 2.5)

Option 10 a: Integrate environmental- and bio- monitoring based on hazard identification

Option 10 a	
Option for action:	
	Integrate environmental- and bio- monitoring based on hazard identification • In surveillance programs biomonitoring should be applied in a context that allows a link to the environmental exposures or to health effects under study 1. Integration with environmental monitoring programs (soil, water, food , air, biota) 2. Integration in health monitoring programs 3. Integration with other epidemiological studies Mother – Child cohort studies could be an appropriate setting for a start of a European activity
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	See inventory of existing and recent biomonitoring projects. Very many monitoring programs of environmental compartments (water, air, soil, food, biota) exist in Europe together with various biomonitoring projects and programs. These activities are often carried out without an evaluation of the potential benefits of integration of hazard identification with appropriate environmental and biomonitoring programs.
What is the problem (qualitatively and quantitatively where possible)?:	
	The information value of these activities could be strongly enhanced with the intended integration..
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparibility – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	

Option 10 a	
	2) to the European Integrated Environment & Health Monitoring and Response System : integration with environmental monitoring is needed to obtain data on pollutant uptake from external media to determine internal dose which is a better metric to predict health risks than environmental concentrations to evaluate the efficacity of environmental measures on health risk related endpoints to obtain data on bioavailability of environmental toxicants for humans to obtain data on biomagnification in humans through the food chain integration with health monitoring programs can be used to identify the predictive value of biomarkers for (long term) health effects integration with mother-child cohort studies allows furthermore efficient use of staff, recruitment facilities , registration of population characteristics, exchange of information and data among a European wide network of scientists easy integration of research projects about biomarkers and other health subjects room for the study of specific problems in the different countries , both in countries with longstanding experience in biomonitoring programs as well as in countries where experience with biomonitoring programs has yet to be build up. 2) integrated monitoring is the only way to obtain data for integrated risk assessment in which uptake from different exposure pathways is included to predict adverse health effects. Integration of biomonitoring with environmental monitoring in a multidisciplinary setting will enhance the identification of risk factors and will increase knowledge of the cause effect chain.
Main stakeholders affected by the option and how they are affected:	
Health professionals and environmental professionals Public Health and Health professionals and Environmental professionals	Improved obtainment of information with a more efficient use of funds and enhanced exchange of information and collaboration between these disciplines
Policy makers	Information on risk factors will be important for priority setting of environmental policy

Option 10 b: Develop Biomonitoring Programs based on integrated system and focused on mother-newborn pairs (by using, as much as possible, less invasive and cost effective methods), to characterize pre- and post-natal exposure to critical pollutants

Option 10 b	
Option for action:	
	Develop Biomonitoring Programs based on integrated system and focused on mother-newborn pairs (by using, as much as possible, less invasive and cost effective methods), to characterize pre- and post-natal exposure to critical pollutants
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?	
	For some countries in the EU, there is a reasonable (or even good) knowledge of the situation related with environmental exposure to the more recognized critical pollutants, mainly in children, while for other countries, due to their specific circumstances, this knowledge is limited or almost unknown. On the other hand, studies developed in this latter rank of countries, are mostly local studies, normally addressed to exposure through contamination of different environmental compartments (usually to integrate models), but rarely directed specifically to internal dose.
What is the problem (qualitatively and quantitatively where possible)?	
	The problem is the usually very high costs associated with Biomonitoring Programs, developed at a national or regional level, which require expensive sampling and analytical strategies, making it easier to develop environmental monitoring programs, more or less useful to estimate human exposure (depending on the objectives) but unable to characterize levels in the human body and the related adverse health effects.
How does this option contribute to the goals of the Strategy? 1) To the European Integrated Environment & Health Monitoring and Response System: – Improved data availability, accessibility, comparability – Facilitate the sharing of data – Identification of highly exposed groups – Enhanced standardisation and exchange of information by developing common procedures and databases 2) To improve public health with respect to environmental risk factors o Identification of geographical areas of major concern within EU	

Option 10 b	
o Follow up of the efficacy of environmental measures for children o Support to set priorities for environmental protection 3) To the research agenda 4) To raise awareness, to educate • Exchange of information between MS EU may alert policy makers, general public, social scientists, ethicists and health professionals • Involvement of general public requires an intensive communication and information program	
	This option will permit the characterization of human long-term and pre- and post-natal exposure to environmental agents in order to assess health impact and spatial/temporal trends, for regulatory and/or policy decision-making, to protect health and/or prevent related diseases.
Main stakeholders affected by the option and how they are affected:	
Policy makers	Information on human exposure levels, mainly to chemical mixtures, will contribute to set priorities for environmental policies and establishment of preventive measures for environmental and health protection.
General public	Better knowledge about the reality of environmental exposure to critical pollutants, avoiding false alarms, mainly if there are public particular concerns.
Social scientists, ethicists, health professionals	This option will generate more data on potential impacts of environmental agents in human health and will improve the exchange of information and collaboration within experts groups from all EU MS. Health professionals will be directly involved in recruitment and sampling procedures.
Benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	
Health	Better understanding and knowledge about human exposure to critical pollutants, and thus the risk for the related adverse health effects. Definition of hot spots in EU MS related to those pollutants. Improvement of support for public health policies in relation to environmental exposure to those substances.
Environmental	Support to define and implement adequate measures for environmental protection.
Social, familial	

Option 10 b	
Other	If successful, the proposed methodology could be extended to other relevant environmental agents
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Elevated costs associated with Biomonitoring Programs, mainly if more invasive methods are used
Health	Motivation of health professionals from health institutions, which obligatory should be involved in recruitment of participants and sampling procedures.
What would be the work programme?	
	Recruitment procedures • Pregnant women recruited (written informed consent) at health Centres or Maternities. A questionnaire for lifestyle, health data and socio-economical factors can be administered at that time. **Target environmental agents** • Heavy metals (lead and mercury) • Dioxins and dioxin-like compounds **Sampling procedures** • From pregnant women, immediately before delivery, collection of pubic hair o N.B. Biological "waste" commonly produced during women's preparation for delivery is used • During delivery, collection of cord blood • One month after delivery, collection of breast milk, eventually in the domicile or at Health Centre, by the time of first obligatory check-up of the newborn • Along lifetime until 6 years of age, periodical follow-up collection of children's scalp hair (eventually, at 2 and 4 years old children, blood sample collection by the time of medical examination, when and only if it also includes blood collection) **Analytical procedures** • Biomarkers of exposure o Lead and mercury in cord blood o Lead and mercury in pubic and/or scalp hair

Option 10 b	
	○ Lead and mercury in children hair ○ Eventually, lead and mercury in children's blood, as well as relevant clinical parameters (biomarkers of effect) ○ Metil-mercury in breast milk ○ Dioxin and dioxin-like compounds in breast milk • Analysis of (a few) individual samples for all biomarkers ○ To account for the inherent variability of human samples ○ To follow up disorders or adverse health effects (when needed) • Analysis of pooled samples for all biomarkers ○ To reduce needed volume of biological materials ○ To reduce cost of analysis ○ To evaluate spatial and temporal trends • Analysis of milk samples for the determination of dioxins and dioxin-like compounds ○ By instrumental technology (a few samples) ▪ To determine the congeners profile and thus to identify sources ▪ For screening methods confirmation ○ By bioassay/screening methods (most samples) ▪ To reduce needed sample volumes ▪ To reduce cost of analysis ▪ To evaluate spatial and temporal trends Note: Using less invasive sampling procedures, sample volumes will very likely be suitable (unless for pubic hair) for the establishment of bio-banks, in view of prospective and retrospective biomonitoring of emerging critical environmental agents

Additional input

Umbilical and cord-blood sampling is invasive and possibly detrimental to the long-term health of children. Instead of promoting these forms of sampling, it is probably better to promote sampling of placentas themselves. This would involve more work (extraction of the determinants out of placental tissue) but is potentially just as reliable as cord and umbilical blood, without the risk of causing long-term (relative) aplasias.

Option 11 a: Identify children that are at increased risk and derive recommendations for biomonitoring

Option 11 a	
Option for action:	
	Identify children that are at increased risk and derive recommendations for biomonitoring
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	Biomonitoring studies are currently being performed in cross-sectional population groups, and in longitudinal cohorts of healthy, "normal" children. Sporadically small selected populations are studied, but not structurally.
What is the problem (qualitatively and quantitatively where possible)?	
	We have chasms in our knowledge of chemical exposures and the health and development of children, and most specifically so in children at risk. Children at risk include: 1. premature infants 2. dysmature infants 3. seriously ill children requiring hospitalisation, and especially on neonatal and paediatric intensive care units 4. children living in areas of abnormally high exposure, such as in the vicinity of waste incinerators and chemical factories 5. children of mothers with relatively higher exposure, such as mothers giving birth later in life whom have accumulated more life-long exposure 6. children known to have been exposed to endocrine disruptors, such as DES-children.
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparability – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors	

Option 11 a	
3) to the research agenda 4) to raise awareness, to educate	
	1. a more complete picture will emerge of the extent of contamination in the children of Europe and to what manner. Knowledge as to health effects will increase as more health effects are related to the exposures, whereby legislation and medical care can be better tailored and more effective. A better awareness of the problem would increase public pressure to instigate change and promote a less environmentally hazardous manner of existence (and treatment). Hospitals and other medical institutions would be obligated to environmentally friendlier methods of operation. Naturally knowledge gained would be unique and of enormous benefit to experts in the field and others. 2. The new data would encourage change which in turn could be expected to reduce the negative health effects (in time). 3. The plan could fit into currently running cohort studies. 4. The studies and outcomes would certainly attract media coverage whereby awareness in the general public and amongst professionals would increase, stimulating improvement.
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to encourage and finance the research, education and the promotion of improvement, and possibly required medical intervention.
	Member States will need to encourage and finance the research, education and the promotion of improvement, and possibly required medical intervention.
	Health Research Institutions will need to devote manpower and resources to the research and look for children at extra risk, in order to form study cohorts for analyses.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	Better usage of resources as health issues are more directly addressed.
Health	More specific interventions, in the long-term possibly reduced morbidity and even mortality from certain diseases.
environmental	More commitment amongst the general population to a more environmentally friendly manner of life.
Social	Better awareness of the danger of environmentally hazardous chemical exposures
Other	

Option 11 a	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Costly research
Health	None
environmental	None
Social	It is possible that some may develop an unnatural fear of contamination from the environment.
Other	
Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.	
At this stage none imaginable.	
Is further analysis needed?:	
	Possibly an analysis as to how many children would fall into the group of children at extra risk.
What would be the work programme?:	
	1. Identify groups at extra risk and standardise laboratory testing/equipment and the sampling protocol should be aligned. 2. Treating physicians should be educated on the need and purpose of the monitoring and the expected outcomes. 3. Treating physicians should be requested to recruit subjects for the cohort and attain informed consent from the (children and their) parents/guardians. 4. The parents/guardians are to additionally be informed with printed matter as to the need, importance and modus operandus of the study, and should have a contact person whom can be approached with questions/problems. 5. A co-ordinating body (locally, nationally or pan-EU as necessary), including experts in the field, should guard the stream-lining of the study and the co-ordination of the evaluation and interpretation of the outcomes. 6. The subjects and parents/guardians of the children need to be informed of the outcomes in general sense. 7. Study results need to be personally discussed with the parents/guardians of the child when negative health effects have been elicited. 8. The results/outcomes need to be published in peer-reviewed (medical) journals.

Option 11 b: Identify children that are at increased risk and derive recommendation for biomonotoring

Options 11 b	
Option for action:	
	Identify children that are at increased risk and derive recommendation for biomonotoring Age dependent risk/sensitivity. Children should be separated by age into groups due to differences in age related metabolism, excretion, food and air intake, behaviour and hormonal activity (new borns, up to 2 year, up to puberty, puberty-18y) Generaly speaking there is a question about genome damage caused in children as a consquence of parental exposure to antineoplastic drugs, radiation or other drugs and chemicals during medical diagnostics or therapy. Such children express increased sensitivity. Children exposed to radiation, antineoplastic drugs etc in diagnistics or therapy represent vulneravle population to environmental factors and the number of such children is relevant. It is shown in some studies from USA there is increase in leukemia in such children and also even some commonly used antibiotics are suspected genotoxicants. It is a separate area but it is for sure that there is no specific interest on that topic especially not from the pharmaceutical industry. Children living in vaccinity of nuclear plants, coal-fired power plants, fertilizer plants, waste disposals, industrial suburbs, . Children of parents occupationally exposed to radionation and carcinogens/mutagens.
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
What is the problem (qualitatively and quantitatively where possible)?:	
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship	

Options 11 b	
– Improved data availability, accessibility, comparibility – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to …
	Member States will need to …
	Health Research Institutions will need to …
	… etc
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	
Health	
environmental	…
Social	
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	
Health	None
environmental	Ecological data will become less specific, due to compromise
Social	
Other	

Option 12 a: Promote guidelines for necessary training, education and skills of institutions/person with special emphasis on GPs and paediatricians

Option 12 a	
Option for action:	
	Promote guidelines for necessary training, education and skills of institutions/person with special emphasis on GPs and paediatricians
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	Currently, little attention is paid to environmental influences on health in children, by medical schools and even less so by training programmes for General Practitioners and Paediatricians. As a result, treating physicians have little knowledge of environmental factors affecting health. Insight constantly increases but few treating physicians are kept up to date on new insights into environmental effects on health.
What is the problem (qualitatively and quantitatively where possible)?:	
	Currently, little attention is paid to environmental influences on health in children, by medical schools and even less so by training programmes for General Practitioners and Paediatricians. As a result, treating physicians have little knowledge of environmental factors affecting health. Insight constantly increases but few treating physicians are kept up to date on new insights into environmental effects on health. There is a need for a qualitative and regular (e.g. quarterly) newsletter/mini-journal wherein the newly published environmental health studies relevant for clinical practice are summarised.
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparibility – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda	

Option 12 a	
4) to raise awareness, to educate	
	1. Should the knowledge of treating physicians about environmental influences on health be increased, then there would be an increase in interest and consequently research in this field. This would result in more data becoming available, specifically on clinical outcomes, which in turn would be invaluable for (non-clinical) experts in the field and legislative bodies throughout the EU. Furthermore, treating physicians are acquainted with the stringent studies performed before new medication is allowed onto the market, and this insight could prove extremely valuable for instance in setting up strict legislation before a new chemical may be introduced onto the market. Finally, as increased awareness amongst treating physicians of environmental influences on health occurs, so might the treatment/intervention in patients improve. 2. As increased awareness amongst treating physicians of environmental influences on health occurs, so might the treatment/intervention in patients improve, with knowledge being the basis for intervention (evidence based). 3. Involving clinicians would increase interest and hence increase research in this field. 4. As more professionals are involved in the monitoring programmes, and as more knowledge of the effects of chemical exposures on children are documented, so treating physicians may be kept up to date with, for example quarterly newsletters sent to all GPs and paediatricians in the EU. This would naturally increase awareness, also amongst the patient populations.
Main stakeholders affected by the option and how they are affected:	
	The European Commission should strongly encourage medical schools and teaching hospitals, as well as post-graduate institutions, to amend their syllabi to include courses on environmental influences on the health and well-being of children. The EC will need to institute an editorial body for a regular newsletter/mini-journal and finance this body and the publication of the journal.
	Member States should strongly encourage medical schools and teaching hospitals, as well as post-graduate institutions, to amend their syllabi to include courses on environmental influences on the health and well-being of children.

Option 12 a	
	Synergies with WHO/EURO office has to be developed for training Programs for professionals
	Universities and teaching hospitals will need to amend their syllabi.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	Possible long-term reduction in medical costs as knowledge and awareness increases.
Health	Better awareness of the environment and health problem may lead to a better approach to clinical problems. This might lead to more efficient and effective interventions, whereby morbidity and possibly mortality may be reduced.
environmental	Stimulating research and awareness, which in turn would be expected to increase the need for environmentally safe products.
Social	More treating physicians would be better informed, whereby their patients would also be better informed.
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Financial costs involved need not be high. Producing a quarterly newsletter/mini-journal would incur costs.
Health	None.
environmental	None.
Social	More information for clinicians to read. GP and paediatrician training programmes will have to be amended, as will medical school syllabi.
Other	
Is further analysis needed?:	
	No.
What would be the work programme?:	
	1. Strongly encourage medical schools and training hospitals to incorporate a course on the environmental influences on children's health in their syllabi for general medical school and for training programmes for GPs and paediatricians.

Option 12 a	
	2. Form an editorial committee burdened with the responsibility for producing a qualitatively good newsletter/mini-journal on a regular (for instance quarterly) basis, wherein recently (peer-reviewed and) published articles on environmental influences on children's health are summarised. This newsletter/mini-journal should be sent to all GPs and paediatricians in the EU.

Option 12 b: Promote guidelines for necessary training, education and skill of institutions/persons with special emphasis on GPs and pediatricians

Option 12 b	
Option for action:	
	Promote guidelines for necessary training, education and skill of institutions/persons with special emphasis on GPs and pediatricians Educational programme should be planed and launched by SCALE or some other organization within EC. Programme will be up dated and give to partner countries every 2 or 3 years. Programme will be adjusted to national needs and sections with special interests would be available. For GPs and pediatricians such education should be a part of their regular national obligations of continuous education which majority of EU countries already have. Programmes should be prepared by multidisciplinary committee which members will follow literature and FP projects in order to as soon as possible apply new facts in real life and practice. In this way Europe will have harmonized level of education.
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
What is the problem (qualitatively and quantitatively where possible)?:	
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparibility – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	

Option 12 b	
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to …
	Member States will need to …
	Health Research Institutions will need to …
	… etc
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	
Health	
environmental	…
Social	
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	
Health	None
environmental	Ecological data will become less specific, due to compromise
Social	
Other	

Option 13 a: Establish a priority list of factors for which there is only scarce information on biomonitoring data in Europe

Option 13 a	
Option for action:	
	Establish a priority list of factors for which there is only scarce information on biomonitoring data in Europe • such as Flame retardants, Pesticides, Certain Endocrine Disrupters (input from TWG ED), what are appropriate biomarkers for allergies (research need) input from TWG, what are appropriate biomarkers for childhood cancer (research need) input from TWG, vPvBs, radiation
What is happening just now(describe the current situation qualitatively and quantitatively where possible)?:	
	- Information on environmental fate of POP is now prevalent in respect of those on other important xenobiotics such as pesticides - Environmental and health relationship is not completely understood No balance exist between ecological and human health requirements : monitoring for ecological purposes will need to be oriented to obtain more consistent information in biomonitoring
What is the problem(qualitatively and quantitatively where possible)?:	
	Possible order of priority : - Pesticides(focus on molecules relevant for persistence, bioaccumulation, immune-, neuro-, reproductive-toxicity, EDS.) - POP(PCB, PCDF, PCDD….) flame retardants - metals and their compounds - nitro-IPA - plasticiser - pharmaceuticals - radiation

Option 13 a	
	Approach : - Obtain more information on pesticides on extent of adsorption and its effects on transport trough soils, their transformation in soils, aquatic system, plants, mammals and fish, and the toxicological significance of the compounds to animals, avian and aquatic organisms and through environmental compartments to humans. - Use environmental modelling to evaluate and predict the fate of pesticides - Assess significance from the stand point of acute and chronic toxicity, reproductive effects, tetratogenicity, oncogenicity, of any pesticide or xenobiotic - Choice of better biomarkers of exposure and/or effects as function of environmental fate, overall degradation rates, metabolic pathway: adsorption, distribution, metabolism, elimination for better information on human exposure and especially for children. - Introduce data on female exposure in work place to implement database of prenatal exposure - Comparison on background level of exposure indicators and related effect indicators for short and long term environmental exposures - For improve data comparability - Thousands of chemical compounds and formulations are marketed; information on identity, toxicity and exposure of specific pesticide and their metabolites is often difficult to obtain. - Environmental exposure due to accidents and spills , to use in house and garden, to residual contamination of food and water, to skin contamination is frequent for children. - Quality assurance on sampling and analysis and participation to external quality control programs. - Decision on priority of programs in contaminated areas. - Reviewing safety of older pesticides
How does this option contribute to the goals of the Strategy ? **1) to the European Integrated Environment & Health Monitoring and Response System :** – **Generate synergies and facilitate the sharing of data and methodologies** – **Increase the understanding of the environment and health relationship** – **Improved data availability, accessibility, comparability** – **Enhanced exchange of information** **2) to improve public health with respect to environmental risk factors** **3) to the research agenda**	

Option 13 a		
4) to raise awareness, to educate		
Main stakeholders affected by the option :		
	The European Commission will need to : - reregistering pesticides to ensure that older pesticides meet current safety standards. - reassessing tolerances (maximum residue limits) for pesticides in food and water for better protection also of children (more vulnerable) - implement more severe pesticide use regulations - ban production or limit use of more toxicologically relevant pesticides - state control on pesticide production, formulation, processing, transport, storage, use, disposal - Encourage cooperation in biomonitoring activities between member states	
Benefits, advantages:		
Health	Sustainable use of pesticides, reduced exposure	
Environmental	Better control on quality of soil, water, food…	
Economic		
Social		
Costs, disadvantages		
Health		
Environmental		
Economic	Cost of biomonitoring and search	
social		
Timing (specific if possible)		

Option 13 b: Establish a priority list of factors for which there is only scarce information on biomonitoring data in Europe: Pesticides as priority for biomonitoring in Europe - Criteria for choice of active substances and metabolites to be biomonitored

Option 13 b	
Option for action:	
	Establish a priority list of factors for which there is only scarce information on biomonitoring data in Europe: **Pesticides as priority for biomonitoring in Europe.** **Criteria for choice of active substances and metabolites to be biomonitored**
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	At present time, mostly POPs pesticides are biomonitored. Studies in USA published in early 2003 (Environmental Working Group (EWG), Center for disease Control and Prevention (CDC)) have looked both for organophosphates pesticides and CDC also for some carbamates, some fungicides and herbicides. This shows that more pesticides can be found just when they are looked for. According to the Commission Communication on the 6th Environmental Action Programme, there is sufficient evidence to suggest that the scale and trends of problems caused by pesticides are serious and growing. Particular concerns include the contamination of groundwater and foodstuff and the continuing accumulation of certain pesticides in plants and animals. Parents and children can be contaminated by various routes (oral through dust, food and water, atmospheric, dermal)
What is the problem (qualitatively and quantitatively where possible)?:	
	Pesticides are the only chemicals developed to kill organisms that are voluntarily released into the environment. Eurostat data show that annual pesticides sales (in tons of active ingredients) have increased in EU countries over the last decade despite a clear trend in arable farming towards active ingredients that are effective at lower dosage. Such an increase in pesticide dependency is likely to increase the overall exposure to pesticides of the general population including foetuses , infants and children.

Option 13 b	
	For Plant Protection Products (PPP), about 800 active substances (a.s) were in use in Europe. Since July 2003 nearly 300 a.s. are taken off the market because they were not anymore defended by the industry which is developing a lot of new low dose products, sometimes more specific but generally much more difficult and expensive to analyse into the environment. About 23 existing active substances were actively taken off the market in the context of their revision under Directive 91/414/EEC. About 30 new a.s. are already on the market and more that 90 others are waiting for authorisation. The authorisation process is based solely on risk assessment of each substance tackled individually. There is no exclusion criteria based on intrinsic properties. Moreover, as stated in the 2002 WHO/EEA report "Children's Health and environment- a review of evidence", current core test and risk assessment methodologies do not fully ensure pesticide safety for foetuses, infants and children which are more vulnerable and often more exposed. Besides PPP, parents and children are also exposed to number of biocides which might be of concern. As all pesticides cannot be biomonitored, selection criteria have to be established such as: - pesticides still on the market in Europe and having intrinsic toxicological properties of concern (PBT, suspected to be carcinogenic, mutagenic, reprotoxic, or suspected endocrine disruptors, sensitising , immunotoxic and neurotoxic pesticides. - Depending on the design of the study, also selection criteria according to geographical mapping of emission sources of each specific pesticide. - Pesticides taken off the European market , having above mentionned intrinsic properties of concern but also persistence and bioaccumulative properties - Pesticides off the market in Europe with properties of concern and present as residues on imported food.
Main stakeholders affected by the option and how they are affected:	
	Commission will need to publicise a list of pesticides (including for those taken off the market) with their hazard characterisation for the above mentioned toxicological properties as most of the toxicological studies made by the industry for pesticide (re)registration are confidential for a long period and as EU categorisation of substances according to Directive 67/548/EEC does not reflect real picture due, among others, to lack of studies for key toxicological endpoints .

Option 13 b	
	Commission and Member States will need to collaborate to provide public access to geographical mapping of individual pesticide use. Commission and Member States will have to provide funding for pesticides biomonitoring studies.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?):	
Financial	
Health	Better insight of body burden and , depending of the design of the study, possible additional level of evidence of a causal link between exposure , effects and diseases or disorders
environmental	
Social	
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Expensive studies
Health	
environmental	
Social	
Other	Risk to delay actions for exposure reduction
Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.	
In order to achieve a high level of protection of Health and the environment, a reduction of pesticides dependency in Europe has to be seriously considered for PPP as well as for Biocides	
Is further analysis needed?:	
What would be the work programme?: results not expected at short term.	

Options 14: Lessons to be learned from previous and ongoing programs within EU

Option 14	
Option for action:	
	Lessons to be learned from previous and ongoing programs within EU
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	During the process of describing the baseline level several national projects were identified, as described in the base line report. EU projects with children and environmental exposures were identified: QLK4-1999-01266 PDCAAE; QLK4-1999-01391 PARSIFAL; QLK4-2000-00263 E21-4AYC;QLK4-2000-000538 Allergyflora; QLK4-2001-0250 PASTURE; QLK4-2001-00366;Chemokines-Atopy; QLK4-1999-01308 HELIOS; QLK4-2000-00073 AIRALLERG;QLK4-1999-01287 Nofer; QLK4-2000-00197 RANCH; QLK4-2000-00261 COMPARE;QLK4-2000-00279 PLUTOCRACY; QLK4-2001-00186 ANEMONE; QLK4-2001-02544 PATY;QLK4-2001-0243 Gendisrupt; QLK4-2002- 02395 PINCHE; QLK4-2002-02198 CHILDRENGENONETWORK; National programs are identified in the baseline report in eg Poland, Czech Republic, Germany, France
What is the problem (qualitatively and quantitatively where possible)?:	
	A set of common issues within these programs should be addressed relating to • Aim of activity • Target groups • Information during process of establishing and performing activity • Impact on societal and legal initiatives **Problems and deficits** Problems and deficits (non exhaustive) in conducting biomonitoring in children, as highlighted in the questionnaires and by the group members, relate to : 1. recruitment of study population 2. biomarkers addressed 3. the logistics of conducting biomonitoring 4. biosafety

Option 14	
	5. collaboration between disciplines 6. comparability of questionnaire data 7. communication of results 8. authorisation of study **1. Recruitment of study population** A major problem in biomonitoring studies or programmes reported is to achieve good participation of the population, i.e. a sufficiently high response rate, in order to guarantee the representativeness of the study. Measuring biomarkers often means that biological samples such as blood and urine need to be obtained. Collection of blood samples is perceived in some Member States as a significant disincentive to participation (e.g. participation less then 30 %), leading to a loss of data and therefore to lower representativeness and consistency of results. Development of less- or non-invasive sampling techniques is suggested to be crucial for the success of future large-scale biomonitoring studies. Other Member States, however, report response rates over 60% and report financial incentives or gifts to be appropriate tools to increase the response rate. This problem is even be more marked in studies or programmes involving children. Neonates and infants are a more difficult study population for biomonitoring because recruitment can be particularly problematic. Liquid samples are reported to be more difficult to obtain: both newborns and infants are too young to easily collect urine in bottles or other vessels. Also parents are reluctant for a blood sample at that age. Blood sampling needs to be performed by personnel experienced in infant blood-withdrawals and obtaining urine samples. On the other hand, these two groups are of high interest because of various reasons6. Also in teenagers the collection of blood samples may be a significant disincentive to participation. Other material such as hair or buccal scrape is easier to collect. Particular problems are also mentioned on the recruitment of children belonging to lower social classes, of single working mothers and of immigrants. When response rate was reported to decline with time, in some studies the reduced response was linked with the level of education and the social class of the mother. Participation level was reported to increase when siblings of selected children were accepted for the study or if a gift and/or reimbursement of travel cost were offered. In some countries such practices are, however, not ethically accepted or commonly used, resulting in a lower participation level.

Option 14	
	Parents are mostly interested in the results (e.g. blood level) of an agent in their children. Some reports remark that in the case of low (normal) levels being found, parents may refuse further health examination. Others report participation to increase with good experiences from previous participation **2. Biomarkers addressed** Validation of markers is incomplete. Gaps in knowledge exist on the differences between children and adults and within different age groups of children within areas of mechanistic actions, uptake, distribution, metabolism, storage and excretion of environmental agents. Questions arise on the best available techniques and the interpretation of results, particularly in children. Whereas, for example, in adults urine results are generally expressed by creatinine level to take into account the diuresis, in children the variability of urinary creatinine may be more important due to growth of the muscular mass, to an important physical activity, and to puberty. Also Specific Physiologically Based Pharmokinetic (PBPK) models for children need to be developed to allow a better health risk assessment. Children.s health parameters seem not to have the same sensitivity at different ages, and shows great inter-subject variability. In genetic toxicology, reference data are missing for children. For some markers (e.g. related to dioxins), the volume of blood needed is too large for children. Alternatives using smaller volumes or blood or other material should be studied. *6* (i) the body composition of the foetus, neonate and infant are very different to that of the adult, especially with regard to the adipose tissue to body ratio. This is very important to consider in lipophilic and hydrophobic toxicants such as dioxins, PCBs, solvents, etc. The storage of these substances in adipose tissues means that the substances are difficult to metabolise, resulting in long periods of exposure (for instance, dioxins have a half-life of 7 to 12 years in humans); (ii) the foetus, neonate and infant (and young child) are growing and developing (this includes the brain). Exposure in this period, during the various developmental windows, may lead to various (long-term) effects; (iii) the neoanate and infant consume relatively huge amounts of feed, approximately 150 mL/kg/day while older children and adults consume approximately 30-40 mL/kg/day. Contaminated food stuffs (especially dairy products) then result in far larger exposures to the neonate and infant than to older children and adults.

Option 14	
	3. Logistics of conducting biomonitoring Recruitment may be difficult and slow and sufficient staff are not always available. Also, personnel (other than the scientific staff) to implement the logistic aspects of the study or programme is sometimes lacking. High time-investment of medical staff is often required. In one member state, medical services or centres were reported to refuse to participate in studies for this reason. Also in other studies it was reported that individuals satisfying the inclusion criteria were sometimes .lost. from the study due to lack of involvement of health professionals. Transport and storage of samples requires particular attention. Recruitment of laboratories that perform chemical analyses may be time consuming. Continued funding of long-term studies was a recurrent problem. Reasons reported for this were e.g. that studies do not produce quick results which the funding agencies would want to see. Also funding for studies with .sensitive data. was not easy to find. **4. Biosafety** Biological media can serve as vectors of infectious disease, such as HIV and hepatitis. Because of this hazard, rigorous procedures must be used when collecting, transporting, storing, analysing and disposing of any human biological samples. All personnel must be trained for the proper handling of biological samples and protocols must include instructions for this. **5. Collaboration between disciplines** Collaboration between disciplines (e.g. epidemiologists, toxicologists, molecular biologists, paediatricians, oncologists, exposure assessors, environmentalists and regulators) in order to develop and implement systematic biomonitoring systems to produce additional useful results for regulatory and/or policy decision-making is lacking in many of the activities reported. Reporting results to the relevant authorities is often not foreseen in the research projects at hand. **6. Comparability of questionnaire data** In international studies especially, an important methodological problem is the collection of comparable data through questioning of children or parents, despite the cultural differences between ethnicities, regions, countries. International standardisation of obtained data in questionnaires is lacking.

Option 14	
	7. Communication of results For many biomarkers the link to health risk, especially at the individual level, is not well defined. Reporting of these results to the individual may therefore be problematic. Ethical questions on communication and on access to own data (right to know, right not to know) are therefore raised: e.g. is it acceptable not to report on the individual results? Also communication with the public was reported to raise difficulties and to need careful consideration and preparation. An active involvement of professionals in the field of communication and sociology may contribute to resolving these constraints. **8. Authorisation of study** Obtaining the necessary legal agreements by the bodies concerned (national authorities, ethics committees, privacy commissions) may cause substantial delay in implementing a study or programme. The question was raised if legislation needs to be adapted in view of the public interest of the activities at hand.
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparability – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
	Will produce comparable information on ongoing programs and feed ideas for improvements of future programs
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to promote the release of the required information about actual organisation of programs and impacts on social and legal issues…
	Member States will need to inform about previous and ongoing activities
	Health Research Institutions will need to provide the necessary information
	Users will have to evaluate the impact of the programs

Option 14	
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	More efficient use of existing resources will be possible from reductions in duplication or inefficiencies
Health	In general, better information at the European level on the environmental drivers of health issues. More knowledge about how to promote preventive policy to be better targeted.
environmental	
Social	
Other	

Option 15 a: Research needs related to biomonitoring of children

Option 15 a	
Option for action:	
	Research needs related to biomonitoring of children
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	Calls are made for research needs in relation to environmental health and children
What is the problem (qualitatively and quantitatively where possible)?:	
	More concerted action regarding 1. data sharing, necessitating common protocols regarding study design, analysis, data analysis, data management and protection, dissemination of results and ethical issues 2. elaboration of a European ethical standard in relation to studies with children 3. common design and protocols for mother/child cohorts with biological and prospective information collection 4. compilation of existing information in Europe from preliminary database and by collaboration with other initiatives (WHO, US) More basic research concentrating on mechanistic research related to 1. Age differences in environmental exposures 2. Age differences in metabolism of environmental agents 3. Age differences in DNA damage and repair of selected environmental agents 4.
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparibility – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors	

Option 15 a	
3) to the research agenda 4) to raise awareness, to educate	
	Will produce comparable information
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to initiate research programs
	Member States will need to support European initiatives…
	Health Research Institutions will need to contribute by applying etc
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	More efficient use of existing resources will be possible after implementation.
Health	In general, better information at the European level on the environmental drivers of health issues, to allow preventive policy to be better targeted. More specifically, data will improve in the following ways….
environmental	Additional ecological benefits, over and above the health benefits …
Social	Raised awareness regarding the environmental impact on health
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Cost for development will be €Xm per annum, based on assumption of 1 FTE person in Y countries. These people will be responsible for implementation and maintenance at EU and MS level
Health	None
environmental	
Social	
Other	
Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.	
.	
Is further analysis needed?:	

Option 15 a	
What would be the work programme?:	
	Technically, how would the option be delivered and what would be the indicative timetable?
	The local governments will nominate research institutions responsible for planning and coordinating activities in particular countries.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	- financial: less funds spend on development of strategy , methods and quality assurance programs in NAS
Health	- health: better information at the European level on the health risk, implementation of health promotion programs
environmental	- methods: harmonization of analytical methods, transfer of knowledge, the most sophisticated determinations can be performed in selected European laboratories.
Social	
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	financial : organization of the system in NAS countries depending on the present level. The cost of BM of children surveillance system implemented in 1994 in The Czech Republic (about ten millions of inhabitants) amounts to about 100 000 Euro per year .

Option 15 b: Research in breast milk as a widely used indicator

Option 15 b	
Option for action:	
	Research on breast milk as a widely used indicator Breast-milk sampling is relatively simple, reliable and non-invasive way of biomonitoring in infants. Research in lactation, the influence of chemicals on breast milk synthesis, better understanding of lactation mechanisms and metabolism in the infant (for e.g. excretion of bio-accumulative substances over the whole lactation period, the 24h rhythm of composition, different chemical half-lives related to fat intake or synthesis of breast-milk based on body stores, differences in half-life in vivo) would allow better intake/exposition calculations for infants. Breast-milk monitoring should be continued for the well-documented chemicals, such as dioxins and PCBs, but the monitoring should also be extended to include newer and newly-produced chemicals. Research should also be done in alternative ways of biomonitoring to replace the very "sensitive fluid" by f. ex earwax
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	Numerous surveillance programs are currently making use, or have made use, of breast-milk samples. Most MS have surveillance programs looking at dioxins and PCBs, and the WHO breast-milk surveillance program is repeated at regular intervals, on a global scale. Little research has been performed on the newer chemicals, and understanding on the mechanisms of chemical interference is lacking. There are chasms in knowledge about half-lives of most chemicals and the concentrations during the circadian rhythm.
What is the problem (qualitatively and quantitatively where possible)?:	
	Many assumptions need to be made (for instance, continual concentration versus diurnal variance). Many health professionals and parents loose confidence in breastfeeding as the best way of nutrition to protect the health and development of the infant and the mother. Once contaminants are detected in breast-milk, many mothers have (unjust) feelings of guilt ("I poisoned my baby"). Mothers participating in sampling may feel stressed and uncomfortable doing the sampling. Many surveillance programs (such as the WHO studies) pool samples and do not perform individual associative health studies, whereby exposure-related effects may be evaluated.

Option 15 b	
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparability – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
	This would improve the data availability and comparability while limiting invasive investigations. Better understanding of metabolism in breastfed children would result in better knowledge about the different half-lives of these substances. More knowledge would provide better data and would result in better public health by increased awareness and communication with the health system and care-givers. Associating health effects with exposure would facilitate the documentation (and prohibition) of harmful chemicals. Decreasing exposure trends (now visible) would again increase confidence in breast-feeding. Increasing exposure trends would stimulate public opinion and hence governmental institutions to attempt to reduce the exposures. The better comparability would allow better exchange of information between MS and hence better usage of resources, by limiting duplicative studies. Better awareness of breast-milk contamination would increase public awareness of the problem and stimulate improvement and research. Documentation of negative health effects would facilitate more rapid intervention when required. Need for awareness and training about the communication of results to the public not to create view of breastmilk as a dangerous, harmful substance
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to encourage and the finance research, education and the promotion of improvement, and possibly required medical intervention.
	Member States will need to encourage and finance the research, education and the promotion of improvement, and possibly required medical intervention.
	Health Research Institutions will need to devote manpower and resources to the research and look for breast-milk donors in a sensitive way, in order to form study cohorts for analyses.

Option 15 b	
	Increased public awareness would facilitate the easier publication of study outcomes in peer-reviewed scientific journals.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	More efficient use of existing resources will be possible.
Health	Confidence in breastfeeding as the best way of nutrition to protect the health of the infant could be restored, and hence breastfeeding could be stimulated, which in turn has repeatedly been shown to have positive effects of health and development of children. Better knowledge of possible prenatal and postnatal heath effects, and long-term effects , and possibilities to develop actions to better protect the foetus and infant. Earlier required medical intervention may reduce long-term morbidity and possibly mortality. The increased awareness and publicity would stimulate health professionals to increase their knowledge of possible health effects associated with exposure.
environmental	Increased public awareness of breast-milk and in utero contamination will probably increase public need to reduce the exposure and stimulate the public to live more environmentally-friendly.
Social	Improved counselling practice, improved answers to the questions of parents. Increased confidence in breast-feeding as the best method of nutrition for the infant.
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Any surveillance program is costly, and the more extensive the program, the greater the costs.
Health	None Treats to breastfeeding by bad communication
environmental	
Social	Possibly stress and discomfort for the mothers while sampling is being done. Treats to breastfeeding by bad communication
Other	
Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.	
No real ones, an analysis of existing knowledge would only show the chasms of scientific knowledge on this issue	
Is further analysis needed?:	
	Not until after data collection.

Option 15 b	
What would be the work programme?:	
	1. Analysis of which chemicals need to be determined/evaluated in the breast-milk (special attention should be paid to lipophilic, bioaccumulative and hydrophobic chemicals). 2. Standardised laboratory testing/equipment and the sampling protocol should be aligned. 3. Obstetricians, gynaecologists and mid-wives should be educated on the need and purpose of the monitoring and the expected outcomes. 4. Obstetricians, gynaecologists and mid-wives should be requested to recruit subjects for the cohort and attain informed consent from the pregnant mothers. 5. The mothers are to additionally be informed with printed matter as to the need, importance and modus operandus of the study, and should have a contact person whom can be approached with questions/problems. 6. The mothers are to express breast-milk at given time intervals and the samples are to be rapidly collected and analysed. Contact materials for pumps, lids and containers should be evaluated and chosen to avoid any contamination. 7. A co-ordinating body (locally, nationally or pan-EU as necessary), including experts in the field, should guard the stream-lining of the study and the co-ordination of the evaluation and interpretation of the outcomes. 8. The subjects and parents/guardians of the children need to be informed of the outcomes in general sense. 9. Study results need to be personally discussed with the parents/guardians of the child when negative health effects have been elicited. 10. The results/outcomes need to be published in peer-reviewed (medical) journals.

Option 16: Specific actions to be taken in relation to NAS

Option 16	
Option for action:	
	Specific actions to be taken in relation to NAS.
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	Response to questionnaires concerning biomonitoring (BM) of children from NAS countries was low (only 2 of 10 countries). Surveillance programs in Poland included measurements of lead in blood , cadmium in urine and covered about 85 000 children mainly inhabiting contaminated territories. In The Czech Republic BM of children is carried out within the Environmental Health Monitoring System (years 1994-2004; 4244 children and 4142 breast feeding women already screened). Parameters measured: lead, cadmium mercury in cord blood, placenta and hairs; PCB's and chlorinated pesticides in breast milk, It means that the remaining eight countries do not posses the systems of BM or such possibility was exploited only for the assessment of occupational exposure.
What is the problem (qualitatively and quantitatively where possible)?:	
	BM of children constitutes the most effective tool for assessment of environmental exposure and possible health effects. To obtain consistent information of children's exposure to the basic environmental contaminants (Cd, Pb, chlorinated pesticides, benzene, dioxins in breast milk, PAHs) the NAS countries should be included in the common European system of BM of children. Such activity is planned within Option 7. Within the European Integrated Environment &Health Monitoring and Response System this option will: - Generate synergies and facilitate the sharing of data and methodologies between the MS and NAS countries - Improve data availability and comparability - Enhance exchange of information

Option 16	
	This option will produce comparable information of exposure which can help to identify environmental problems within NAS countries, improve health promotion and as result public health with respect to the environmental factors.
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to develop strategy of biomonitoring surveys that can be applied on the European scale including NAS. Harmonization of methods and quality assurance programs should be considered.
	NAS will need to identify: - populations to be monitored - institutions working in the field of BM in particular countries, evaluate the analytical possibilities including the existing quality assurance systems.
	The local governments will nominate research institutions responsible for planning and coordinating activities in particular countries.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	- financial: less funds spend on development of strategy , methods and quality assurance programs in NAS
Health	- health: better information at the European level on the health risk, implementation of health promotion programs
environmental	- methods: harmonization of analytical methods, transfer of knowledge, the most sophisticated determinations can be performed in selected European laboratories.
Social	
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	financial : organization of the system in NAS countries depending on the present level. The cost of BM of children surveillance system implemented in 1994 in The Czech Republic (about ten millions of inhabitants) amo unts to about 100 000 Euro per year .
Health	None
environmental	None

Option 16	
Social	None
Other	None
Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.	
No	
Is further analysis needed?:	
What would be the work programme?:	
	Implementation of BM of children in NAS will follow the strategy of biomonitoring surveys that can be applied on the European scale.

Additional input

The European Commission will need to develop strategy of biomonitoring surveys that can be applied on the European scale including NAS. As a First step a harmonized Survey protocol should be developed. As a second tier harmonization of quality assurance programs and if possible methods. However alternative methods fulfilling specific and agreed quality criteria may be use

Option 17: Develop an internet platform for an European inventory of biomonitoring activities

Option 17	
Option for action:	
	Develop an internet platform for an European inventory of biomonitoring activities.
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	There are various activities in Member States and Accession Countries with respect to biomonitoring. Some of the ongoing projects and of the published studies (within the last 10 years) has been collected by the biomonitoring group. On an European level there is no inventory existing for biomonitoring activities.
What is the problem (qualitatively and quantitatively where possible)?:	
	There is no possibility for a systematic and broad exchange of information and experiences. As a consequence a lot is invented several times and many problems are solved twice. Existing experiences can not be used efficiently.
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparability – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	
	The information objectives of the E&H Strategy are covered, i.e. - improved data availability - improved data accessibility - improved data comparability

Option 17	
Main stakeholders affected by the option and how they are affected:	
	The European Commission should realise the internet platform. Institutions that are involved in biomonitoring should report to the internet platform.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	Saving of financial resources by avoiding double work, by using already existing experiences and by increased possibilities for cooperation and coordination
Health	Not direct
environmental	Not direct
Social	None
Other	None
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Financial resources are necessary to establish and to maintain the internet platform

Option 18: Propose timetables for action

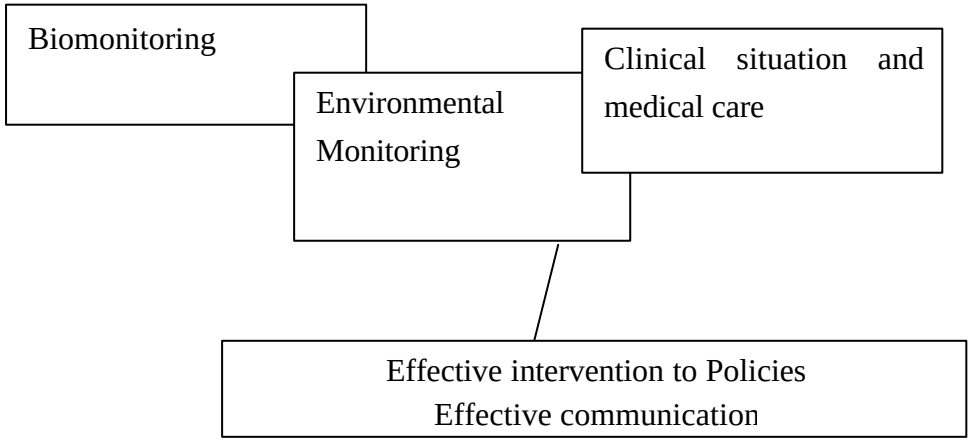
CHILDREN BIOMONITORING

TWO INTERALETED PHASE PROGRAMME

- PHASE 1 Promotional and Capacity Building including a Pilot Biomonitoring EU wide

The aims

a) Integration and synergism of environmental and Health policies and actions e;g environmental monitoring data, bio monitoring, clinical follow up and medical care systems :
Immediate action: establishing a steering Committee with Ministies and stakeholders involved



Synergism with other International activities like WHO, Healthy Environments for Children Alliance at managerial and technical level the
b) Promote education , effective communication and Active involvement of all stakeholder

c) Development of Communication Policy and tools for

- Policy Makers
- Parents
- Public

b) Promote Harmonization of Biomonitoring at EU level in terms of

- Design of the program
- Methodology /QA
- How it will be linked to environmental monitoring and the health to care system
- Biomarkers

c) Identify needs for capacity building and start to promote them;

d) Fine tuning research needs

- On links between exposure and effects on children, particular sensitivities of children
- On new methods and biomarkers
- On how to minimise effects through enhancing mechanisms of defence. etc

- PHASE 2
- The AIM:
- Establish a long term stable Core EU Biomonitoring aiming to support preventive and risk reduction policies. This will achieved through multidisciplinary /multistakeholders concerted actions

Additional options

1. Related to exposure assessment

Option A1: Geographical mapping, at resolution level of administrative entities, of pesticides (active substances of plant protection products) , based on mandatory farm level record keeping of PPP use to be supplied annually to the competent authorities and accessible to the public

Option A1	
Option for action:	
	Geographical mapping, at resolution level of administrative entities, of pesticides (active substances of plant protection products) , based on mandatory farm level record keeping of PPP use to be supplied annually to the competent authorities and **accessible to the public.** This obligation can be extended to non-agricultural users of PPP and to biocides users. This measure can be adopted at first in the context the Thematic Strategy on the sustainable use of pesticides (in elaboration at Commission level).
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	Member States belong over sales data which are used as a proxi for use data. These data are however aggregated for each country and for categories of pesticides. Under the TAPPAS programme, some Member States had the opportunity to have a better information on use patterns for certain crops. The European Crop Protection Association (ECPA) undertakes regular surveys at farm level to determine use patterns for major crops. These data are published , but in an aggregated form and for categories of pesticides, together with Eurostat. However due to discrepancies in use data provided by Member States mainly under the TAPPAS project and by ECPA, it was agreed between Eurostat and ECPA to provide revised use data. Farm level use reporting is already mandatory in pioneer countries in Europe implementing pesticide use reduction programmes like the Netherlands, Denmark and Sweden and also in Norway.

Option A1	
What is the problem (qualitatively and quantitatively where possible)?:	
	Diffuse pesticide pollution sources are not known. This geographical mapping action is in line with the objectives of the E & H Strategy to achieve a better understanding of the environmental threats to human health and to plan policy responses to reduce the disease burden and to prevent new health threats.
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to propose to Member States a system to request mandatory farm level use record keeping and data supply. The competent national authority shall submit the information to the Commission, annually. Mapping could be done at Eurostat level for instance. Farmers will have to keep journals recording all applications of pesticides and when the applications were made.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	More efficient use of studies ressources
Health	Specific pesticide diffuse pollution mapping (such as developped in US such as New York, Oregon and California States) are powerful tools for epidemiologists and physicians to evaluate the degree of scientific evidence of a causal link between exposure and diseases or disorders. This could prompt policy action. It is also an important tool for the choice of biomarkers for biomonitoring surveys or biomonitoring research studies as well as for hot spots identification.
environmental	Links to be made more easily between pesticide use and biodiversity
Social	The right to know will be effective for citizens
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Costs to organise the system and to run it
Health	none
environmental	none
Social	Some additional organisation requirements for farmers but these could turn out as advantage for farm management.
Other	

Option A1	
Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.	
Is further analysis needed?:	
What would be the work programme?:	
	Request for pesticide use reporting is possible at very short term in Member States developing an integrated pesticide reduction programme . Set up of a geographical mapping system is to be seen, at first, in the context of the Thematic Strategy on the sustainable use of pesticides and later also in the context of the elaboration of an EU Regulation on Pollution Release and Transfer Registers (PRTR), in line with the Kiev Protocol on PRTR.

2. Related to exposure reduction

Option A2: Adoption of a legislation on pesticide dependency reduction in Europe, in the context of the elaboration by the Commission of a Thematic Strategy on the sustainable use of pesticides aimed at addressing the use phase of pesticides as a complement to the pesticides authorisation Directive 91/414/CEE.

Option A2	
	Preliminary statement : *Because many chemicals might act together to give rise to adverse effects, and there are no unexposed populations, it will be very difficult to identify meaningful associations between exposures to certain chemicals and adverse health effects. Indeed, it may take many years to collate data sufficient to prove a particular chemical is responsible or partly responsible for certain effects. This argues for the need for a precautionary exposure reduction strategy.* *According to the Commission Communication on the Sixth Environmental Action Programme, there is sufficient evidence to suggest that the scale and trends of problems caused by pesticides are serious and growing. Particular concerns include the contamination of groundwater and foodstuff, and the continuing accumulation of certain pesticides in plants and animals.*[36] *The effects of small quantities of pollutants that accumulate in human bodies are also poorly understood. There is consequently a need to protect vulnerable groups such as children and the elderly.*[37]
Option for action:	
	Adoption of a legislation on pesticide dependency reduction in Europe, in the context of the elaboration by the Commission of a Thematic Strategy on the sustainable use of pesticides aimed at addressing the use phase of pesticides as a complement to the pesticides authorisation Directive 91/414/CEE. This can be achieved by a set of integrated measures to be implemented at national level and by a progressive shift from intensive agriculture to integrated crop management - to be defined for each crop type by Member States and

[36] *Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the Sixth Environment Action Programme of the European Community 'Environment 2010: Our future, Our choice'*, Section 5.5 on pesticides.

[37] *Id.,* Section 5.1 on environment and health issues.

Option A2	
	Commission -, integrated farming systems and organic farming.- (see proposed text for a Directive on Pesticide Use Reduction in Europe at http://www.pan-europe.net , supported by many stakeholders in 27 countries in Europe)
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	Eurostat data show that annual pesticides sales (in tons of active ingredients) have increased in EU countries over the last decade despite a clear trend in arable farming towards active ingredients that are effective at lower dosage. Such an increase in pesticide dependency is likely to increase the overall exposure to pesticides of the general population including foetuses , infants and children.
What is the problem (qualitatively and quantitatively where possible)?:	
	According to the Commission Communication on the 6th Environmental Action Programme, there is sufficient evidence to suggest that the scale and trends of problems caused by pesticides are serious and growing. Particular concerns include the contamination of groundwater and foodstuff and the continuing accumulation of certain pesticides in plants and animals. The effects of small quantities of pollutants that accumulate in human bodies are also poorly understood. There is consequently a need to protect vulnerable groups and the elderly. Experience shows that the controls set in place by Directive 91/414/EEC are not sufficient to prevent significant contamination of water, air, and soil by pesticides.This action will contribute to the ultimate objectives of the environment and health strategy by « reducing the disease burden caused by environmental factors » and by « preventing new health threats caused by environmental factors »
Main stakeholders affected by the option and how they are affected:	
	Commission will need to prepare a legislation with targets and timetables to be implemented by Member States which will have to elaborate national pesticide reduction plans. Farmers will need incentives and technical support from Member States and Commission for conversion to low pesticides farming systems.
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples	

Option A2	
and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	less health and research costs Commission study (Integrated management systems in te EU, Agra Consulting , 2002) has shown that integrated crop management/ integrated farming systems result in the same profitability for farmers as conventional intensive agriculture. The "externalisated " costs of pesticides will be reduced
Health	immediate prevention of diseases or disorders in the general population exposed trough food, and in those exposed directly to pesticides in the environment
environmental	increase of biodiversity and decrease of ecosystem compartments contamination.
Social	Commission studies have shown that integrated crop management/ integrated farming systems result in the same profitability for farmers as conventional intensive agriculture.
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Financial : need to invest money to develop research in alternative crop production systems , independent extension services, farmers education. There can be a possible decrease of share of market for the pesticide industry and related businesses
Health	None
environmental	None
Social	
Other	
What would be the work programme?: linked with the agenda of the Thematic strategy on the sustainable use of pesticides	

Option A3: Definition, in the context of the review of Directive 91/414/EEC on Plant Protection Products authorisation, of exclusion criteria from Annex I (positive list of active substances of pesticides agreed at EU level) of substances having PBT or CMR or vPvB or endocrine disrupting properties.

Option A3	
Option for action:	
	Definition, in the context of the review of Directive 91/414/EEC on Plant Protection Products authorisation, **of exclusion criteria from Annex I** (positive list of active substances of pesticides agreed at EU level) of substances having PBT or CMR or vPvB or endocrine disrupting properties.
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
	No exclusion criteria exist for such substances, based on intrinsic properties. The authorisation is based solely on risk assessment of each substance tackled individually. No consideration is given to possible combination effects, among substances sharing the same mechanism of toxic action or likely to interact synergistically. Moreover, as stated in the 2002 WHO/EEA report "Children's Health and environment- a review of evidence", current core test and risk assessment methodologies do not fully ensure pesticide safety for foetuses, infants and children which are more vulnerable and often more exposed. This request for exclusion criteria has also been made by the European Parliament (Resolution May 2002) and by the Council of Environment Ministers (Conclusions December 2001) but it is not yet clear if it will be proposed by the Commission and if proposed at which level of evidence of the above mentioned properties .
What is the problem (qualitatively and quantitatively where possible)?:	
	We are just beginning to understand the health effects of exposure to small quantities of pesticides, often over a period of time as well as the way different contaminants interact in our bodies. A clear overall picture of health impacts resulting from complex real life exposure is missing and will be very difficult to obtain. Pesticides are the only chemicals designed to kill organisms and voluntarily released into the environment. Therefore, exclusion from the market of pesticides showing properties of high concern is a measure that will contribute to the goals of the Strategy to reduce the disease burden and to prevent new health threats.

Option A3	
Main stakeholders affected by the option and how they are affected:	
	Pesticide industry will have to prove the toxicological safety of their products and available toxicological and epidemiological literature will have to be considered by the Commission, EFSA and Member States representatives
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	Less health costs
Health	Disease-disorders prevention
environmental	Additional ecological benefits
Social	
Other	Stimulation of innovation in alternative products or crop protection systems
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	Less profitability for the pesticide industry
Health	None
environmental	none
Social	None
Other	
Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.	
Is further analysis needed?:	
would be the work programme?: In the context of the adoption of a revised Directive 91/414/EEC	

3. Related to health data

Option A4: Supporting of developing of child cancer registers and spontanous abortion register

Option A4	
Option for action:	
	Identify actions that could start immediately at a European level **Supporting of developing of child cancer registers and spontanous abortion register.** Children cancer is incorporated in cancer registers and very few countries has separated databases. The work would be administrative and requests reconstruction of existing databases for adults and launching of new database. Of course it would be of unique value to have as an additional information exept pathological report occupational exposure of parents and address by which local exposure could be identified. The register of spontanous abortions is key in monitorng and detection of possible exposure in environment (rofessional exposure should also be concluded). Hospital archives contain these data and once again it would be job which could be performed by medical students, regarding investment. Central European database would be up dated annualy and trends would indicate deviations in much shorter time than cancer register where latency even from leukemia is 3-5 years. Investment in database will have long term benefit in improving health care after overexposures or implamantation of preventive health care measures in conditions where elimination of some agent from enviroment is not possible in a requested time. Database will give also transparency of mostly affected areas in Europe and force stakeholders to act more effectivly as improving would be also detectible and monitored. At the national level oragnization of multidisplinary collaborative projects with already runnig project with the child as a topic. Such collaboation gives new opportunity and could have as a benefit racionalization of funds for common or overlaping research aims. In R Croatia recently was launched collaborative project with title « Biomedical research of reproduction and development». Partners on the project are scientists from several research institutes, medical school but also clinicians. In a such way there is perfect combination of research , interactive input and education between professions.

Option A4	
	Taking part on organiziation of sessions at major international conferences on environment, cancer, immunology, nutrition etc. Each of us can be proactive and offer child as a topic. EC in the same time as supportive authority gives to conference significance. Introduction of interviews at pediatric departments. Each pacient intervju except regular information on disease should be additionally accompanied with information on parents exposure, living environment and diet. This is in close relation with education of pediatricians and stimulation of pediatrician to perform such interviews. Stimulation could be solve through participation at conferences, waved registration fee at conferences or decrease in the price of literature. Preparing of protocol for actvities in a case of nuclear accident (nuclear plants, terroristic actions). All protocols are prepared for adults. Such protocols should include special treatment of children (diet with vitamins and antioxidants, etc). Supporting projects in order to get control values for methods applied in genetical toxicology. All we have is from Chernobyl studies.
What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:	
What is the problem (qualitatively and quantitatively where possible)?:	
How does this option contribute to the goals of the Strategy ? 1) to the European Integrated Environment & Health Monitoring and Response System : – Generate synergies and facilitate the sharing of data and methodologies – Increase the understanding of the environment and health relationship – Improved data availability, accessibility, comparibility – Enhanced exchange of information 2) to improve public health with respect to environmental risk factors 3) to the research agenda 4) to raise awareness, to educate	

Option A4	
Main stakeholders affected by the option and how they are affected:	
	The European Commission will need to provide support for training and coordination activities…
	Member States will need to identify national priorities, develop a plan of action to coordinate national activities and effective cooperation with EU and International activities
	Health Research Institutions will need to promote research on open issues
	… etc
benefits, advantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions. For example, how will the impacts relate back to the problem identified above?)**:**	
Financial	
Health	
environmental	…
Social	
Other	
Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)	
Financial	
Health	None
environmental	Ecological data will become less specific, due to compromise
Social	
Other	
Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.	

Additional input

Establisment of Multidisciplinary National Steering Committee which will coordinate all activities at National Level, identify priorities and promote links, input and cooperation with EU and WHO relevant activities.
Supporting specific training and workshops for health professionals to optimise their abilities to understand and treat environmental related health problems in children. To this effect cooperation with WHO should be promoted.