Report on Actions and Recommendations for
”Integrated Monitoring of Endocrine Disrupters”
in the framework of the European Environment and Health Strategy (COM(2003)338 final)

Produced by the Technical Working Group on
Integrated Monitoring

subgroup
Integrated Monitoring of Endocrine Disrupters

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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.

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EXECUTIVE SUMMARY

1. This document has been produced by the Endocrine Disrupters Sub-group of the Technical Working Group on Integrated Monitoring, as part of the European Commission’s SCALE initiative (Science, Children, Awareness raising, Legal instruments, and Evaluation).

2. In January 2004 the Endocrine Disrupters Pilot Project Technical Working Group (ED TWG) delivered the Baseline Report, which provides an analysis of requirements for and advantages of an integrated monitoring system, based upon an overview of monitoring activities provided by eleven European countries, as well as the European Commission and NGOs.

3. Major points highlighted in the Baseline Report include: a) the need to prioritise candidate endocrine disrupting chemicals (EDCs), as well as natural, synthetic and/or plant hormones present in the environment and food; b) the need to take into account three different types of data sources, i.e.: environmental monitoring (including foods, biota, consumer products), biomonitoring of humans, and monitoring of health effects that may have a plausible association with early exposure to EDCs; c) the considerable amount of available relevant information that could be important for an integrated monitoring system if properly exploited; d) the need to feed-back new research into monitoring strategies; e) the need for careful consideration of potential problems related to quality and harmonisation of methods and procedures.

4. Thus, the Baseline Report has provided the necessary basis to evaluate, elaborate and prioritise the options for further actions. Overall, the proposals for Options for Action recommend that priority be given to linking and integrating available data sources, so giving an “integration added value”. The proposals also aim to build up a tiered approach where targeted action is driven by signals (including hotspots of exposure, of markers of effects on biota, of potentially relevant health effects). Other critical recommendations include: feed-back of research deliverables into an integrated monitoring system; the need for most Options (1, 2, 3, 4, 5, 7, see below) to undergo feasibility studies before full implementation; the need for all Options to provide appropriate feed-back to and from the EU strategy on Endocrine Disruption; full involvement of stakeholders through awareness raising and risk communication.

5. Specific options mainly targeted to generate synergies and facilitate data sharing and methodologies (Family 1) include the following:

5.1 Option for Action 1 (Integration of existing national monitoring activities with a focus on Bio-banks/Human Bio-monitoring) puts emphasis on the development, harmonisation and integration of biomonitoring activities and biobanks, in order to pinpoint possible risk factors for populations/groups with high incidence of certain health effects. It has also to be recognised that development of biobanking entail ethical, legal and policy issues (e.g. privacy) that need to be dealt with through a joint effort between DGs ENV, SANCO and RESEARCH. Accordingly, further development of biomonitoring, with special emphasis on long-term biobanks related to long-term effects of in-utero exposures was identified as a priority research need.

5.2 Option for Action 2 (Endocrine-related Health Effects for Integrated Monitoring) identifies a list of endocrine-related diseases with potentially well-established diagnostic
criteria and surveillance tools, *i.e.* hypospadia/cryptorchidism; neonatal hypothyroidism; precocious puberty; testicular cancer; breast cancer. Moreover, a pilot study should evaluate whether other diseases (*e.g.*, endometriosis) can be included. Identification of existing structures collecting data and harmonisation of diagnostic and investigative criteria (*e.g.* registries) will allow a European-wide mapping of selected conditions. Hotspots of such diseases will serve as first-tier signals for further investigation and possible intervention/management in an integrated system for monitoring relationships between environment and health (see 9).

6. Specific options mainly targeted to *improve data accessibility* (Family 3) include the following:

6.1 *Option for Action 3* (Develop Criteria for Prioritising ED Substances to be Monitored) that identifies a set of Pilot monitoring programmes to be conducted within SCALE in line with the Community Strategy for Endocrine Disrupters. The Option requires a harmonised procedure on which substances to be monitored as priority from a health risk perspective (especially concerning children and pregnant women); as outlined in the Baseline Report prioritisation should include relevant natural, synthetic hormones and phytohormones. Moreover, the comparability of data by adopting reference methods for sample treatment and EDC detection will improve since European monitoring activities in the different MS/AC will focus on the same (most relevant) ED assessed by the same methodologies. This will support the realistic estimate of human exposure to priority EDC at European level; moreover, identification of potential exposure hotspots could direct targeted studies on ED-related health effects in particularly exposed populations.

6.2 The complementary *Option for Action 3.1* proposes the full exploitation of the already existing *EUSES* (European Uniform System for Evaluation of Substances). EUSES can be a valuable tool for pre-selection of priority EDCs, integrating data on toxicological potency and exposure determinants (production volume, use pattern, physicochemical properties *etc.*) to predict both presence in the environment and the potential for uptake by humans. Moreover the system can work on a local level as well as on a larger geographic scale. Since EUSES has been developed, mostly for occupational exposures, a feasibility study should assess the modifications required to fit within the SCALE objectives. Obviously, understanding of the environment and health relationship cannot rely solely on exposure assessment and epidemiology; instead it will also require mechanistic and toxicological research, as underlined in Option for Action 10 (see 9).

7. Specific options mainly targeted to *enhance information exchange and better use of existing data* (Family 5) include the following:

7.1 *Option for Action 4* refers to the need for integration of the existing information relevant to ED which has to be reported by member States to the EC under various directives and regulations and, where feasible, research programmes. The proposal will promote the exploitation and “integration added value” of the considerable amount of mandatory data that are being generated. These will include data sources on releases and concentrations of various ED (*e.g.* the IPPC Directive, the Dangerous Substances Directive, *etc.*) as well as reported through the health-related initiatives (*e.g.* the “Europe against Cancer programme”, “Health Monitoring Programme” *etc.*). However, to date, the most valuable information is not adequately accessible, or searchable by governments, researchers or the public. The Option recommends that the Commission carry out a feasibility study on putting all the relevant information into a relational database to make the data accessible,
with a view to getting a more precise and better focused picture, both on the occurrence and sources of EDCs, and possible links with health effects. Different key issues to be dealt with carefully have been identified, including: the need to clearly identify what degree of quality assurance has been applied in the generation of information; the need for a thorough examination of what databases exist. It is also recognised that a similar situation would probably exist for heavy metals and dioxins, and that the proposal may be relevant not just for ED.

7.2 Option for Action 5 (To Develop a Framework for Integrating Exposure Information). The Option will allow monitoring programmes to be designed with a broader perspective, in order to fully exploit the outcomes for exposure analysis of human health and ecosystems. An integrated framework will allow the iterative flow from Type I monitoring programmes (production, uses, etc.) through to Type II (emission releases), Type III (measures in abiotic compartments) and IV (measures in biota). The related Option for Action 6 (Transfer Information from Wildlife Effects to Human Health Assessment) deals with a critical point to develop a framework (both conceptual and operational) for integrating “exposure” and “effect” data. The Options deals with the potential to use information on endocrine disruption effects observed in wildlife (particularly in hot spots) to establish what is the relevance of the different chemicals considered as endocrine disrupters for human health; emphasis should be given to evaluating the relevance for the human population of routes of exposure of wildlife. This Option will contribute to setting priorities for the monitoring of chemicals relevant for humans at the regional, local and continental scales.

7.3 Option for Action 7 is a more general one, though directly relevant to the above issues. Nicknamed “How to run with weak limbs?” this option underlines the need to develop a network of centres, starting from existing structures in MS and AC, in order to implement and update the Environment and Health Strategy. Although it is intended as a general option for the Strategy, it will be especially relevant to the endocrine disruption field, where monitoring activities are less well established than for other pollutants (e.g. heavy metals, PCBs/dioxins) since a consensus has yet to be reached over actual priorities and health risks. Additionally, analytical standards and reference values have yet to be fully developed and harmonised.

8. Specific options mainly targeted to risk communication and awareness raising (Family 6) include the following:

8.1 Option for Action 8 (Feasibility study on risk communication and awareness raising). The proposed feasibility study should focus on “case studies” dealing with priority areas of SCALE such as childhood respiratory diseases, asthma or endocrine disrupting effects. Special emphasis should be placed on mechanisms for co-operation and network building between stakeholders. Taking into account already existing experiences (OECD, Germany etc.) guidelines for risk communication and awareness raising should be defined.

8.2 Option for Action 9 (An approach to promote active involvement of human health and environment professionals in integrated monitoring programmes). The goal is to integrate, promote and support the already established networks of Environmental Health Professionals and the Medical Community of Doctors, Scientists and Health Care Providers that can work with monitoring programmes, thus providing highly valuable inputs on the linkages between human health and environmental factors as well as on the
awareness of the community. The truly multidisciplinary character of the ED-related topics (as outlined in the Options for Actions summarised in the above paragraphs) allows for a good Pilot Project that could be extended or replicated as appropriate for the full Environment and Health Strategy. In particular, it is proposed to utilise the existing framework of the Commission’s Erasmus Mundus Programme, and the Policy Interpretation Network on Children’s Health and the Environment (PINCHE) in order to offer the opportunity for a solid, cost-effective implementation. Moreover, key venues for supporting and disseminating the integrated monitoring programme can be the higher education institutions in all MS as well as International Associations such as the International Federation of Environmental Health (IFEH) and The International Society of Doctors for the Environment (ISDE). The first step of the work programme will be the assessment of current activities and actions on education and awareness-raising in environment and health at MS and EC levels. An important outcome of the Option will be to promote the integrated approach developed through SCALE in the training and practical work of environmental and health professionals in Europe.

9. Option for Action 10 includes the Recommendations from the Technical Working Group on Endocrine Disruptors to the Technical Working Group on Research Needs. Obviously, emphasis is given to those research deliverables that can be especially critical to the development of an integrated monitoring system for EDCs and endocrine-disrupting effects. In particular, major topics recommended are i) the development of mother-child cohorts, encompassing effects other than reproductive ones (e.g., immune, neurological) as well as factors other than endocrine-active chemicals (e.g., dietary, noise, genetic); ii) the elaboration of biosensors/biomarkers for all major mechanisms of endocrine disruption (i.e., including thyroid disruption, enzyme inhibition, etc.) as well as taking into account the advances of genomics and proteomics, iii) the development of research cross-linking environmental and human health issues, iv) the development of experimental models to better understand different exposure routes, low-dose effects and genetic susceptibility, as well as to support the OECD programmes on ED identification and testing.

10. Besides specific Options for Actions, the Technical Working Group on Endocrine Disrupters considered other key related issues which need to be addressed.

10.1 Issues to be addressed under the Environment and Health Strategy

10.1.1 Education and Awareness raising of mothers-to-be. As a general statement it is recommended that pregnant women and parents-to-be should have access to well-considered advice on all aspects related to helping to ensure the birth of a healthy baby, such as diet, lifestyle and officially recommended supplements. In particular, it was considered appropriate to provide balanced advice relating to ED, because available scientific data suggest that an uncontrolled exposure may lead to long-term impairment of the health of exposed conceptus. Therefore, advice to pregnant women should also include indications on precautionary action to avoid unnecessary exposure to ED and other chemicals. Experts on communicating medical and health issues would need to be involved in the elaboration of recommendations.

10.1.2 Mechanisms to ensure rapid, accurate and efficient iterative updating of monitoring programmes and policy measures. The ED TWG recognised that it was extremely important, in order to protect human health and the environment, to put mechanisms in place which can respond quickly and appropriately when, e.g. the results of monitoring
programmes reveal significant new information, new substances are shown to possess ED activity, or research programmes reveal new mechanisms and symptoms. It was also felt essential that such new findings should be assessed by a body of officially approved experts/policy makers in order that appropriate follow-up action could be taken to verify the findings and that, if appropriate, policy measures could be taken, if necessary, in line with the EU Communication on the Precautionary Principle. One option could be for a working group to be set up within the EU ED Strategy in order to consider relevant information and how to deal with it.

10.1.3. As a follow-up to Option for Action 1 (see 5), the ED TWG discussed problems and constraints for biomonitoring needs a careful consideration concerning both harmonisation of technical aspects (what samples, storage conditions etc.), privacy and informed consent (what can be asked in the accompanying questionnaire? Can samples being taken from people without them knowing their future utilisation?) and more general legal and ethical issues (accessibility of data, acceptance of invasive sampling). The problems outlined need to be dealt with carefully at EC level.

10.1.4 Integrated monitoring will reveal individuals/groups in which the body burden of environmental persistent toxicants is high. The ED TWG feels ethically obliged to recommend that information should be gathered on possible remedial measures in order to reduce exposure and to prevent possible health effects and that such information, when available, should be disseminated to health services of all MS/AC.

10.2 Actions needed under the EU ED Strategy

10.2.1 The ED TWG acknowledges that a lot of very useful information has been generated on candidate EDCs under the EU ED Strategy. However, because such information is distributed in various reports it is still not in an easily accessible form that enables users to clearly identify the concerns and data-gaps. It is therefore recommended that the EC should work towards a publicly accessible data-base for holding information on candidate EDCs. Mechanisms for the regular updating of this data-base would need to be put in place as proposed, e.g., by the Danish Environmental Protection Agency.

10.2.2 Some chemicals have been identified as candidate endocrine disrupters under the EU ED strategy, but for many other chemicals data are currently lacking. It was therefore considered appropriate that an important step in the development of an integrated monitoring strategy for ED would be to support the identification of chemicals with endocrine disrupting properties. It is thus proposed that the CSTEE, or another relevant independent EU scientific advisory body, should review whether the toxicity information required in various legislative frameworks is sufficient to identify EDCs, with particular attention to the toxicity information currently required under the draft REACH legislation. Moreover, the relevant scientific body should identify which endocrine disrupting chemicals might not be picked up in the current REACH testing proposals, and which currently available screening and/or test methods could be included to improve the identification of EDCs. In particular, the review of the ability of current and proposed EU legislative frameworks to identify EDCs and the gaps, would provide a useful foundation for the active role of the EU within the OECD Task Force on Endocrine Disrupters Testing and Assessment.

11. Overall, the aim of the proposed Options are directed towards creating a smooth and consistent flow from integration of existing activities, through to priority setting,
identification of areas critical for further targeted actions and more general issues related to networking, policy and awareness raising, with research providing the necessary iterative feedback for implementation and updating.
INTRODUCTION

In January 2004 the ED-Pilot Project Technical Working Group (ED TWG) delivered the Baseline Report, which provides an analysis of requirements and advantages of an integrated monitoring system. This Baseline Report identifies problems and deficits and missing links and was based upon an overview of monitoring activities provided by eleven European countries, as well as the European Commission and NGOs. Hence, the Baseline Report provided the necessary basis to evaluate, elaborate and prioritise the Options for further Actions.

The main points that were highlighted in the Baseline Report include:

- the need to prioritise candidate endocrine disrupting chemicals (ED) (as well as natural, synthetic and/or plant hormones in the environment and food), through both toxicological information and assessment of available exposure data.
- the need to take into account three types of data sources, collected for different purposes, i.e.: environmental monitoring, (including also biota, food and consumer products), biomonitoring, and monitoring of health effects that may have a plausible association with exposure to ED during early life stages (e.g. hypospadias; testicular cancer).
- the considerable amount of relevant information from both monitoring programmes and research activities, which are not specifically targeted to ED, but that can become a major data source for an integrated monitoring system.
- the need to feed-back new research into monitoring strategies,
- the need for careful consideration of potential problems related to quality and harmonisation of methods and procedures, including sampling, analysis, diagnostic criteria for relevant health effects, reporting, etc.

Overall, the proposals for Options for Action recommend that priority be given to linking and integrating available data sources, so giving an “integration added value”. Thus, Option for Action 4 relates to integrating available information relevant to ED which has to be reported by MS to the EC under various directives, regulations and research programmes. The strongpoint of this proposal is that it will allow integration of the mandatory data that is being generated, possibly including, in addition, major EU research programmes (Networks of Excellence, Integrated Projects, Clusters); therefore this proposal is relevant to the activities of other DGs (SANCO, Research) as well as DG ENV. The possible lengthy time-lag between suspected exposures (occurring in-utero and/or early childhood) and the onset of some potentially ED-related effects (e.g. some types of cancers) was carefully considered.

Accordingly, Option for Action 1 (Integration of existing national monitoring activities with a focus on Biobanks/Human biomonitoring) and the priority research activity agreed by the group (which was to establish a long-term biobank related to in-utero exposures) put emphasis on the development, harmonisation and integration of biomonitoring activities and biobanks, in order to pinpoint possible risk factors for populations/groups with high incidence of certain health effects. It has also to be recognised that development of biobanking entail ethical, legal and policy issues (e.g. privacy) that need to be dealt with through a joint effort between DGs ENV, SANCO and RESEARCH.

The proposals also aim to build up a tiered approach, where targeted action is driven by signals (including hotspots of exposure, of markers of effects on biota, of potentially relevant health effects). In this respect, Option for Action 2 (A list of endocrine-related diseases with
potentially well-established diagnostic criteria and surveillance tools). **Option for Action 3** (Criteria for sorting priority ED substances for monitoring) and the complementary option **3.1** (exploiting the European Uniform System for Evaluation of Substances-EUSES for priority screening), **Option for Action 5** (Integrating different exposure data sources) and **Option for Action 6** (Transfer information from wildlife effects to human health assessment) are all appropriate to the development of a framework (both conceptual and operational) that will allow integration of data relevant to both “exposure” and “effect” and to identify different priorities (for research, assessment, management, enforcement of legislative actions, harmonisation).

**Option for Action 7** is a more general one, though directly relevant to the above issues. Nicknamed “How to run with weak limbs?” this option underlines the need to develop a network of centres, starting from existing structures in MS and AC, in order to implement and update the Environment and Health Strategy. Although it is intended as a general option for the Strategy, it will be especially relevant to the endocrine disruption field, where monitoring activities are less well established than for other pollutants (e.g. heavy metals, PCBs/dioxins) since a consensus has yet to be reached over actual priorities and health risks. Additionally, analytical standards and reference values have yet to be fully developed and harmonised.

Recommendations from the ED TWG to TWG Research Needs (**Option for Action 10**) deal with those research deliverables that can be especially critical to the development of an integrated monitoring system for ED and endocrine-disrupting effects. In particular, major topics recommended are i) the development of mother-child cohorts, encompassing effects other than reproductive ones (e.g. immune, neurological) as well as factors other than endocrine-active chemicals (e.g. dietary, noise, genetic); ii) the elaboration of biosensors/biomarkers for all major mechanisms of endocrine disruption (i.e. including thyroid disruption, enzyme inhibition, etc.) as well as taking into account the advances of genomics and proteomics, iii) the development of research cross-linking environmental and human health issues, iv) the development of experimental models to better understand different exposure routes, low-dose effects and genetic susceptibility, as well as to support the OECD programmes on ED identification and testing.

It should be realised that several of these Options for Action require a significant effort to evaluate the approaches and the extent of integration of databases and/or activities. Thus, *feasibility studies* are envisaged for many Options for Actions (1, 2, 3, 4, 5, 7). Full implementation may then ensue, pending the outcomes of feasibility studies.

Finally, all the above Options need appropriate feed-back to and from the EU strategy on Endocrine Disruption.

Some of the Options for Action proposed here (**numbers 8 and 9**) are additional options that focus on the key issue of *awareness raising*, which is required in order to strengthen, develop and support the Environment and Health Strategy. In particular, **Option for Action 8** outlines a feasibility study on risk communication, to gather details about some initiatives within the EU and provide recommendations for taking this forward. **Option for Action 9** deals with approaches to promote active involvement of health operators in integrated monitoring programmes.

The TWG ED has also identified additional issues (see section on "Key Related Issues") to be considered within the *Environment and Health Strategy* as well under the *EU Endocrine Disrupters Strategy*. 
The former include: i) well balanced advice to mothers-to-be and pregnant women in order to avoid unnecessary exposures to chemicals; ii) the need to develop the Integrated European monitoring system as an iterative process, taking into account information from research as the results become available; accordingly, the need for mechanisms to ensure rapid, accurate and efficient iterative updating of monitoring programmes and policy measures is presented; iii) the need to carefully consider at EC, as follow-up of Option for Action 1, problems and constraints for biomonitoring, including harmonisation of technical aspects, privacy and informed consent and more general legal and ethical issues; iv) the recommendation to consider and disseminate, whenever available, valid remedial measures for people with high internal levels of ED.

The latter are based on the basic need to clearly identify candidate EDCs in order to perform sound and knowledge-based integrated monitoring. Thus, the ED TWG issued the following recommendations: v) that the EC should work towards a publicly accessible data-base for holding information on candidate ED as well as on mechanisms for the regular updating; vi) that relevant independent EU scientific advisory bodies should review whether the toxicity information required in various legislative frameworks (with special emphasis on the current draft REACH legislation) is sufficient to identify EDCs, and identify which test methods should be prioritised for development. The ED TWG considered that this information could be used as a basis to promote the active role of the EU within the OECD Task Force on Endocrine Disrupters Testing and Assessment.

Overall, the aim of the proposed Options are directed towards creating a smooth and consistent flow from integration of existing activities, through to priority setting, identification of areas critical for further targeted actions and more general issues related to networking, policy and awareness raising, with research providing the necessary iterative feed-back for implementation and updating.
OPTIONS FOR ACTIONS AND RECOMMENDATIONS

FAMILY 1 - OPTIONS TO GENERATE SYNERGIES AND FACILITATE DATA SHARING AND METHODOLOGIES

Option for action 1: Integration of existing national monitoring activities with a focus on Bio-banks / Human Bio-monitoring

(This action also fits under families 3, 4 and 5)

There are many ongoing activities in Member States dealing with integrated health and environment monitoring assessments for chemical residues. Activities include large scale “environmental surveys” and food monitoring programmes, which are performed at regular intervals as well as single projects. However, there is a lack of co-ordinated European-wide activities on integrated bio-monitoring, especially when it comes to “human monitoring”. One reason seems to be that “human monitoring” is not covered by harmonised EU-legislation. Different legal and ethical views in Member States concerning “human bio-monitoring” in general and “bio-banks” in particular seem to be an additional obstacle for deriving, in the short-term, a unique EU-wide approach. Bio-banks (banks for samples of blood, breast milk, environmental species etc.) seem to be an important tool for facilitating improved co-ordination and integration of bio-monitoring activities within the European Union.

As an Option for Action, it is proposed that a feasibility study be performed in the first instance, which will include creation, on a voluntary level, of a panel of experts (ring panel) consisting of individuals involved with existing Member States' bio-banks. Based on the outcome of the feasibility study, a concept for the extension and promotion of bio-bank activities as a tool for a tailor-made integrated monitoring system for chemical residues should be developed.

It was also recognised by the ED TWG that further bio-bank initiatives were needed, and that sufficient funds would need to be ensured so that long-term storage of samples could be guaranteed. The tissues to be stored should be carefully chosen in order to provide the best information on in-utero exposures, and in such a way that the individual’s levels of contaminants of current concern, and those suspected in future could be determined. To find potential associations with adverse health outcomes, long-term health surveillance of the people included would also be needed. It was suggested that EU countries with varying degrees of industrialisation and different geographical locations should be included in such initiatives. Therefore, future EU co-ordinated bio-banks were put forward as a priority research need (see Option for Action 10).

Option for Action 2: Endocrine-related Health Effects for Integrated Monitoring

(This action also fits under families 2 and 4)

As stated in the Baseline Report, integrated monitoring should target both endocrine disrupting chemicals and endocrine-related effects. Hence, this Option for Action focuses on a list of endocrine-related diseases with potentially well-established diagnostic criteria and surveillance tools. The diseases identified within the ED Pilot Project are:

- hypospadia/cryptorchidism;
- neonatal hypothyroidism;
- precocious puberty;
- testicular cancer;
- breast cancer.
Hotspots of such diseases will serve as first-tier signals for further investigation and possible intervention/management in an integrated system for monitoring relationships between environment and health.

As the Baseline Report of the ED Pilot Project highlighted, there are several surveillance systems in MS and AC related to the diseases listed above. However, such systems have variable geographical coverage (from regional to international) as well as requiring integration and harmonisation. Moreover, there is a general lack of integration with exposure (environment, food, biomonitoring) data sources and a poor utilisation of diseases surveillance data in order to trigger or direct identification/management of risk factors. Finally, insufficient attention is given (partly due to an understandable methodological difficulty) to exploring possible environmental risk factors for endocrine-related diseases in adults arising during early (prenatal/neonatal) life stages.

Option for Action 2 will be implemented through the following steps:

- identification (inventory) of existing structures in MS and AC that gather data on the relevant diseases. All National Health Institutes of MS would be involved in such a study, as well as medical societies and NGOs (patient’s associations) as appropriate.

- providing a harmonised set of diagnostic criteria for selected diseases when required (e.g. for hypospadia/cryptorchidism and for frequent “borderline” forms of neonatal hypothyroidism with high TSH).

- a European mapping of the selected disease.

- a harmonised tool (life-style questionnaire; a set of possible biomarkers to be investigated) for assessing potential risk factors, related to environment or lifestyles.

- a pilot study could be proposed to explore if other, highly prevalent ED related diseases (e.g. endometriosis) can be integrated into a monitoring system, as well as to integrate the surveillance of endocrine-related diseases with that of cognitive disorders.

Overall, it is necessary to implement permanent national programmes of health surveillance in MS which are harmonised at EU level, thus promoting data retrieval and accessibility at the European level. Data analysis, as well as co-ordination and promotion work can be performed by centres of the E&H Network, as outlined in Option for Action 7. However, some additional resources will need to be allocated, in order to support specific activities of harmonisation, personnel training and networking.

The harmonised, European-wide data set will provide an information basis for investigating potential risk factors, identifying hotspots of relevant effects and monitoring disease trends in each MS. Moreover, implementing this option will identify relationships between surveillance systems of different endocrine-related diseases that might share some common risk factors; also, it will facilitate the integration of “effect” and “exposure” data bases and it will promote the involvement of health services and medical associations in the E&H Strategy.

The implementation of the proposal will require a feasibility phase (final selection of diseases to be considered, inventory of structures collecting data), together with further inputs from
DG SANCO, in order to deal with co-ordination issues, legal instruments and policy requirements for data collection and reporting.

**FAMILY 3 - OPTIONS TO IMPROVE DATA ACCESSIBILITY**

**Option for Action 3: Develop Criteria for Prioritising Endocrine Disrupting Chemicals to be Monitored**

Currently, most monitoring programmes on EDCs are a result of research activities or part of regular monitoring programmes, where the EDCs were included due to characteristics other than their ED potential (e.g. monitoring programmes on organochlorinated pesticides). It should be noted that there is still not enough scientific knowledge for establishing the real relevance of the endocrine disrupting potential for substances in the current "list of substances for further evaluation" developed under the Community Strategy for Endocrine Disrupters. As defined in the Baseline Report, the role of natural hormones and phytohormones must be also addressed in the design of monitoring programmes. In addition, new substances, such as chemicals with low-medium production volume but high release level should also be considered. Therefore, it is suggested not to recommend large scale monitoring programmes on EDCs but to analyse and review the current programmes and to conduct small scale initiatives. Under guidance from the Community Strategy for Endocrine Disrupters it is suggested to conduct within SCALE a set of pilot monitoring programmes. The pilot programmes require a set of initiatives at the EU level to develop:

1. A harmonised procedure on which substances are to be monitored (and in what media). The selection should be based on the most relevant from a health risk perspective (and especially children and pregnant women, factors not yet considered in the prioritisation scheme of the Community Strategy).
2. A common European strategy for monitoring the most relevant EDCs would provide valuable information that can contribute to the understanding of human exposure to these compounds. Furthermore, identification of potential hotspots could direct targeted studies on Endocrine Disruption-related health effects in predominantly exposed populations. However, an understanding of the environment and health relationship also requires mechanistic and toxicological research in addition to epidemiological studies of highly exposed populations.
3. By adopting reference methods for sample treatment and detection of EDCs, the comparability and quality of data generated on a European level will improve, since monitoring activities in the different MS/AC will focus on the same (i.e. the most relevant) EDCs (from a human/child perspective) which will be assessed by the same methodologies.
4. The monitoring data will be more effective in validating human and environmental exposure models.

The Pilot Monitoring Programmes could be conducted on a voluntary basis by Member States, industry or other stakeholders; however, to be considered within SCALE they should follow the principles agreed from the implementation of the above proposals and be approved by a committee/panel of experts. The final goal of these pilot proposals should be to develop the required expertise in ED monitoring for the future implementation of the Community Strategy for Endocrine Disrupters and to address some specific concerns on human health, and particularly on children, which could be identified within SCALE and require urgent ad
hoc actions. It is recommended that the monitoring programmes should cover not only chemical analysis, but explore additional possibilities such as monitoring biological responses such as oestrogenicity, androgenicity, etc. following biological methods currently available or developed by the on-going research activities in this area.

**Option for Action 3.1: Taking advantage of the already existing EUSES system**

This sub-Option for Action can, to all intents and purposes, be considered as an extension to Option for Action 3 since it contributes to the process for defining criteria for sorting priority EDs for monitoring.

The number of chemicals with potential endocrine disrupting effect is large. Monitoring too many of these chemicals would be costly; monitoring too few might leave certain chemicals that pose a risk go undetected. Moreover, the mere presence of a compound in the environment does not mean that it is a human health risk because the ultimate concern centres around how much is finally taken up (bioaccumulated) and induces adverse health effects.

Determining internal exposures, by means of human biomonitoring and biobanks, would be an expensive and resource-consuming effort that could streamlined by concentrating effort on the chemicals of greatest concern, therefore pre-selection of substances would be advantageous.

Such a pre-selection may be achieved by improving existing instruments for the modelling and prediction of exposure. This Option for Action is proposed in addition to Action 3 as a supplementary means to prioritise chemicals for (bio)monitoring. The existing computer program EUSES (European Uniform System for Evaluation of Substances), that was originally conceived for risk assessment, should therefore be adapted for this purpose.

EUSES can take into account the toxicological potency of compounds, route of entry into the body, production volume, use pattern, type of chemical, purpose of use, physicochemical properties etc., to predict their presence in the environment (soil, water, drinking water and the potential for uptake by humans. It can do this at the local level as well as on a larger geographic scale. The programme has so far been used mainly for risk assessment and it may be used in the first instance to predict occupational exposure. The knowledge that has accumulated over the years may allow the programme creators to incorporate toxicological data that specifically deals with endocrine disrupting effects; additionally, the programme could be modified to make it better suited to predicting exposure in the general population or in specific groups, for example mothers-to-be or children.

As a first step, the feasibility of incorporating the above mentioned modifications should be assessed in conjunction with the experts that developed EUSES. Subsequently, specific endocrine disrupter endpoints need to be identified and incorporated into the programme, possibly in collaboration with the OECD Endocrine Disrupter Testing and Assessment Task Force (EDTA). A list of potential endocrine disrupting chemicals with different structures, use pattern etc. should be identified for validation in the context of the EU Strategy on Endocrine Disrupters.

Following successful implementation of all these pre-requisites, the predictive value of the modified EUSES programme should be assessed using the selected chemicals.
FAMILY 5 - OPTIONS TO ENHANCE EXCHANGE OF INFORMATION, COMMUNICATION, CO-OPERATION, BETTER USE AND LINKAGE OF EXISTING DATA

Option for Action 4: Integrate existing information relevant to endocrine disrupters which has to be reported by Member States to the EC under various directives and regulations and, where feasible, research programmes.
(This also fits under families 1 and 3)

It is a fact that a great deal of relevant information on releases and concentrations of various endocrine disrupting chemicals is reported to the EC (for example under the IPPC Directive, the Dangerous Substances Directive, and in future the Water Framework Directive). Additionally, various initiatives are underway, such as the Thematic Strategy on Soil, which will provide further information. Information is also reported under the health-related initiatives and/or research programmes (for example, the “Europe Against Cancer programme”, “Health Monitoring Programme” and the “Automated Childhood Cancer Information System”). This information provides a valuable resource on environmental concentrations and sources of a significant number of EDCs in many countries, and provides a significant opportunity to link it with information which is also provided on health effects.

However, to date, this information is not accessible, or searchable by governments, researchers or the public. Reports go into the Commission and are never seen again.

The ED TWG therefore unanimously agreed to recommend that the Commission carry out a feasibility study on entering all the relevant information onto a relational database to make the data accessible, with a view to getting more precise and better focussed picture both on the occurrence and sources of EDCs, and possible links with health effects. The ED TWG also recognised that a similar situation would probably exist for heavy metals and dioxins, and that a joint proposal for these 3 groups would be a sensible approach.

The ED TWG identified some key issues that would need to be addressed, such as:

- the importance of getting the specification for such a database right in order to generate the right answers
- the need for a thorough examination of what databases exist in this area
- the need to clearly identify what degree of quality assurance has been applied in the generation of information, to judge whether it is comparable with other data
- the usefulness of a geographical database, which allows spatial resolution of hotspots of chemicals and overlays with disease incidence

A detailed proposal, including an initial feasibility study to judge the practicability of the proposal, is given in the Annex. This is in the format proposed by the Commission and includes an appreciation of why the problem has arisen, how the objective could be achieved, the benefits, advantages and drawbacks and ideas about a possible working method.
Option for Action 5: To Develop A Framework for Integrating Exposure Information
(This also fits under family 4)

Monitoring programmes for chemicals in general and for EDCs in particular are currently designed with a very specific human health or environmental perspective. This situation has two main aspects:

- The competencies (for regular programmes) or interests (for research based programmes) of the monitoring institution rarely cover both human and environmental issues.
- The current protocols for risk assessment are not integrated and employ different raw monitoring data for human health and environmental assessments.

However, if monitoring programmes are designed with a broader perspective, it should be possible for the monitoring effort to support the exposure analysis of both human health and ecosystems.

It should be considered that the raw monitoring data are rarely direct measurements of the population (or sub-population) exposure levels. In most cases, the raw data must be transformed into “exposure information”, and several scenarios, models and procedures are available. For example, even if a monitoring programme measures the concentration of an EDC in the edible part of a fish, the data must be handled using a “food basket” model to estimate the final contribution of fish levels to humans exposed via food.

Figure 1 summarises the different types of exposure-based monitoring programmes. Types I (production, uses, etc.) and II (emission releases) offer generic estimations, where the data could be perfectly incorporated into integrated frameworks. Types III (measures in abiotic compartments) and IV (measures in biota) require additional efforts to obtain a sound compromise, balancing human health and ecological interests.

It is proposed to establish an Integrated Framework allowing the optimisation of Type I to Type IV monitoring programmes for gathering information suitable for human health and ecosystem assessments.

The initial step should be an analysis of the current use of monitoring data; then it is recommended to conduct a feasibility study, evaluating options and alternatives for integrating monitoring programmes. Finally, the agreed options should be implemented, adapting the models/scenarios/protocols and the monitoring programmes.
Option for action 6: Transfer Information from Wildlife Effects to Human Health Assessment
(This also fits under family 4)

The design of monitoring programmes for EDCs is very complex, since EDCs are not a single class of chemicals but comprise several chemical categories, several mechanisms of action, and several levels of concern. However, there are some studies showing ED related effects on wildlife, either as hot spots or on a larger scale. It is suggested to establish mechanisms for using these data as one of the sources for human health assessment. In particular, two specific objectives are proposed:

1. To use information on endocrine disruption effects observed in wildlife (particularly in hot spots) to establish the relevance of the suspected causative chemicals for human health.
2. To use information about wildlife populations exposed through routes that are also relevant for human populations, in order to facilitate setting priorities for the monitoring of chemicals relevant for humans at the regional, local and continental scales.

The first objective is based on the growing scientific evidence suggesting that the endocrine system is conserved across species and many relevant mechanisms of action are shared by different taxonomic, although the responses could lead to different consequences. The current level of scientific knowledge does not allow a direct extrapolation from wildlife effects to human effects. Nevertheless, the identification of ED related effects in wildlife should be considered as evidence of the ED potential of that chemical (or chemical mixture) and, in the short-term should trigger the need for specific monitoring studies for assessing potential effects in humans. In the medium term, research programmes should be conducted to assess the possibilities for extrapolating the effects among species, based on the mechanism of action of each chemical.

The second objective advocates the potential use of wildlife effects as bioindicators of potential human exposure. This is based on the high level of exposure of some organisms to environmental pollutants, due to behaviour and geographic location. If the observed effects on wildlife are associated with an exposure route which is also relevant to humans, it should
be considered that humans will also be exposed, and applying the precautionary principle, those chemicals would be prioritised in the monitoring programmes.

The implementation of this proposal requires two main contributions. First, there is a need for compiling the available data on wildlife effects associated with EDCs, creating a database which could be used for future evaluations. Second, there is a need for prioritising research efforts to study a) the ED mechanisms which could be relevant for different taxonomic groups including humans, and b) the expected consequences (endpoints which can be measured in a monitoring programme) in different wildlife species of ED mechanisms that are particularly relevant for human health assessment.

**Option for Action 7: A European Network to Implement the Strategy**  
(This also fits under family 1)

The Environment and Health Strategy sets ambitious goals. But how to run with weak limbs?

Option for Action 7 deals with the use of existing structures in MS in order to create a network of centres to implement the Environment and Health Strategy.

As outlined in the Baseline Report, major critical requirements and missing links at EU level concern information flow, procedures (sampling, analysis, reporting, diagnostic criteria, etc.), priority selection, etc. These items are particularly critical for a developing, not yet well-established area such as endocrine disrupters and other endocrine stressors.

Notwithstanding a widespread availability of first-rate expertise and a generally increasing interest on the subject of endocrine disrupters, there are no, or very few, structures in the MS that currently undertake environment and health monitoring from an integrated point of view. Inconsistent approaches may jeopardise the Strategy, producing a large quantity of data with variable, uncontrolled quality, or which are not properly collected, analysed, circulated, integrated and/or utilised. Moreover, emphasis on single contaminants and compartments has led to insufficient co-ordination and communication among different expertise's and/or Agencies. For instance, there is insufficient use of environmental data for human risk assessment, and insufficient involvement of the health services in the monitoring and assessment of environmental risk factors.

The proposed Network will contribute to the aims of the Strategy such as:

- **harmonised approaches for quality assurance** of relevant data bases

- harmonisation of assays and procedures, including the development and dissemination of analytical standards and reference values (badly needed for EDCs, where such tools are far less established compared to other pollutants),

- a sound EU-wide information basis for investigating the relationships between environment and health, through the integration and exploitation of different data sources, thus contributing, e.g. a) to the necessary integration of environment-relevant and health-relevant data bases; b) to identify and further investigate hotspots for ED-exposure or endocrine-related effects, c) to develop harmonised European guidelines for health surveillance of endocrine stressors.
- Improved data availability, comparability and exchange of information. For instance, the network may support area-specific risk management and risk communication, through the dissemination of efficient models that worked in other areas.

It has to be stressed that the Network will exploit existing structures in MS, whereas new resources may be allocated to support increased tasks and networking. The most efficient way to implement the Network when the E&H Strategy is published, will be to give the task to each MS to make their own arrangements. Thus, MS will appoint institutions, propose a work programme and provide resources. Moreover, there is no need to overload the network with routine work. In order to generate the synergies needed to implement the E&H Strategy, a rotating programme of lead organisations within MS, tasked in turn with priority topics, may be envisaged.

The proposal has some requirements (providing sufficient resources, close monitoring, avoiding inter-agency conflicts) but has the obvious advantages of promoting the active involvement of MS in the implementation and updating of the Strategy, as well as efficient and knowledge-based use of resources in strategies for health prevention and risk management.

Finally, since this is a complex and ambitious move, the EC and MS should agree on terms for a preparatory and feasibility phase, with the contribution of stakeholders. Further implementation, and possible resetting of aims and approaches, will be based on the outcomes of the feasibility phase.

FAMILY 6 - OPTIONS WITH RESPECT TO RISK COMMUNICATION, TRAINING AND EDUCATION, INFORMATION AND AWARENESS RAISING

Option for Action 8: Feasibility Study on Risk Communication and Awareness Raising

Stakeholders, especially environment and health authorities, are increasingly confronted with the public demand to be informed on potential impacts of environmental factors on health. However, risk communication can be based both on what science has already determined and on the uncertainties. Where sufficient scientific evidence is still lacking, risk communication will need to be in line with the precautionary principle. Recognising that different people may wish to take personal action based on different levels of concern, it is not easy to provide the public with “well-balanced messages”. EU-wide accepted guidelines for risk communication are currently missing. However, useful experience in this field already exists (e.g. OECD, Germany) and should be taken into account. The current lack of co-operation between stakeholders would need to be addressed when aiming towards efficient and transparent EU-wide risk communication and awareness raising.

For this Option for Action it is proposed to perform a feasibility study for risk communication and awareness raising. The study should focus on “case studies” dealing with priority areas of SCALE such as childhood respiratory diseases, asthma or endocrine disrupting effects. Special emphasis should be placed on mechanisms for co-operation and network building between stakeholders. Taking into account existing experience (OECD, Germany etc.), guidelines for risk communication and awareness raising should be defined.
Option for Action 9: An Approach to Promote Active Involvement of Human Health and Environment Professionals in Integrated Monitoring Programmes.

The goal of this Action is to integrate, promote and support the already established networks of Environmental Health Professionals and the Medical Community of Doctors, Scientists and Health Care Providers that can work with monitoring programmes to improve further integration, awareness-raising and education activities concerning the linkages between human health and environmental factors.

Utilising the existing framework of the Commission’s Erasmus Mundus Programme, and the Policy Interpretation Network on Children’s Health and the Environment (PINCHE) with the objective of establishing a solid foundation in the Commission’s E & H Strategy, offers the opportunity for cost-effective implementation. The higher education institutions in all Member States would be a key venue for disseminating the integrated monitoring programme.

The approach to utilise existing professional networks, entities and educational institutions is further supported by the fact that EDCs cross many technical, legal, medical, and health fields. This truly multidisciplinary character supports the proposed approach and allows for a good Pilot Project that could be extended or replicated as appropriate for the full E & H Strategy.

The International Federation of Environmental Health (IFEH) and The International Society of Doctors for the Environment (ISDE) promote technical training and educational programmes. The goals above are specifically promoted on the European level with more than 10,000 Professionals in the EU, Accession, Candidate and Neighbouring states. There are several initiatives to support the European Health Plan. IFEH, ISDE and A.R.T.A.C work together with other stakeholders in the EU to achieve these goals.

A problem is that the training and practical work of Environmental Health professionals in MS does not always include an integrated approach for environment and health.

Affected stakeholders, including end-users of information and data generated from a monitoring programme, as well as related educational and awareness-raising activities would be consulted from the beginning. This affords practical application of any monitoring, awareness-raising or educational outputs.

The major contribution would be an improved communication and co-ordination among professional education programmes networks and organisations so as to promote understanding of the interactions and relationships between environment and health. This will lead to a basis for harmonising approaches to implement and manage environment and health issues in the Commission Strategy. This approach would also lead to increased awareness among environment & health and medical professionals, and programmes, networks and educational institutions.

The work programme proposed would include an assessment of current activities and capacity within Environment & Health and Medical Professions and Educational Institutions related to monitoring. A bench mark study of the capacity of national, regional and local authorities to effectively manage environment and health training and education would be instigated. An evaluation of existing Commission programmes and activities related to a plan to integrate environment and health activities into educational institutions would also be made.
FAMILY 9 - OPTIONS WITH RESPECT TO RESEARCH


The Endocrine Disrupters TWG discussed this issue at the working group meeting in Brussels, January 20, 2004, and agreed on the following specific recommendations at the final meeting in Brussels, February 10 and 11 2004.

The members of the technical working group recommend intensified research in the following areas:

1) Mother-child cohort studies should be initiated at a European scale to establish frequencies of potentially endocrine related effects (*e.g.* hypospadia, cryptorchidism, sperm mobility and concentration, testicular cancer, hypothyroidism, precocious puberty and breast cancer) and relate these effects to the individual’s *in utero* exposure, with an approach to assess long term effects of early life exposures.
   a. Since causal links between specific chemicals and endocrine related effects have not been established at present, it is very important that
      i. a limited set of potentially relevant chemicals (including phytoestrogens) will be selected according to the available information and
      ii. adequate plans for maintaining biobanks for future further chemical analysis are implemented.
   b. Moreover, investigation should not be restricted to disorders related to the reproductive system; other endocrine endpoints (thyroid, *etc.*) should be considered as well as effects on neurological and immune development.
   c. Adequate questionnaires and possibly other tools (*e.g.*, biomarkers) should seek to evaluate the influence of chemicals from all* other confounding environmental factors (diet, lifestyle, smoking, vegetarianism, *etc.*); relevant genetic polymorphisms should also be considered.
   d. Effects of post-natal exposures should be included in the investigations.
   e. All current knowledge on mother-child cohorts should be taken into account and the possibility of linking the investigation to already existing cohorts should be considered.
   f. The role of paternal genetic background as well as of paternal exposure should be carefully considered.
   g. *Note: all factors may not be feasible: The influence of other factors may be variable; they may not be just confounding factors, but they can really contribute together with EDC to detrimental effects: Or the opposite can be true, as some factors might lower the risk of certain effects (*e.g.*, appropriate iodine intake and thyroid disruption).

2) Development and validation of biomarkers/biosensors, covering different mechanisms of endocrine disruption, including but not limited to, interactions with receptors. The markers/sensors should comprise:
   a. Markers of exposure.
   b. Markers of effects.
   c. Markers of susceptibility.
   d. They should include genomic and proteomic tools.
e. Special attention should be given to development of biomarkers/biosensors able to investigate “real life” exposures, i.e. to mixtures or to multiple EDCs.

3) Better animal models should be developed. These should aim at improving:
   a. Understanding of dose-effect relations
   b. Understanding routes of exposure (including transport of chemicals from mother to foetus).
   c. The possibilities of using transgenic animals (issues of sensitivity, etc.).

4) Can exposures and effects in animals in the environment be used to provide an indication of potential human exposures, and serve as early warnings for human health? Research should be initiated which attempts to investigate the body burdens of pollutants in predator mammals (and possible effects in these), informed by giving due regard to the EU’s list of very persistent and very bioaccumulative (vPvB) and PBT chemicals.

5) An urgent requirement is to strengthen research that can support the development of OECD test guidelines. In particular, development of guidelines on EDCs will benefit from increased knowledge of endocrinology, molecular biology, etc., of humans, laboratory species as well as target species.

**OTHER KEY RELATED ISSUES TO BE ADDRESSED**

**ISSUES TO BE ADDRESSED UNDER THE ENVIRONMENT AND HEALTH STRATEGY**

- **Education and Awareness Raising of Mothers-to-Be**

  The ED TWG noted that the issue of EDCs had been the subject of many articles in newspapers and magazines. Some articles might distress people, such that they would seek independent advice. It was considered appropriate to provide balanced advice relating to chemicals, because available scientific data did suggest the need for special attention to be paid to chemicals with endocrine disrupting properties, since an uncontrolled exposure may lead to long-term impairment of the health of exposed individuals.

  It was therefore suggested that pregnant women and parents-to-be should have access to well-considered and balanced advice on all aspects related to helping to ensure the birth of a healthy baby. This advice should stress the benefits of a healthy diet and healthy lifestyle, and the benefits of any officially recommended supplements, and with regard to chemicals, would need to be written in careful language, which was not alarmist, but which acknowledged any uncertainties. The advice should also recognise that, if there were uncertainties, then particularly pregnant women and parents-to-be might want to take precautionary action to reduce their exposures to certain chemicals. Experts on communicating medical and health issues would need to be involved with the drafting of this advice. Alternatively, it was noted that it might be more appropriate for the Working Group’s concern about pregnant women’s exposure to chemicals, to be forwarded for the attention of
those who are responsible for the health affairs of pregnant women, for inclusion in their recommendations to pregnant women.

- **Mechanisms to Ensure Rapid, Accurate and Efficient Iterative Updating of Monitoring Programmes and Policy Measures.**

The ED TWG recognised that it was extremely important, in order to protect human health and the environment, to put mechanisms in place which can respond quickly and appropriately when, for example:

- the results of monitoring programmes, both on the health aspect and the environment aspect reveal significant new information (this might include where clusters of disease, or new exposure routes are revealed, or where concentrations of known or candidate EDCs show up.
- Substances not currently on the BKH list of EDCs are shown to possess ED activity
- Research programmes reveal new ED mechanisms and symptoms.

It was also felt essential that such new findings should be assessed by a body of officially approved experts/policy makers in order that appropriate follow-up action could be taken to verify the findings and that, if appropriate, policy measures could be taken in line with the EU Communication on the Precautionary Principle if necessary, to protect public health and wildlife.

The ED TWG did not have a lot of time to consider the modalities of how such mechanisms could operate, and there was no consensus about exactly how it could be achieved, and whether specific groups of chemicals such as pesticides might be covered in a generic way. However, it was agreed that one option could be for a working group to be set up within the EU ED Strategy who would consider relevant information and how to deal with it and, inter alia, make proposals for mechanisms to ensure rapid, accurate and efficient iterative updating of monitoring programmes and the adoption of relevant policy measures.

- **Problems and Constraints for Biomonitoring.**

With the aim of implementing a biobank of biological samples for consecutive biomonitoring of possible endocrine disrupting effects in a mother and child cohort, numerous problems and constraints should be considered. Among them are:

- **Technical aspects.**

  Since it is anticipated to make use of the samples in numerous ways (with regards to the biological parameters to be analysed), some relevant items to consider here are:

  **Samples to collect and when?**

  Specific attention should be paid to biological samples that allow evaluation of biological parameters that are not just relevant for the assessment of an impaired activity of the reproductive system. Samples such as those that can provide valuable information on e.g. the immune or thyroid status should also be collected. Examples would be:
- Placenta
- Meconium
- Milk: colostrum, transitional, mature
- Blood (whole blood, plasma, serum, separated red and white cells) from the cord vein, mother, children (if possible, father). Sampling must be repeated at different ages
- Urine (several times in day and life)
- Fat: depending on possibility (and opportunity?). Extracted from regular and easy sampling. However, there is no specific biopsy, and there are ethical considerations here. How useful (informative) would this be in the absence of a standardised protocol?
- Sweat, hairs, tears, teeth, nails, epithelial cells

**Storage conditions:**
- temperature (+4°C, -25°C, -80°C, liquid nitrogen). Depending on specific reactivity/sensitivity of the biological parameters to be assessed, one or another could be preferable. May be advantageous to store sub-samples under different conditions to cover all eventualities.
- light/dark, humidity: dryness
- packaging material: glass, plastic, paper or aluminium foils (need to be aware of possible contamination of samples from packaging)
- drying: freeze-drying
- as collected, after fixation (?) or extraction and purification (from a matrix)

In any case sub-sampling should be considered.

**Statistical considerations.**
The number of samples required in order to achieve a reliable statistical evaluation must be evaluated *a priori."

**Selection of criteria for inclusion in the cohort.**
Consideration must be given to the criteria used for selecting the study population - what it is representative of and whether it is relevant for the goal in mind. Are there specific advantages associated with including twins?

- **Questionnaire**

Its design should include any relevant information which allows the identification and assessment of factors that are known to influence the level of biological parameters. Therefore knowledge of: occupational exposures, age at and number of pregnancies of the mother, lifestyle conditions (outdoors/sporting activities, diet, drinking, smoking, use of medicines, drugs, stress conditions such as living in a noisy environment, loneliness, housing/moving, pets *etc.*) is required. In addition, follow up and regular updating of the information is necessary.
• Ethical considerations

In this respect, it should be useful to collate, follow and take advantage of the numerous processes of reviewing ethical aspects currently ongoing in European institutions, hospitals and research centres.

Additional issues are:

✓ Is it ethical to harvest samples for a use unknown by the donor? What would be the process for keeping them informed as much as possible?
✓ Invasive sampling: blood, milk
✓ How to handle ethically the issue of biomonitoring of the genetic father.
✓ Accessibility of the public (donors, health professional?) to the questionnaire?

• What can be done for Individuals With a High Body Burden of Persistent Chemicals?

No remedy is proposed for people in which the body burden of environmentally persistent toxicants is high (i.e. in hot spot areas such as in Brescia, Italy, where people have been exposed to PCBs for years and are under periodical monitoring by the local health service, as well as in other parts of the world).

There are two relevant papers on this topic.

1. Geusau, A. et al. (1999). The Lancet, vol. 35, October 9: reports the results of a study showing that Olestra, a non-digestible, non-absorbable dietary fat substitute can accelerate the rate of excretion of TCDD in intoxicated subjects by 8 to 10 fold. This is sufficient to reduce the normally observed elimination half-life of TCDD from about 7 years to 1-2 years.

2. Herron, R. et al. (2002). Alternative Therapies, Sept/Oct, vol. 8 (5): reports results of a study conducted on people with a body burden of common pesticides. The application of the non-conventional procedure of the traditional Ayurvedic medicine, here indicated as Lipid-mediated detoxification procedure, is shown to lower the serum level of lipophilic environmental chemicals by up to 50% in a few weeks.

Both these works deserve attention and should stimulate new investigations to determine if such approaches can be applied to intoxicated human subjects to decrease their body burden of poisonous chemicals; the second study might be more effective, since positive results are obtained in much shorter time. Ayurveda is practised around the world as a preventive medicine to increase human health and well being. Since Western medicine offers no remedy to clear the body from these substances, this approach should not be ignored.

ACTIONS NEEDED UNDER THE EU ED STRATEGY

• Data-Base for Holding Information on Candidate EDCs

It was acknowledged that a lot of very useful information had been generated on candidate
EDCs under the EU ED Strategy. However, because such information was distributed in various reports it was not in an easily accessible form that enabled users to clearly identify the concerns and data-gaps. It was therefore concluded that the European Commission should work towards getting a publicly accessible data-base containing the information collated and related to each candidate EDC under the EU ED Strategy. Furthermore, it was noted that mechanisms for the regular updating of this data-base would need to be put in place. One possible model for such a data-base had been the subject of a paper submitted to the EU ED Stakeholder Forum meeting in October by the Danish Environmental Protection Agency (711/17-0016 PJN/13), and this should be given due consideration in determining the structure of such a data-base.

- **To Improve the Identification of Chemicals with Endocrine Disrupting Properties**

The working group was charged with making proposals for an EU integrated endocrine disrupter monitoring system. However, it was acknowledged that this was problematic given the difficulty of knowing which chemicals were indeed endocrine disrupters. Some chemicals had been identified as candidate endocrine disrupters under the EU’s ED strategy, and some of these are considered to be category 1 EDCs, but there are many other chemicals that did not feature on any candidate list, and for which data were currently lacking. Moreover, it was recognised that tests to identify all endocrine disrupters are not yet available. It was therefore considered appropriate that an important step in the development of an integrated monitoring strategy for EDCs would be to try to ensure the identification of chemicals with endocrine disrupting properties.

Thus, to improve the identification of endocrine disrupting chemicals, it was proposed that the CSTEE, or another relevant independent EU scientific advisory body, should review whether the toxicity information required in various legislative frameworks was sufficient to identify endocrine disrupting chemicals. In particular, it was considered important that this scientific advisory body should review whether the toxicity information required under the draft REACH legislation was sufficient to identify EDCs, and to report on which endocrine disrupting effects might not be picked up in these current testing requirements. In the light of these gaps, the proposal was also that the relevant scientific body should then identify which currently available screening and/or test methods could be included to improve the identification of EDCs. In addition the scientific body would be charged with prioritising which test methods could be developed in future, in order to best address the data gaps, taking into account how near to being finalised such ‘new’ test methods were. Political level discussions would then be needed to determine the best way forward.

It was recognised that there was ongoing discussions at the OECD Task Force on Endocrine Disrupters Testing and Assessment (EDTA), and that the EU should take an active role in this process. However, in order to ensure that the needs of the European Union were properly considered, it was felt that there was a need to get an EU consolidated position on which tests methods would be most useful to develop as a priority. A review of the ability of current and proposed EU legislative frameworks to identify EDCs and the gaps, would provide a useful foundation to discussions to determine a co-ordinated EU position at OECD EDTA meetings.

Therefore, in summary, a proposed action is for a scientific review of the ability of the current REACH proposals to identify EDCs, and for this review to identify gaps, and if possible, to suggest ways of filling these gaps, and test development needs.
**ANNEX - REPORTING FORMATS FOR OPTIONS FOR ACTION**

**Preliminary statement:**

**Working group:** Endocrine Disrupters  
**Name:** R. Paumann, B. Heinrich-Hirsch, G. Lyons, P. Illig

**Option for action 1: Integration of existing national monitoring activities with a focus on Bio-banks / Human Bio-monitoring**

Integrate already existing and propagate improvement, further establishment and dissemination of environmental specimen banks / bio-banks for the purpose of:

- prospective (bio)monitoring and
- archiving environmental species and “human samples” for retrospective (bio)monitoring of emerging health (and environmentally) relevant chemicals *e.g.* chemicals with endocrine disrupting properties, persistent substances, *etc.*

For this purpose a stepwise approach is envisaged:

(i) **Short term:** perform a *feasibility study including a ring panel* (panel of experts) on a voluntary basis on existing Member States' bio-banks (sample banks for blood, breast milk *etc.*) as a first step for better co-ordination and integration of bio-monitoring activities within the Union.

The feasibility study in particular should focus on the following issues:

- How / what should be collected by bio-banks? (how to conduct representative sampling?, how to use questionnaires?, *etc.*)
- Legal and ethical framework (obstacles and legal demands for specimen / data sampling, sharing and integration)
- Possibilities for an adaptation of the legislative framework if necessary

(ii) **Medium term:** based on the outcome of the feasibility study, a concept for the extension and promotion of bio-bank activities as a tool for integrated monitoring should be developed. Currently, a “tailor-made” integrated monitoring concept seems to be favourable (that means activities should be focused on “hot spots” and areas / regions where specific concern is given).

**What is happening just now** (describe the current situation qualitatively and quantitatively where possible)?:
Some Member States already run national bio-banks (e.g. Germany, Sweden – see footnote) or repeatedly perform large-scale representative population studies including bio-monitoring (e.g. Germany). Some Member States perform single projects on chemical residues in human body (blood, breast milk etc.) and try to connect these findings to environmental exposure including dietary habits. At least one Member State runs a national food monitoring programme, which goes beyond the legislative requirements of food surveillance. None of these activities is specifically targeted to (bio)monitoring for chemicals with endocrine activities, however, it is conceivable that the indicated tools could be used and extended also for this purpose. Although there are many efforts at the Member States level, it seems that there is a fundamental lack of co-ordinated EU-wide activities on integrated bio-monitoring, especially when it comes to “human monitoring” (some exceptions can be assumed for research activities, as the 6th FWP lays already a focus on “food quality & safety”).

What is the problem (qualitatively and quantitatively where possible)?

On one hand Stakeholders are increasingly confronted with the demand of the public to be informed on the effects of environmental factors (such as chemicals in food, products etc.) on their health in a transparent and understandable way. On the other hand the situation is characterised by the lack of a larger pool of bio-monitoring data and a big lack of harmonisation and co-ordination, especially when “human bio-monitoring” is concerned. One reason seems to be that “human monitoring” is not covered by harmonised EU-legislation, such as it’s the case for most “environmental” monitoring as well as for food surveillance based on EU-legislation. As one consequence there is a body / network (e.g. network of national reference centres) missing, which is mandated to deal with the integration of human monitoring data with environmental monitoring data on an EU-wide level. Different legal and ethical views in Member States concerning “human bio-monitoring” in general and “bio-banks” in particular seem to be a further obstacle for deriving, in the short term, a unique EU-wide approach. However better co-ordination between Member States on bio-monitoring is crucial for a cost-efficient improvement of data availability, accessibility and comparability.

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 a larger pool of bio-monitoring data, which is useful for the qualitative and quantitative evaluation of human exposure to environmental pollutants in the context of human health risk assessment. Might help to create a database to develop reference values. Will establish a tool to identify temporal trends and spectra of environmental pollutants relevant for human health (also retrospectively). Thus, will contribute to the generation of information for the development of strategies for health targeted exposure prevention and as a tool for assessing the effectiveness of intervention measures.

**Main stakeholders affected** by the option and how they are affected:

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Commission</td>
<td>As a first step the European Commission should launch a feasibility study on bio-banks / bio-monitoring (7th Framework-Programme possible?). Furthermore the EC (in particular DG Sanco, DG Env) will have to stimulate the installation of a network of experts / institutions in Member States which deal with integrated monitoring (see also <strong>Option for Action 4</strong> for integration of existing mandatory monitoring) and will have to co-ordinate these efforts with existing international activities (such as WHO-approach).</td>
</tr>
<tr>
<td>Member States</td>
<td>Member States will have to support the feasibility study on bio-banks / bio-monitoring. They will have to integrate national environmental and health institutions as well as other stakeholders. They will have to put resources in “network-building” and will have to communicate their activities to the public (ethical discussion on Bio-banks, awareness raising for environmental related diseases).</td>
</tr>
<tr>
<td>Health Research Institutions</td>
<td>Health Research Institutions will need to provide their expertise on bio-banks / bio-monitoring.</td>
</tr>
<tr>
<td>Legal departments of involved EU Agencies and Member states</td>
<td>Legal departments of involved EU Agencies and Member states will have to assess the impact of human bio-banking/bio-monitoring upon privacy and ethical issues and on data safety/ownership.</td>
</tr>
<tr>
<td>NGOs and Industry</td>
<td>NGOs and Industry as providers and users of information will have to support the whole process.</td>
</tr>
</tbody>
</table>

**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?):
In General: at long term more efficient way to use resources and to make the environment and health relationship more transparent, especially for the public.

| 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.)

In General: on a short term more resources are needed (e.g. cost for feasibility study on bio-banks, costs for building a system for data integration). However it can be assumed that these resources are covered partly by already existing resources (Member States activities, Research Framework Programmes *etc.*).

| Financial |  |
| Health |  |
| environmental |  |
| Social |  |
| Other |  |

**Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.**

**Is further analysis needed?:**

No

**What would be the work programme?:**

---

**Footnote** - Existing Member States bio-banks

**GERMANY:**

Federal **German Environmental Specimen Bank** (started in 1985, full scale operation since 1994)
**Rationale/Main functions:**
- instrument for monitoring the effectiveness of legal environmental regulations
- core element of environmental observation
- archive for retrospective monitoring

**Current Performance:**

1) **annual sampling and archiving according to standard procedures of**
   - 17 different environmental (marine, limnetic, terrestrial) specimen of 6 different types of ecosystems from 13 different sample areas
   - 6 different human specimen (whole blood, blood plasma, scalp hair, pubic hair, saliva, 24-hour urine) from student groups (aged 20-29 years) from 4 different cities (Münster, Halle/Saale, Greifswald, Ulm)

2) **annual screening (routinely done prior to storage of specimen)** for a set of certain chemicals:
   - in environmental specimen: organochlorine compounds, PAHs, inorganic substances (elements & heavy metals)
   - in human specimen: of HCB, PCB 138, 153, 180, PCP, As, Pb, Cd, Ca, Cu, Mg, Hg, Sr, Zn

3) **retrospective monitoring** - up to now triggered by emerging questions, however not by a consented procedure or mechanism examples:
   - in environmental specimen: organotin-compounds, alkylphenols, PFOS, Triclosan
   - in human specimen: PBDEs in blood, phthalates in urine

4) **SOPs established**
   - for sampling, processing, storage and transport of specimen for chemical characterisation/analytes
   - for the human part extension of the environmental specimen bank for an additional archive of "perinatal" specimen and in return renunciation of scalp and pubic hair is currently under discussion

more information: www.umweltprobenbank.de

**SWEDEN:**

Annual sampling of environmental specimens; work on extending the sampling programme. Actual monitoring of a fixed set of substances as well as retrospective studies of emerging substances from time to time. Screening for different substance groups, which have been prioritised depending on use, production volume and PBT-criteria. Human blood from health related environmental monitoring programmes is stored in regional banks.
### Preliminary statement:
*Working group: Endocrine Disrupters  Name: Alberto Mantovani*

### Option for action 2: Endocrine Related Health Effects for Integrated Monitoring

A list of endocrine-related diseases with potentially well established diagnostic criteria and surveillance tools. Such diseases have been identified within the Pilot Project ED as:  
**hypospadia/cryptorchidism; neonatal hypothyroidism; precocious puberty; testicular cancer, breast cancer.**

Hotspots of such diseases will serve as 1st tier-signals for further investigation and possible intervention /management in an integrated system for monitoring relationships between environment and health.

### What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:

As the Baseline Report of the Pilot Project ED shows, there are several surveillance systems in MS and AC related to the above listed diseases. However, such systems have variable geographical coverage (from regional to international) as well as needing integration and harmonisation.

### What is the problem (qualitatively and quantitatively where possible)?:

At the moment a European-wide surveillance of endocrine-related diseases is jeopardised by the following factors: lack of harmonisation of diagnostic criteria; different geographical coverage, purposes and quality assurance of registries and other surveillance systems.

### Why has the problem arisen?:

It has to be recognised that major advances have been performed in the last few years in order to improve the quality and harmonisation of data collection for several diseases (e.g. for birth defect registries the network EUROCAT has provided an important step forward). However, such data are collected to have general information and/or to identify priorities for resource allocation.

They are, generally, *not collected* within the general conceptual framework of providing a sound basis of information to evaluate the relationship among diseases and environmental or dietary risk factors. Thus, there is a general lack of integration with *exposure* (environment, food, biomonitoring) data sources and a poor utilisation of diseases surveillance data in order to trigger or
direct identification/management of risk factors.
Finally, inadequate attention is given (partly due to an understandable methodological difficulty) to explore possible environmental risk factors for endocrine-related diseases in adults arising during early (prenatal/neonatal) life stages.

<table>
<thead>
<tr>
<th>General objective in context of a European Integrated Environment and Health Monitoring and Response System:</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Generate synergies and facilitate the sharing of data and methodologies</td>
</tr>
<tr>
<td>– Increase the understanding of the environment and health relationship</td>
</tr>
<tr>
<td>– Improved data availability, accessibility, comparability</td>
</tr>
<tr>
<td>– Enhanced exchange of information</td>
</tr>
</tbody>
</table>

*Generate synergies and facilitate the sharing of data and methodologies*

Through:
- providing a harmonised set of diagnostic criteria for selected diseases, where necessary
- an European mapping of the selected disease
- a harmonised tool (a questionnaire; a set of possible biomarkers to be investigated) for assessing potential risk factors, related either to environment and to lifestyles
- *Increase the understanding of the environment and health relationship*

The sound, harmonised, European-wide data set will provide an information basis for investigating the relationships between environmental and health, in particular to identify potential risk factors, pinpoint specific risk areas (*hotspots*)

Enhanced exchange of information

Implementing this option will generate relationships between registries and surveillance systems of different MS and AC for different endocrine-related diseases that might share some common risk factors.

Moreover, it will facilitate the integration of “effect” and “exposure” databases and it will promote the involvement of health services and medical associations in the E&H Strategy.

<table>
<thead>
<tr>
<th>How will the objective be achieved?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification (inventory) of existing structures in MS and AC that gather data on the relevant diseases.</td>
</tr>
<tr>
<td>Medical societies and NGOs (patient’s associations) can be involved as appropriate.</td>
</tr>
<tr>
<td>As outlined above the steps will be</td>
</tr>
<tr>
<td>- providing a harmonised set of diagnostic criteria for selected diseases when required (e.g. for hypospadia/cryptorchidism, as well as the frequent “borderline” forms of neonatal hypothyroidism with high TSH)</td>
</tr>
</tbody>
</table>
- an European mapping of the selected disease
- a harmonised tool (a life-style questionnaire; a set of possible biomarkers to be investigated) for assessing potential risk factors, related either to environment and to lifestyles

Thus, to identify hotspots it is necessary to set permanent national programmes of health surveillance in MS, harmonised at EU level. All National Health Institutes of MS would be involved in such a study, thus promoting data retrieval and accessibility at the European level.

Data analysis as well as co-ordination and promotion work can be performed by centres of the E&H Network, as outlined in **Option for Action 7**.

However, some additional resources will need to be allocated, in order to support specific activities of harmonisation, personnel training and networking.

Moreover, a pilot study could be proposed to explore if other, highly prevalent ED related diseases (*e.g.* endometriosis) can be integrated into a monitoring system.

**Main stakeholders affected** by the option and how they are affected:

<table>
<thead>
<tr>
<th>Stakeholder Type</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health services of MS and AC medical associations, research Institutes NGOs (<em>e.g.</em> patient’s associations)</td>
<td></td>
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</tbody>
</table>

**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**

The proposal will contribute to give the “health” component its due weight in the E&H strategy concerning ED. Valuable, European-wide epidemiological data, identification of hotspots and of potential risk factors (environment, diet and lifestyle) will be major deliverables to support sound prevention strategies. Moreover, this would also ensure good base-line data to identify future disease trends in each MS.

**Health**

The proposal will give a sound European-wide basis of “effect” data that can be usefully integrated with other “exposure” data sets, in order to fulfil the aims of the E&H strategy.
**Costs, disadvantages** (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tbody>
<tr>
<td>Financial</td>
<td>Most co-ordination and promotion work can be performed by centres of the E&amp;H Network, as outlined in <strong>Option for Action 7</strong>. However, some additional resources will need to be allocated, in order to support specific activities of harmonisation, personnel training and networking. It is conceivable an average 100,000 €/year/country, during phases 1-2 (see below)</td>
</tr>
<tr>
<td>Health</td>
<td>None, if the process is performed properly</td>
</tr>
<tr>
<td>Environmental</td>
<td>See above</td>
</tr>
<tr>
<td>Other</td>
<td>See above</td>
</tr>
</tbody>
</table>

**Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.**

- A) Focussing resources on gathering “exposure” data: this will ignore the major question of selecting priorities to prevent human health effects
- B) Other endocrine-related diseases might be considered: examples are osteoporosis, auto-immune thyroiditis, prostatic cancer, endometriosis.

**Is further analysis needed?:**

- Other diseases may be included in the proposal after further evaluation. Thus, a pilot study could be proposed to explore if other, highly prevalent ED related diseases (e.g. endometriosis) can be integrated into a monitoring system.
- Particular attention should be given to the possibility of integrating the surveillance of endocrine-related diseases with that of **cognitive disorders**.
- Further input by **DG SANCO** is necessary, in order to deal with co-ordination issues as well as to clarify legal instruments and policy requirements for data collection and reporting.

**What would be the work programme?:**

- Feasibility phase: (month 0-6)
  - selection of diseases to be considered
  - inventory of structures gathering data on selected diseases
- Phase 1: setting harmonised criteria for diagnosis and collection of information (month 7-12)
- Phase 2: start surveillance; set and harmonise criteria to identify hotspots (month 12-24)
<table>
<thead>
<tr>
<th>Phase 3: integrating data on different diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>integrating data on diseases with environmental data (month 25-)</td>
</tr>
</tbody>
</table>

**What be the working method?**

Iterative process through
- a) Inventory
- b) setting and harmonisation of criteria and approaches
- c) collection of data
- d) integration of data
- e) evaluation
### Preliminary statement:
**Working group:** Endocrine Disrupters  **Name:** Annika Hanberg, José Tarazona, Teresa Borges

### Option for action 3: Develop criteria for prioritising Endocrine disrupting chemicals to be monitored

**Develop criteria for prioritising Endocrine disrupting chemicals to be monitored and validation and calibration of reference methods.**
Harmonise and concentrate monitoring resources on the EDCs most relevant for human health.

### What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:
Large variations in which (and if) EDCs are monitored in environmental and/or human media in the various MS/AC. Most of the present monitoring activities of EDCs concerns dioxins, PCBs and regulated organochlorine pesticides, which are monitored due to other concerns than their ED potential.

### What is the problem (qualitatively and quantitatively where possible)?:
There is not enough scientific knowledge for establishing the real relevance of the ED potential for chemicals in the current list of candidates developed under the Community Strategy for Endocrine Disrupters to develop large scale monitoring programmes but there is a need for conducting specific initiatives which could allow the implementation of the Community Strategy for Endocrine Disrupters.
For on-going programmes the main problems are: Bad comparability. EDCs other than those presently monitored may be equally or more relevant from a health perspective. There is an insufficient amount of data of priority EDCs to allow analysis of time trends and geographical differences. Low reproducibility and repeatability of monitoring data by non-validated analytical methods.

### Why has the problem arisen?:
ED is a prioritised area of concern, however, there is a lack of data concerning which of many candidate EDCs are the most important chemicals from a health risk perspective. No consensus on which EDCs to be prioritised for monitoring from a health perspective and which methods to adopt for sample treatment and EDCs detection.

### General objective in context of a European Integrated Environment and Health Monitoring and Response System:
1. Generate synergies and facilitate the sharing of data and methodologies
2 - Increase the understanding of the environment and health relationship
3 - Improved data comparability
4 - Enhanced exchange of information

1 – A harmonised procedure on which substances to be monitored (and in what media). The selection should be based on the most relevant from a health risk perspective (and especially children and pregnant women).

2 - A common European strategy for monitoring the most relevant EDC would provide valuable information that can contribute to the understanding of human exposure to these compounds. In addition, identification of potential hotspots could direct targeted studies on ED-related health effects in particularly exposed populations. However, an understanding of the environment and health relationship requires also mechanistic and toxicological research in addition to epidemiological studies of highly exposed populations.

3 - By adopting reference methods for sample treatment and EDCs detection, the comparability of data will improve, since European monitoring activities in the different MS/AC will focus on the same (the most relevant) EDCs (from a human/child perspective) and be assessed by the same methodologies.

4 - The monitoring data will be more effective to validate human exposure models (and environment ones?).

**How will the objective be achieved?**

It is suggested not to recommend large scale monitoring programmes on Endocrine Disrupting Chemicals but to analyse and review the current programmes and to conduct small scale initiatives. Within SCALE a set of Pilot monitoring programmes should be conducted under guidance from the Community Strategy for Endocrine Disrupters. The pilot programmes require a set of initiatives at the EU level described above.

Candidate ED substances are ranked for relevance as concern for human health. Prioritisation is based on current and future up to date knowledge on both hazard and human exposure (routes and levels). The process shall be iterative starting from “Category 1” list of substances (the “list of substances for further evaluation regarding their endocrine potential”) as presented in the BKH report for DG Environment (study prepared in the framework of the “Community Strategy for Endocrine Disrupters”). However, in the prioritisation also low and medium production volume chemicals are considered as they may be relevant in case of high toxicological potency. Also not highly persistent chemicals shall be taken into considerations if the use or expected human exposure
is high. To get the full picture of human exposure to endocrine disrupting compounds also natural estrogens, phytoestrogens and pharmaceutical estrogens in drinking water and food shall be considered.

Important data on exposure and hazards of different candidate EDCs shall be evaluated, both research data and information from health risk assessments, such as those within the EU Existing Chemicals programme and Biocides Product Directive (98/8/CE) programme.

Priority shall be given to relevant chemicals and pollutants that are not adequately covered by current monitoring (as are dioxins, PCBs, old organochlorine pesticides and some heavy metals). The priority monitoring chemicals should be updated continuously.

A mechanism for sending message to research regarding important/hazardous chemicals with deficient knowledge in human exposure routes shall be developed.

Recommendations for which media to monitor, which sampling procedures and analytical methods are most appropriate shall be identified for individual EDCs proposed. Regarding proposals for media to monitor a focus on child exposure and exposure in pregnant women is important.

A first step resulting in pilot projects involving a few MS and after evaluation enlargement to EU level.

(possible to include a prioritisaiton also on new dioxin-like compounds and new heavy metals in the same or parallel procedures??)

<table>
<thead>
<tr>
<th>Main stakeholders affected</th>
<th>the option and how they are affected:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All activities should be conducted under the umbrella of the Community Strategy for Endocrine Disrupters</td>
</tr>
<tr>
<td></td>
<td>National and regional administrations in MS/AC that are responsible for environmental and health monitoring programmes. These shall follow the recommendations from the expert committee/panel. This will result in changes in present monitoring programmes. Industry and other stakeholders should be invited to participate in the initiative</td>
</tr>
</tbody>
</table>

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 cost effective monitoring programmes, *i.e.* more useful information to the same (?) cost. |
Providing reliable information on exposure models to the most relevant EDCs (from a health perspective).

Identifying hotspots for important EDCs and the biological effects mechanisms that can be associated.

**costs, disadvantages** (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial</td>
<td>Increased monitoring? New compounds initially more costly to analyse? Costs for the Committee/panel Increased number of analytical determinations/sample type by intercalibration tests.</td>
</tr>
<tr>
<td>health</td>
<td>?</td>
</tr>
<tr>
<td>environmental</td>
<td>More focus on EDCs relevant for protection of children's health might contrast environmental priorities</td>
</tr>
<tr>
<td>other</td>
<td></td>
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</tbody>
</table>

**Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.**

Considerable increase in monitoring activities, i.e. much less cost-effective

**Is further analysis needed?:**

These activities should be associated to the implementation of the Community Strategy

**What would be the work programme?:**

- Define criteria for prioritised EDCs to monitor
- Define criteria for calibration and validation of analytical methods/type of sample
- Appoint members of the committee/panel of experts
- Committee/panel work (continuously)
- Recommendations of pilot projects
- Evaluation of pilot projects
- Enlarge to EU-level of harmonised environmental and health monitoring of EDCs

**What be the working method?:**
The pilot projects could be conducted on a voluntary basis by Member States, industry or other stakeholders. However, to be considered as EU relevant studies the study design should be reviewed by and EU committee/panel of experts. Committee/panel of experts prioritising the most relevant EDCs to be monitored and the reference methods to be adopted. The expert committee/panel shall perform the prioritisation in close contact with EC/DG Environment to ensure consistency with ED strategy. They also give recommendations on appropriate media, sampling and analysis procedures (technical guidance documents/test guidelines).
**Preliminary statement :**
**Working group:** Endocrine Disrupters  
**Name:** Walter Janssens

<table>
<thead>
<tr>
<th><strong>Option for action 3.1:</strong> Take advantage of the already existing EUSES system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take advantage of the already existing EUSES system (European Uniform System for Evaluation of Substances) and the already existing knowledge to construct an <em>in silico</em> model that can predict the presence of an endocrine disrupter in the environment and the human exposure that may result from it. This could be a useful contribution to <strong>prioritise</strong> the chemicals to be monitored, in particular if can be linked to dose-response data on potential adverse effects induced by a chemical. EUSES can be used to predict exposure at the local or at an international level. Such a program is not intended to replace monitoring but to help focusing on the right substances.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>What is happening just now</strong> (describe the current situation qualitatively and quantitatively where possible)?:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECB has developed and refined a program EUSES that is used for risk assessment. This program is widely accepted and available. Many years of accumulated knowledge to build such models is present.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>What is the problem</strong> (qualitatively and quantitatively where possible)?:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The reason for this proposal is that the number of candidate chemicals to be monitored is large. Monitoring too many of these chemicals would cost a lot of resources, monitoring too little might leave certain risks undetected. EUSES can take into account the toxicological potency of compounds, route of entry into the body, production volume, use pattern, type of chemical, purpose of use, physicochemical properties <em>etc.</em> to predict their presence in the environment (soil, water, drinking water…) and the potential for uptake by humans. In particular the latter may be of interest. Indeed, the mere presence of a compound in the environment does not mean that it is a human health risk because the ultimate concern is how much is finally taken up and induces adverse effects. Determining internal exposures would be an expensive and resource consuming effort that can better be concentrated on the chemicals of largest concern.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Why has the problem arisen?</strong>:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>General objective</strong> in context of a European Integrated Environment and Health Monitoring and Response System:</th>
</tr>
</thead>
<tbody>
<tr>
<td>– Generate synergies and facilitate the sharing of data and methodologies</td>
</tr>
</tbody>
</table>
- Increase the understanding of the environment and health relationship
- Improved data availability, accessibility, comparability
- Enhanced exchange of information

This effort would help to make a link between exposure, risk assessment and finally risk management, of which monitoring should be a part. The classification and risk management part is already in use at ECB.

**How will the objective be achieved?**

The team that has developed EUSES could be asked to take into account the considerations that are particular for endocrine disrupters and for monitoring of chemicals. A list of known chemicals with endocrine disrupting activity, that have already been measured in the environment or in humans and that have undergone risk assessment should be established to validate the model that is going to be used for prediction.

**Main stakeholders affected** by the option and how they are affected:

Contributions from the ECB risk assessment group may be required and their work would have a follow up in terms of monitoring and risk management. Industry could provide much of the data required and maybe also could provide more knowledge about other computer programmes that they are developing. Monitoring agencies could give their advise about the specific purpose of the program to be developed and might benefit from such a programme because it may help them to devote resources to monitoring those chemicals that are of particular concern. NGO’s may also be asked whether they have experience that could be useful to develop such a programme.

**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?):

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial</td>
<td>After an initial stage, the use of such an in silico method may help to reduce monitoring cost.</td>
</tr>
<tr>
<td>health</td>
<td>Would benefit from a monitoring programme and resulting risk assessment that can be better focused on the most likely needs.</td>
</tr>
<tr>
<td>environmental</td>
<td>Would benefit from a monitoring programme and resulting risk assessment that can be better focused on the most likely needs.</td>
</tr>
<tr>
<td>other</td>
<td>Such a programme may be helpful to adjust the substances to be monitored at the local and at the European Community level to existing needs and concerns. This approach may also be helpful for chemicals with other effects or mechanisms of action and may be helpful in the end to prioritise for monitoring between all chemicals. It may also be helpful to adjust the list of chemicals to be monitored.</td>
</tr>
</tbody>
</table>
monitored to the needs at any location or time.

**costs, disadvantages** (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)

<table>
<thead>
<tr>
<th>Financial</th>
<th>Would initially cost money but may rely heavily on existing knowledge that can cut the costs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>health</td>
<td>It may not be easy to take into account long term effects and surrogate endpoints may need to be used.</td>
</tr>
<tr>
<td>environmental</td>
<td>EUSES assumes a static exposure and more dynamic processes may be more realistic. The use of this system would depend on the emissions data available in the EUSES database. Using default values wouldn't justify going on to develop monitoring programmes without further investigation.</td>
</tr>
<tr>
<td>other</td>
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</tr>
</tbody>
</table>

**Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.**

Direct large scale monitoring in environment and also of internal exposure. This is ultimately what needs to be done, but the proposed in silico approach may help to focus the direct monitoring. It may reinforce a link between risk assessment and risk management.

**Is further analysis needed?:**

Yes

**What would be the work programme?:**

- Assess feasibility with the experts that developed EUSES.
- Define the specific endocrine disrupter endpoints to be included.
- Make a list of chemicals with different structures, use pattern *etc.* for validation.
- Develop a modification of EUSES.
- Validate the adapted programme and after validation use it on a regular basis to determine the chemicals that should be monitored.

**What be the working method?:**
Preliminary statement:

Working group: Endocrine Disrupters  
Name: Richard Moxon

Option for action 4: Integrate existing information relevant to endocrine disrupters

Integrate existing information relevant to endocrine disrupters which has to be reported by Member States to the EC under various Directives and Regulations, and, where feasible, research programmes.

What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:

A lot of relevant information on releases of various potential Endocrine Disrupters is reported to the EC, for example under, the IPPC Directive, the Water Framework Directive, the Air Quality Framework Directive (in the future monitoring programmes are going to be implemented under the Thematic Strategy for Soil) and information is also reported on the health-related initiatives and/or research programmes, for example the “Europe against Cancer Programme”, “Health Monitoring Programme” Comprehensive Cancer Monitoring Programme in Europe” and Automated Childhood Cancer Information System.

What is the problem (qualitatively and quantitatively where possible)?:

This information provides a valuable resource to help link environmental concentrations and sources of a significant number of potential endocrine disrupters with health effects, and as far as we know,

1. “Europe against Cancer Programme”, focusing on inter alia improving health information through exchange of information and experience related to collection and dissemination of reliable and comparable data for cancer registers. In particular the project “EU Network of Cancer Registers” should provide a solid basis for further work. http://www.iarc.fr

DG SANCO funded “Comprehensive Cancer Monitoring Programme in Europe” which is the cancer surveillance system for cancer occurrence and outcome and the system for analysis of situation and monitoring of cancer burden in the MS. The system contains also data on environmental exposures. http://www-dep.iarc.fr/hmp/camon.htm

DG SANCO co-funded “Automated Childhood Cancer Information System” which collects, presents, interprets and disseminates data on childhood cancer in Europe. http://www-dep.iarc.fr/accis/about.htm

“Health Monitoring Programme”, focusing on improving health information by establishing Community health indicators, developing a Community-wide network for sharing health data, analysis and reporting, development of comparable data and health monitoring. http://www.euro.who.int/air
it is not accessible, or searchable by governments, researchers or the public. The information goes into a black hole and with some exceptions (e.g. the EPER database) is never seen again!

**Why has the problem arisen?:**

We suspect that it is because environmental and health legislation tends to have been developed piecemeal without thinking about co-ordination of the information and public accessibility to the data. Also, some of it was developed before information technology was well advanced.

**General objective** in context of a European Integrated Environment and 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

This recommendation covers all of the above points

**How will the objective be achieved?**

The objective could be simply achieved by the Commission reviewing the various bits of information which they hold in their files and contracting consultants to prepare a feasibility study for linking it together on a relational database. However, as there will doubtless be similar calls from other working groups (e.g. dioxins, heavy metals) then a general project would probably be the best way to make data held by the EC searchable and relational.

**Main stakeholders affected** by the option and how they are affected:

- The European Commission, EC Contracting Parties, the Research Community and the general public could all benefit from such a co-ordinated dataset

**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?):

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial</td>
<td>More efficient use of existing resources would be possible following implementation. The use of harmonised electronic reporting systems would, in the longer term, save administrative costs.</td>
</tr>
<tr>
<td>health</td>
<td>Better linking of particular medical conditions associated with endocrine disrupters with hard evidence on exposure and sources</td>
</tr>
<tr>
<td>environmental</td>
<td>The state of the environment with respect to endocrine disrupters would be more transparent, and assist policy making for controls</td>
</tr>
<tr>
<td>other</td>
<td>??</td>
</tr>
</tbody>
</table>

**costs, disadvantages** (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?):

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>
Financial Costs for developing the database would depend to a large extent on what systems the EC currently has for storing the information received from Member States. However, a rough estimate for developing the database on a broad scale, transferring existing information, and possibly modifying existing reporting arrangements might be around [1.5 million Euros]

<table>
<thead>
<tr>
<th>Health</th>
<th>Confidentiality of data might be a problem (this will depend on the nature of the individual reports and directives and their requirements)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

**Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.**

Is further analysis needed?:

Yes: the practicability of setting up the database would need to be scoped

**What would be the work programme?:**

The European Commission would first look at this recommendation in a broader context, and then carry out a scooping study to assess the feasibility of setting up such a relational database.

**What be the working method?:**

Probably done in-house, or though using a consultant familiar with the issues. This could be done in 2 or 3 months

---

- *work programme* is related to those commitments including technical details and an *indicative timetable*.
- the *working methods* in question are those methods that the WG thinks are most appropriate to meet the technical objectives.
### Preliminary statement:
**Working group:** Endocrine Disrupters.  
**Name:** JV Tarazona, JM Navas

### Option for action 5: To develop a framework for integrating exposure information

<table>
<thead>
<tr>
<th><strong>To develop a framework for integrating exposure information</strong></th>
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</thead>
</table>

### What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:
Chemicals exposure monitoring and assessment run independently for the environment and for humans.

### What is the problem (qualitatively and quantitatively where possible)?:
As a result of the independent exposure monitoring and assessment for humans and environment, data generated in the environmental exposure assessments are not taken into account in the human exposure assessments and vice versa. As a consequence, efforts are duplicated to obtain similar sets of data, and at the same time, available data are not used in the right way to extract all the information they contain.

Particularly serious is the fact of considering in the human exposure assessment only chemical levels detected in human tissues, food, or drinking water, without exploring the alternatives for maximising the use of monitoring environmental levels, taking into account that environmental chemicals will finally reach humans.

It should be noted that even in the risk assessments of specific chemicals the reported environmental monitoring data are not always employed in the human health part and even the models and scenarios for assessing the exposure of humans through the environmental are not integrated with those employed for wildlife.

### Why has the problem arisen?:
As stated in other actions probably it is because environmental and health legislations have been developed without adequate co-ordination.

In addition there has been a lack of co-ordination between different agencies (health, food, environment, water) at both European and National levels leading to accumulation of data that are not accessible to other agencies, public, scientific communities or even authorities.

### General objective in context of a European Integrated Environment and 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

<table>
<thead>
<tr>
<th>How will the objective be achieved?</th>
</tr>
</thead>
<tbody>
<tr>
<td>It would be necessary to perform an exhaustive analysis of the required information for direct and indirect exposure assessment of different human subpopulations and ecologically relevant taxonomic groups. Current models for transferring raw data into exposure estimations should also be analysed in order to develop new models producing estimations for humans and ecosystems on the same raw data base set.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Main stakeholders affected by the option and how they are affected:</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Agencies related with biota, food, air, and water monitoring; Scientific Community; and European Commission</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>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?):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial</td>
</tr>
<tr>
<td>health</td>
</tr>
<tr>
<td>environmental</td>
</tr>
<tr>
<td>other</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Costs, disadvantages (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial</td>
</tr>
<tr>
<td>health</td>
</tr>
<tr>
<td>environmental</td>
</tr>
<tr>
<td><strong>Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.</strong></td>
</tr>
<tr>
<td>---</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Is further analysis needed?:</strong></th>
<th>Yes</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th><strong>What would be the work programme?:</strong></th>
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</thead>
</table>
| The work programme can be described as four main steps. It is suggested that the main responsibility for the action should be allocated to the Commission and in particular to the DG Environment, due to the relationships with other environmental strategies. However, several steps require a strong contribution from risk assessors and risk managers. The four steps are:  
1. A working group would analyse all the different models, scenarios and protocols currently used to transfer raw monitoring data in exposure assessments for wildlife and humans to endocrine disrupters.  
2. A feasibility study, analysing the different options and possibilities for developing integrated programmes should be conducted under the supervision of the European Commission.  
3. The application of the conclusions of the feasibility study will be used in the implementation of a framework for integrating exposure information developing models, scenarios and protocols based as much as possible on the same raw monitoring data.  
4. The monitoring programmes should be modified and adapted to the new integration framework. |
|---|---|

<table>
<thead>
<tr>
<th><strong>What be the working method?:</strong></th>
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<tbody>
<tr>
<td>Steps 1 and 2 could be conducted in 6 to 9 months and the implementation in 1 or 2 years</td>
</tr>
</tbody>
</table>
**Preliminary statement :**
*Working group: Endocrine Disrupters  Name: JV Tarazona, JM Navas*

<table>
<thead>
<tr>
<th>Option for action 6: Transfer information from wildlife effects to human health assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfer information from wildlife effects to human health assessment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:</th>
</tr>
</thead>
<tbody>
<tr>
<td>At present “true” monitoring programs of effects in wild life are being carried out only for imposex in marine molluscs and some research oriented programs on fish populations. No work for trying to use this information in human health assessment is conducted.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What is the problem (qualitatively and quantitatively where possible)?:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Since endocrine disrupters comprise several chemical categories without a specific and common mechanism of action, to set monitoring programs for Endocrine disrupters in general is very complex. In addition, it is still not clear which chemicals produce relevant endocrine disruption effects on human health and wild life, and in fact the TWG is using a list of potential candidates.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Why has the problem arisen?:</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is not enough scientific information to predict the final consequences on human health or environment from studies assessig potential endocrine mechanisms such as oestrogenicity, androgenicity, anti-estrogenicity, anti-androgenicity, etc.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General objective in context of a European Integrated Environment and Health Monitoring and Response System:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generate synergies and facilitate the sharing of data and methodologies</td>
</tr>
<tr>
<td>Increase the understanding of the environment and health relationship</td>
</tr>
<tr>
<td>Improved data availability, accessibility, comparability</td>
</tr>
<tr>
<td>Enhanced exchange of information</td>
</tr>
</tbody>
</table>

|  |
|  |
| (1) To use information on endocrine disruption effects observed in wild life (particularly in hot spots) to establish which is the relevance of the different chemicals considered as endocrine disrupters for human health |
| (2) To use information about wild life populations exposed through routes also relevant for human populations, to set priorities for the monitoring of chemicals relevant for humans at the regional, local and continental scales. |
**How will the objective be achieved?**

The first part of the action requires a compilation of all the effects potentially associated to endocrine disruption observed in the EU. The second part would need a significant effort in research to translate wildlife effects into human health relevant effects.

**Main stakeholders affected by the option and how they are affected:**

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member states, scientific communities and European Commission</td>
<td></td>
</tr>
</tbody>
</table>

**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?):

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial</td>
<td>A better definition which chemicals can produce Endocrine effects. At the same time setting priorities based on human exposure will allow the implementation of human health exposure monitoring programs.</td>
</tr>
<tr>
<td>health</td>
<td></td>
</tr>
<tr>
<td>environmental</td>
<td>Recompilation of data sets for endocrine disruption effects in wildlife will be very useful for setting protection measures for the EU ecosystems, implementation of EU strategies and policies including the Water Framework Directive, Nature 2000 and the European Strategy on Sustainable Development.</td>
</tr>
<tr>
<td>other</td>
<td>The knowledge for the extrapolation of wildlife effects to potential human effects will be highly valuable for moving to integrate risk assessment. Particularly for biologically active chemicals.</td>
</tr>
</tbody>
</table>

**costs, disadvantages** (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial</td>
<td>The cost for the database should be limited to the implementation of one of the current systems e.g. for reporting effects on biodiversity.</td>
</tr>
<tr>
<td>health</td>
<td></td>
</tr>
<tr>
<td>environmental</td>
<td></td>
</tr>
<tr>
<td>other</td>
<td></td>
</tr>
</tbody>
</table>

**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?:**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three different phases are considered at this level:</td>
<td></td>
</tr>
</tbody>
</table>
1. A group of mammalian toxicologists and ecotoxicologists with enough expertise on EDC should be appointed for analysing all the information related with endocrine disruption in wildlife in order to prioritise endocrine disrupters in relation with their possible relevance for human health
2. To create a database on endocrine disruption effects observed in wildlife, and about possible routes of exposure to humans. Mechanisms to share these data must also be taken into account
3. All this work will produce a specific proposal for the establishment of priority research lines in order to develop the above mentioned objectives.

<table>
<thead>
<tr>
<th>What be the working method?</th>
</tr>
</thead>
<tbody>
<tr>
<td>The full implementation of this proposal requires a significant research effort.</td>
</tr>
</tbody>
</table>
**Preliminary statement:**
*Working group: Endocrine Disrupters  
Name: Alberto Mantovani*

**Option for action 7: A European Network to Implement The Strategy**

The Environment and Health strategy sets ambitious goals. But how to run with weak limbs? The proposal is to use existing structures in order to create a network of centres in MS and AC to implement the Environment and Health Strategy. The Network will contribute to the aims of the strategy such as monitoring of environmental pollutants and human populations at risk, quality assurances of data bases, harmonisation of assays and procedures (including analytical standards and reference values), developing better tools for early warning of emerging risks and designing approaches prevention and early warning.

**What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:**

MS and AC have different approaches to integrated environment and health strategies, due to both - different perception of social and health priorities and - insufficiently harmonised methodological approaches

The BR of the Pilot project has already identified critical requirements and missing links at EU level, such as: information flow, procedures (sampling, analysis, reporting, diagnostic criteria, etc.), priority selection, etc.

These items are particularly critical for a developing, not yet well-established area such as endocrine disrupters and other endocrine stressors.

**What is the problem (qualitatively and quantitatively where possible)?:**

The above situation may lead to different commitment of MS and AC into the Environment and Health strategy, with overall insufficient critical mass for implementation throughout Europe. Inconsistent approaches may jeopardise the strategy, producing masses of data with variable uncontrolled quality, or which are not properly collected, analysed, circulated, integrate and/or utilised.

**Why has the problem arisen?**

Notwithstanding a wide availability of first-rank expertise and a generally increasing interest toward health and environmental effects of endocrine disrupters, here are no, or very few, structures in MS...
and AC that currently undertake environment and health monitoring from an integrated point of view. Priority given to single contaminants and compartments has led to lack of co-ordination between sectorial expertise's; lack of proper communication between different national Agencies (e.g., environment, food and health); inefficient information flows. Lack of communication between the “toxicological” and “ecotoxicological” sectors has led to insufficient use of environmental data for human risk assessment (and vice versa). Lack of communication between the overall “xenobiotic” and the “medical” sectors has lead to insufficient involvement of the health operators and health services in integrated health/environment monitoring and assessment. For instance, there is insufficient use of exposure data in conjunction with disease registries, and vice versa.

<table>
<thead>
<tr>
<th>General objective</th>
<th>in context of a European Integrated Environment and Health Monitoring and Response System:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Generate synergies and facilitate the sharing of data and methodologies</td>
<td></td>
</tr>
<tr>
<td>- Increase the understanding of the environment and health relationship</td>
<td></td>
</tr>
<tr>
<td>- Improved data availability, accessibility, comparability</td>
<td></td>
</tr>
<tr>
<td>- Enhanced exchange of information</td>
<td></td>
</tr>
</tbody>
</table>

*Generate synergies and facilitate the sharing of data and methodologies*

To involve all MS and AC in the full implementation of the strategy, making their own specific arrangements within the general requirements of the strategy framework.

A rotating programme of lead organisations within MS, tasking in turn priority topics, may be envisaged. Thus some institutions may act as the “references” for data analysis as well as for improvement and European dissemination of approaches, methods. For instance, the development and dissemination of *analytical standards and reference values* is badly needed in the field of ED, where such tools are by far less established as compared to other pollutants (e.g. lead, PCBs).

Moreover, The network will contribute to develop *harmonised approaches for quality assurance* of relevant databases.

*Increase the understanding of the environment and health relationship*

provide a sounder EU-wide information basis for investigating the relationships between environmental and health, though the integration and exploitation of different data sources For instance, the support of a European-wide network will contribute a) to the necessary integration
of environment-relevant and health-relevant data bases
b) to identify and further investigate specific risk areas (hotspots) for ED-exposure or endocrine-related effects,
c) to develop harmonised European guidelines for health surveillance of endocrine stressors (including biomarkers and co-factors that need to be investigated)

*Improved data availability, accessibility, comparability*

The network will ensure efficiency and harmonisation concerning such major items of the Strategy as: information flow, procedures (sampling, analysis, reporting, diagnostic criteria, etc.), priority selection, etc.

*Enhanced exchange of information*

The network will ensure a European flow of data of controlled quality relevant to environment and health.
Moreover such flow may support area-specific risk management and risk communication, through the dissemination of efficient models that worked in other areas.

### How will the objective be achieved?

There is no need to create new structures. However, resources should be allocated in order to make existing structures able to deal with increased tasks and networking.

The most practical way to achieve this will likely be to have MS make their own decisions.
Therefore, it will be up to each MS to decide how to deal with the implementation of the E&H strategy when it is published.
Institutions will be nominated to act as centres, according to the specific requirements and arrangements within MS.
Thus, it will be up to MS to provide resources and to deal with specific problems, e.g. how to establish a national network supporting the E&H strategy when responsibilities for data collection belong to Regions (like in Germany or Italy) and/or to different Agencies (health, food, environment).

Of course, the EC should be notified of the appointed centres, of their work programme and of resources allocated by each MS.

Moreover, there is no need to overload the network with routine work. In order to generate the synergies needed to implement the E&H Strategy, a rotating programme of lead organisations within MS, tasking in turn priority topics, may be envisaged.

### Main stakeholders affected by the option and how they are affected:

MS and AC
But also research Institutes, Industry, NGOs, all involved both as providers and users of information

**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 way to use resources in the long-term |
| **health** | To make legislation/regulations relevant to environment and health work and be updated |
| | Integration of health data with environmental data: the result will be a sound, extensive and harmonised European data basis in order to programme and implement interventions, identify emerging risks, select priorities for research, etc. |
| | Moreover, the centres participating to the network can be available for major priority issues |
| **environmental** | See above health |
| **other** | All MS and AC (as well as other stakeholders) actively involved in the implementation and updating of the strategy |

**costs, disadvantages** (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.)

| **Financial** | Significant funds required at short term, with special emphasis to implement networking potential: It is conceivable an average 300,000 E/year per national centre, during phases 2-5 (see below) |
| **health** | It is possible that, e.g., insufficient resources will be devoted by MS or that reference centres of insufficient scientific quality will be appointed. Close monitoring is needed. Also it must be clear that, even if the system works very well, many health benefits are expected at long term, as for all preventive strategies. This should be suitable to the needs and priorities of policy makers and the public. |
| **environmental** | See above health |
| **other** | Possible competition between States and within states (e.g. among institutions) |

**Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.**

A) Through research calls, either within the 7th FP or specifically targeted. However, this option will be less efficient in achieving such targets as synergies for action, data sharing, harmonisation etc. A more proactive action is needed.

B) The EC might directly ensue a call to MS and AC to propose Network centres and allocate Commission resources according to a work programme proposed by each centre applying.
Such option, too, appears less practical than a direct involvement of MS in making their own arrangements on how to deal with the implementation of the strategy.

<table>
<thead>
<tr>
<th>Is further analysis needed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>The EC and MS should agree on the term of a preparatory and feasibility phase, with the contribution of stakeholders.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What would be the work programme?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparatory phase (month 1-6)</td>
</tr>
<tr>
<td>Phase 2: feasibility phase: the network will work on few selected, high priority items (month 7-18)</td>
</tr>
<tr>
<td>Phase 3: evaluation of results of phase 2 and possible resetting of aims/procedures (month 19-24)</td>
</tr>
<tr>
<td>Phase 4: further implementation (month 25-..)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What be the working method?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iterative process through</td>
</tr>
<tr>
<td>f) feasibility phase</td>
</tr>
<tr>
<td>g) evaluation of results</td>
</tr>
<tr>
<td>h) further implementation</td>
</tr>
<tr>
<td>i) evaluation of results</td>
</tr>
</tbody>
</table>
### Preliminary statement:

**Working group:** Endocrine Disrupters  
**Name:** Renate Paumann

### Option for action 8: Feasibility study on risk communication and awareness raising in the framework of SCALE.

Feasibility study on risk communication and awareness raising in the framework of SCALE.

Special emphasis should be laid on the following issues:
- Current status of risk communication on national and EU-level (what is communicated, how is it communicated, what does the public think, which stakeholders are involved *etc.*)
- Possibilities and hints for increasing co-operation between stakeholders
- Elements for risk communication and awareness raising (taking into account already existing experience and guidelines, *e.g.* from OECD, Germany)
- Case studies: proposals for risk communication and awareness raising illustrated by case studies from the priority areas of the first SCALE-cycle (*e.g.* childhood respiratory diseases, asthma, endocrine disrupting effects)

### What is happening just now (describe the current situation qualitatively and quantitatively where possible)?:

Stakeholders, especially environment and health authorities, are increasingly confronted with the public demand, to be informed on potential impacts of environmental factors on health. This is the case for risks caused by chemicals / endocrine disrupters (in food, products *etc.*), but also for other health related areas (*e.g.* respiratory diseases caused by traffic emissions *etc.*) However, currently there is no mechanism or network on EU-level for risk communication and awareness raising available.

Furthermore EU-wide accepted guidelines for risk communication are currently missing. As a consequence people are confronted with different views, recommendations and the situation is characterised by a high level of uncertainty. However, there are several ongoing activities - national as well as international - to develop guidelines for risk communication. At national level, for instance Germany developed within its national environment and health action programme a step-wise procedure for risk communication (EriK) as an integrative part. The report will be published by the German Environmental Protection Agency in 2004. Also OECD for several years worked on...
guidance for risk communication in the field of chemicals risk assessments. The outcome was published in 2002 in form of an OECD Guidance Document which provides principles and strategies for risk communication programmes [ENV/JM/MONO(2002)J8].

<table>
<thead>
<tr>
<th>What is the problem (qualitatively and quantitatively where possible)?:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk communication can be based both on what science has already determined and on the uncertainties. Where sufficient scientific evidence is still lacking, risk communication will need to be in line with the precautionary principle (as defined by the EU-Commission). Recognising that different people may wish to take personal action based on different levels of concern, it is not easy to provide the public with “well balanced messages”. EU-wide Guidelines for risk communication and awareness raising would help to improve the situation. However, it is strongly recommended to make use of the already existing experience (OECD, Germany etc.) when building up a risk communication and awareness raising system for SCALE.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How does this option contribute to the goals of the Strategy ?</th>
</tr>
</thead>
<tbody>
<tr>
<td>4) to the European Integrated Environment &amp; Health Monitoring and Response System :</td>
</tr>
<tr>
<td>- Generate synergies and facilitate the sharing of data and methodologies</td>
</tr>
<tr>
<td>- Increase the understanding of the environment and health relationship</td>
</tr>
<tr>
<td>- Improved data availability, accessibility, comparability</td>
</tr>
<tr>
<td>- Enhanced exchange of information</td>
</tr>
<tr>
<td>2) to improve public health with respect to environmental risk factors</td>
</tr>
<tr>
<td>3) to the research agenda</td>
</tr>
<tr>
<td>4) to raise awareness, to educate</td>
</tr>
</tbody>
</table>

Better risk communication and awareness raising will increase the understanding of the environment and health relationship. On long term it will improve public health and safe costs as environmental risks can be lowered or even avoided.

<table>
<thead>
<tr>
<th>Main stakeholders affected by the option and how they are affected:</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Commission (DG Sanco, DG Environment) will have to launch a feasibility study on the development of guidelines for risk communication and awareness raising. All other stakeholders (Member States, NGOs, Industry etc.) will have to support the initiative</td>
</tr>
</tbody>
</table>
**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?):

<table>
<thead>
<tr>
<th>Financial</th>
<th>Health</th>
<th>environmental</th>
<th>Social</th>
<th>Other</th>
</tr>
</thead>
</table>

**Costs, disadvantages** (qualitative description should be provided of all impacts, along with either quantification of the impacts or examples and underlying assumptions.):

<table>
<thead>
<tr>
<th>Financial</th>
<th>Health</th>
<th>environmental</th>
<th>Social</th>
<th>Other</th>
</tr>
</thead>
</table>

**Alternative ways of achieving the same objective, and their pros and cons relative to the option chosen.**

<table>
<thead>
<tr>
<th>Is further analysis needed?:</th>
</tr>
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<table>
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<tr>
<th>What would be the work programme?:</th>
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</table>
**Option for action 9: Approach to promote active involvement of human health and environment professionals in integrated monitoring programmes.**

Integrate, promote and support the already established networks of Environmental Health Professionals and the Medical Community of Doctors, Scientists and Health Care Providers that work with monitoring programmes to improve further integration, awareness-raising and education activities concerning the linkages between human health and environmental factors.

Utilising the existing framework of the Commission’s Erasmus Mundus Programme, and the Policy Interpretation Network on Children’s Health and the Environment (PINCHE) are two major activities already established and which offer the opportunity for cost-effective implementation. A key venue for disseminating the integrated monitoring programme can be the higher education institutions in all Member States, and those already active in the Erasmus Mundus Programme or PINCHE Programme, or other institutions possessing the capacity to educate, train and support the Commission’s strategy for improved environmental health. The Erasmus Mundus Programme and PINCHE will both include higher education institutions and existing networks of Environmental & Health and Medical Professionals with the objective of establishing a solid foundation in the Commission’s environment and health strategy.

By promoting co-operation among existing Professional Environment & Health and Medical organisations, the potential of Programmes such as Erasmus Mundus and PINCHE can be efficiently utilised. This will create an important mechanism to aid implementation of an integrated monitoring programme. An approach to utilise existing professional networks, entities and educational institutions is further supported by the fact that Endocrine Disrupters (ED) cross many technical, legal, medical, and health fields, and is of a truly multidisciplinary character. This proposed approach allows for a good Pilot Project that could be extended or replicated as appropriate for the full Environment and Health Strategy.

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**What is happening just now (describe the current situation qualitatively and quantitatively where possible):**

The International Federation of Environmental Health (IFEH) and The International Society of Doctors for the Environment (ISDE) build and promote technical capacity to address and remedy the environmental sources that impact human health. Specific activities include technical training, educational programmes, awareness-raising activities, seminars, workshops, conferences and related symposia that increase co-operation and capacity building among medical, scientific, technical and health professionals around the globe. These goals are specifically
promoted on the European level with more than 10,000 Professionals in the EU, Accession, Candidate and Neighbouring states. There are several initiatives to support the European Health Plan. IFEH, ISDE and A.R.T.A.C work together with other stakeholders in the EU to achieve these goals.

What is the problem (qualitatively and quantitatively where possible):

There are health care providers in every European country. However, the training and practical work does not include the integrated approach for environment and health. Further, the capacity to address the connections between human health from environmental factors varies greatly. This is due in large part to a lack of representation of these issues within the formal educational curriculum of all European countries. Further, the Accession and Neighbouring countries face the unique dilemma of a lack of historical experience with the management and regulation of environmental factors that impact human health and in particular endocrine disrupters. Some countries have a focus on health and food control, while others have a focus on monitoring environmental variables. Other countries give high priority to strictly medical issues. There is no internal European network for the integrated approach to these issues. This is due in part to a lack of co-ordination across national governments and representative bodies.

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

2) to awareness raising, information, to educate

The Community Strategy on Environment and Health can be improved by integrating existing efforts focused on human health and the environment. Further, new efforts to focus on the issues of environment and health, and in particular endocrine disrupters, primarily by utilising existing networks and programmes, should be considered. Effected stakeholders including end-users of information and data generated from a monitoring programme and related educational and awareness-raising activities would be consulted from the beginning. This affords practical application of any monitoring, awareness-raising or educational outputs. The overall objective is to harmonise national activities related to the environment and health monitoring, education and awareness-raising, primarily through existing professional networks and organisations such as Erasmus Mundus and PINCHE. This should also include an emphasis on the fundamental legal and regulatory requirements associated with implementing and
enforcing a harmonised system for monitoring and management of environmental factors that impact human health. The major contribution would be an improved communication and co-ordination among professional education programmes, networks and organisations so as to promote understanding of the interactions and relationships between environment and health. This will lead to a basis for harmonising approaches to implement and manage environment and health issues. This approach would also lead to increased awareness among environment & health and medical professionals, and members of civil society. An integrated monitoring programme, along with appropriate education and awareness-raising activities is a critical necessity that should be designed and implemented in an effective manner that utilises existing programmes, networks and educational institutions. Opportunities for synergy exist by leveraging, integrating and promoting co-operation among existing Commission Programmes such as Erasmus Mundus and PINCHE.

Alternative ways of achieving the same contribution:

| To send information from the European Commission and national bodies to stakeholders for integrated action. That would probably lead to a delay in action because the co-ordination and priority responsibility in each county is very different and sometimes lack the routine procedures for such co-operation with health operators. |

Main stakeholders affected by the option:

| Environment & Health and Medical Professionals active in the implementation of the Commission Strategy as well as national, regional and local regulators and policy makers responsible for the implementation of the rules and regulations necessary for the implementation of environment and health matters. There would also be a central group of professionals in the strict medical profession, such as Paediatricians, that would have the opportunity to develop technical capacity on the issues of children’s health impacts from environmental factors, which is a primary focus of ISDE in Europe. This is of particularly importance for the new members of the Community that would get the possibility to engage in an early stage of the Commission strategy and engage in capacity building for their Environment & Health and Medical Professionals. |

Benefits, advantages:

| economic |
| Benefits from co-operation within and among Environment & Health and Medical Professions would potentially be high. Currently, there has been limited success in integrating environment and health monitoring or management across these, and other related, professions. An approach to include academic institutions can lend credibility and authority to the Commission’s Strategy. Specific economic benefits include efficiencies in operation that can be realised from an integrated approach to monitor and address environmental sources of human illness. The ultimate |
result is to prevent or elimination these sources. Further, environmental sources of human illness are often the easiest to identify and most cost-effective to remedy. Integrating an approach across related professional sectors and regulatory authorities should focus on addressing environmental sources of human illness via programmes to clean dirty air and water, minimise exposures to toxic chemical substances, and manage hazardous waste. Accordingly, time and resources can thereby be allocated to those areas of human health that lack the desired scientific or cause-effect foundation necessary to make a determination of the most practical approach to address.

| social | Environment & Health and Medical Professionals are trained to handle dialog and interactions with the public on all levels. As Professionals they represent a trusted, objective and authoritative member of civil society. Implementation of the Community Strategy would benefit greatly from co-ordination among these professionals and outreach to local and regional stakeholders. The process of involvement is a crucial step in all action plans and this will be more effective when Environment & Health and Medical Professionals are involved and utilised. An education and awareness-raising activity is also a good tool for acceptance of complex multidisciplinary issues. |
| health | Human health would benefit from an integrated monitoring system and related education and awareness-raising activities. This could include the sharing of information in a format that provides an early warning system and a professional handling of evolving or controversial issues, all of which can benefit from early and active involvement of Environment & Health and Medical Professionals. |
| environmental | Identification of environmental sources of human illness generates real and direct benefit to both the environment and human health. As stated earlier, the ultimate objective is to prevent or eliminate environmental sources that cause or contribute to human illness. Further, environmental sources of human illness are often the most important to identify and most cost-effective to remedy. Integrating an approach across related professional sectors and regulatory authorities should focus on addressing environmental sources of human illness via programmes to clean dirty air and water, minimise exposures to toxic chemical substances, and manage hazardous waste. Accordingly, time and resources can thereby be allocated to those areas of human health that lack the desired scientific or cause-effect foundation necessary to make a determination of the most practical approach to address. |
| Costs, disadvantages | In the short-term, more resources are needed to initiate integration and co-operation within National boundaries prior to integrating across national borders. It is necessary to bench-mark existing capacity within professional association, as well as national and local regulatory authorities. In the long-term, these costs would generate benefits by creating a system for rational, effective and accurate decision-making, and a pool of technical information that will give National Authorities the possibility to optimise resources and save costs when implementing actions in the |
Later context of fulfilling Community Strategy. Further, there will be direct costs associated with identifying and correcting environmental sources that negatively impact human health such as sources of dirty water and air, routes of exposure from toxic chemical substances and related environmental sources of human illness.

Is further analysis needed?  No

What would be the work programme?

A work programme would include:

1. Assessment of current activities and capacity within Environment & Health and Medical Professions and Educational Institutions related to monitoring, education and awareness-raising in environment and health.
2. Assessment and bench mark of capacity national, regional and local authorities to effectively manage environment and health training and education, with a particular evaluation of capacity to implement the environment and health plan
3. An evaluation of existing Commission programmes and activities related to monitoring, education and awareness-raising which lend themselves to effectively deliver the Commission’s Strategy on Health and the Environment
4. A plan to integrate environment and health activities into these existing programmes, networks and educational institutions, and which utilises, as appropriate, the potential of Environment & Health and Medical Professions as well as Educational Institutions of Europe.