# HEALTHY PEOPLE IN A HEALTHY ENVIRONMENT

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Environmental impacts on health: better understanding for better protection

Review of the European information base for policy

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# **EXECUTIVE SUMMARY**

 Studying the impact of environmental pollution on European health is a complex but essential task. Data is needed to ensure that steps taken at European, national or local level to mitigate and prevent environment and health (E&H) problems are on target and complete. This 'Review' – in the context of the Environment and Health Action Plan (2004-2010) – aims to clarify the data needs for the two key issues: identifying new threats to human health (emerging issues) and controlling the impact of the threats already identified.

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- Contamination reaches us and affects our health in myriad ways. To better understand the causes and interaction requires data from different sources – e.g. food and air quality surveillance schemes, health surveys, research programmes, (bio)monitoring studies and networks. These can be difficult to compare and integrate across the European Union.
- A lot of progress has been made: the EU-wide monitoring and information systems and assessment strategies that are now in place cover a range of environmental factors which can affect human health. Efforts are underway in many of these to extend and improve coverage and protection. Current policies include not only regimes for restricting contamination through air, drinking water and food, but also risk assessment regimes controlling the 'stressors' which may cause damage in the first place (and adoption of the REACH Chemicals regulation will improve this further). But policy and action to improve the links between – and access to – existing sources of E&H information is a priority, including data from the EU's new Member States.
- Tackling emerging issues involves ensuring that early signals of potential problems are properly investigated. These signals can come from a wide range of sources. The European Commission has set up the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) whose tasks include identifying and reviewing emerging issues, and advising policy-makers accordingly. Furthermore, linking existing E&H information in novel ways may also help to highlight possible risks, and this will be explored in a pilot phase.
- To manage identified issues, different approaches suit different conditions:
  - 'Non-deliberate releases' are where pollution is released as a by-product of some other activity – for instance, cars producing pollution while moving us from place to place. For these, the Review adopts the health impact assessment (HIA) approach, as used in the Clean Air For Europe (CAFE) programme to assess the scale of health impacts. It then examines the extent to which this approach can be used for other substances and ways people may be exposed.
  - 'Deliberate releases' are where the release of the substance to the environment is done on purpose to produce a specific effect – for instance, spraying houseplants with insecticide to stop bugs. There are many types of deliberate release, ranging from pharmaceuticals and pesticides to industrial chemicals. They are controlled by 'risk assessment regimes' designed to make sure that the proposed use does not pose an unacceptable risk to human health or the environment. These regimes are regularly revised to make sure they deliver a high level of protection of human health and the environment, and take into account the most recent science.



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 'Accidental releases' are neither deliberate nor a by-product, but are the result of some kind of system failure – an explosion in a chemicals factory, say. The risk of such events can be greatly reduced by identifying potential flashpoints and ensuring proper management procedures are in place.

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- Three kinds of cross-cutting problems are also considered: cross-route exposure (e.g. to pesticides through both food and drinking water); the effect of one sector on a range of releases (e.g. the impact of transport on both air quality and noise); and simultaneous exposure to multiple stressors (such as noise and chemicals). The last is a key research issue, although its practical policy implications are limited at this stage.
- Although the systems in place are comprehensive, concrete recommendations are made (through 14 tasks extracted from the Implementation Plan) to rectify some specific weaknesses identified, using EU-backed research, and streamlining and completing of data collection procedures.
- In particular, developing a coherent approach to human biomonitoring (HBM) in Europe is a key commitment of the Action Plan, helping to better understand the total human exposure to environmental pollutants, while potentially identifying new issues and assessing the effectiveness of policy. But more research is needed to ensure that it achieves its full potential. The Review outlines the technical, political, financial and communication steps being taken – via the EU research Pilot Project – to test the feasibility of a coordinated EU approach.
- Finally, the Review assesses current information on the relative scales of environment-related health problems, both in the context of public health as a whole, and relative to each other. Caution is needed here because the methods for estimating the impacts need further development. But on the basis of existing information, the known contribution of E&H to the public health burden in the EU is relatively limited. Of the recognised environmental risks, ambient air pollution appears to be the biggest problem by some margin.
- There are clear limits to our current knowledge on why certain diseases have increased in recent years, and whether the environment is to blame. (Examples are asthma, allergies and child cancer.) Only credible research can determine which stressors are implicated, and further coordination and elaboration of the efforts already in place at EU and national level is critical.

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# **GENERAL INTRODUCTION –** WHY AN INFORMATION REVIEW?

Reliable information on the links between sources of pollution and health impacts is essential to set priorities for action, track progress and evaluate the effectiveness of the measures carried out, and identify emerging issues. The potential problems are well known – access to information, comparability and integration – and in many cases are being tackled, but additional practical measures need to be clearly identified.

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The main task of this Review is to assess the **information base** used to help protect our health; identify **key information needs** – gaps and weaknesses – in current monitoring and information systems; and establish **concrete tasks** to improve how E&H information is used.

The Review focuses on the first four actions of the Action Plan, and their research implications, building on the conclusions of the Dutch Conference on Environment and Health of December 2004. The analysis is based on a programme of consultation with the main political actors, and technical experts, responsible for each of the main environmental exposure routes and stressors. Background documents supporting the analysis are available on the Commission's Environment and Health website (see 'More info').

#### How to read this document

The Review covers the principal environmental exposures affecting human health: chemical and biological contamination via the main exposure routes (indoor and outdoor air pollution, water pollution and food contamination); exposure to physical stressors (noise and radiation); and cross-cutting issues not otherwise covered.

Part 1 of the Review describes an approach to E&H impact assessment and policy. Part 2 then considers practical limitations to implementing this approach, and identifies a series of 'tasks' to improve the information base. Part 3 covers 'crosscutting' issues, and Part 4 the main 'priorities and conclusions'.





# WHAT'S NEEDED?

# Identifying problems quickly: new and emerging issues

Citizens want to feel confident that new or emerging environmental health risks are being dealt with by public authorities. Policy-makers need to be able to act on reliable information about the new problems. Both are calling for greater information sharing and transparency.

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The European Commission has set up a number of Scientific Committees, made up of distinguished scientists from across Europe, which help address these issues. The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) deals, among other issues, with identification of emerging issues. Together with the other two non-food Scientific Committees in the field of consumer safety, public health and the environment (the Scientific Committee on Consumer Products (SCCP), and the Scientific Committee on Health and Environmental Risks (SCHER)) it provides the Commission with the sound scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees are also asked to draw the Commission's attention to specific or emerging problems falling within their remit which they consider may pose an actual or potential risk to these three areas, while being clearly independent of risk management-related activities. As part of its mandate, the SCENIHR provides risk assessment, for example on new technologies. In addition, the European Food Safety Authority (EFSA) identifies emerging risks in areas having a direct or indirect impact on food and feed safety.

In addition to the Scientific Committees, techniques for mapping health and environment problems geographically could also be useful, to scan for upcoming problems and develop models of the relationship between environmental stressors and health impacts.

# Priorities, policy and effective evaluation

Once a problem is identified, information is then needed on its scale, and on the health benefits of measures aimed at reducing the pollution emissions or exposures responsible. A 'matching' process then takes place to find the most efficient and cost-effective management solutions, comparing the costs of the various options for reducing the health burden against the benefits achieved.

As part of this process, health impact assessment (HIA) is an indispensable tool, and can be carried out in a qualitative or quantitative way. The **qualitative** approach gathers the experience, knowledge, opinions and perceptions of populations affected by a given environmental factor, but also evidence from people with expert knowledge. In 2004, a Guide to European Policy Health Impact Assessment (EPHIA) was produced to help set up pilot projects showing how to develop and use HIA, in order to better assess the health impact of Community policies and actions.

But HIA can also be used to **quantify** the health impacts of environmental pollutants and so identify the scale of problems and help determine priorities.



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# How to use HIA

HIA can be used to assess the relative impacts of different approaches to a problem. For instance, a country may want to develop a strategic transport plan, comparing various scenarios with different mixes of rail, road and other transport modes. HIA can be used to estimate the health impacts of each option, and so provide one basis for comparison ('comparative risk assessment').

Another use is in 'cost-benefit analysis', where the health benefits of a given management measure (for instance, a new clean technology for fossil-fuel power plants) are compared with the costs. We can then select the combination of measures that delivers the greatest health benefit for the least cost. The main problem is in quantifying the benefits, but the methods have improved considerably in recent years, although further development is needed.

An attempt to quantify the entire health impact of the environment using such tools is known as an Environmental Burden of Disease (EBD) estimate. Some studies of EBD go beyond environmental pollution as traditionally understood – for instance by including road accidents and the effects of physical inactivity – and so it is hard to get a consistent picture. Mainly due to these differences in methodology, the results

#### Did you know?

#### How to quantify the problem with HIA

A basic approach to quantifying the health impact of a risk factor is to select a set of health 'endpoints' – diseases where sufficient evidence points to an association with the risk factor being studied. Take for example particulate matter – tiny bits of solid materials moving around in the air, produced by transport, industry or other sources – for which the health endpoints would include mortality and morbidity due to cardiovascular and respiratory disease.

For each of these indicators, the following steps should be carried out:

**Assess exposure levels** by combining population density information with exposure data using, for example, geographical information systems (GIS). For air quality, concentrations of ambient (floating) air pollutants are used as a yardstick for personal exposure, and a map of concentrations is overlaid on a map of population distribution to show how many people are exposed and to how much.

**Identify exposure-response relationships and thresholds** of effects – that is, how the risk of disease varies with exposure. This needs careful research (epidemiology or toxicology).

**Estimate the proportion of medical cases** attributable to the risk factor under study. This is calculated using exposure distribution data, the results of exposure-response information and the observed incidence and prevalence of the health endpoint (say heart disease) in the population being investigated.

**Calculate the total** environment-related health loss and where possible, the resulting costs.

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of international studies vary widely, ranging from about 2-20%. The most reliable assessments for the known European impact of 'traditional' pollution are towards the lower end of this range.

A different option is to carry out direct assessment of the effect of policy on health outcomes by conducting a carefully designed 'intervention study' to assess the impact of a measure once it has been implemented on the ground. This could be useful particularly for large-scale problems such as air quality, where impacts are easier to see.

#### When to use HIA

One clear information need is to improve the data for performing HIA. But we need to identify the cases where HIA will provide real added value – there are many existing protection frameworks in place, and some may be fine as they stand.

There are basically two kinds of existing protection framework: **measures to prevent damaging releases**, and **measures to prevent damaging exposures**. These cover the range of environmental stressors: **chemical**, **physical and biological**.

#### Preventing damaging releases

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Prevention of damaging releases can be broken down into three sub-categories depending on whether the pollution release is **deliberate**, **non-deliberate** or **accidental**.

**Deliberate releases** are those where a substance is emitted into the environment to achieve a particular end (for instance, plant protection products deliberately sprayed to protect crops). These are controlled by risk assessment regimes (see box).

Risk assessment requires information on the risk posed by the substance (for instance, whether it is carcinogenic, mutagenic or reprotoxic). It also examines the possible routes of exposure for workers, consumers and the general population, as well as vulnerable groups (such as pregnant women and their unborn children) within each of these groups. The Commission has launched a study to review the treatment of vulnerable groups, including pregnant women, under risk assessment regimes, and to propose modifications if necessary. Regulatory decisions on the use of a substance are based on whether the likely exposure will cause a health risk.

These systems are essential front-line defences to avoid exposures to hazardous substances which may generate adverse health impacts (see box). They are regularly revised to ensure that they provide a high level of protection for human health and the environment, and take into account the latest science. Dialogue between the various Community bodies involved is being promoted to coordinate the overall approach taken.



Environmental Burden of Disease: Europe situation

An OECD study of Europe done in 2001 suggests that 2-6% of all cases of death and disease can be linked to known environmental pollution as traditionally understood, such as chronic urban air pollution. These figures are supported by some individual Member State assessments. But the real figure could be different, taking into consideration the 'unknowns'.





# Did you know?

## Tackling problems before they happen

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Risk assessment regimes try to assess, in advance of using a technology, whether it is likely to cause a problem. Examples of risk assessment regimes are the EC Directive on Plant Protection Products, the Directive on Biocides, and the new system for Registration, Evaluation and Authorisation of existing Chemicals (REACH). All assess potential risks to both human health and the environment. Under these regimes, new substances are subject to prior authorisation (that is, they cannot be marketed unless the risk assessment shows they do not pose unacceptable risks, when properly used, or they can be managed with appropriate measures). And existing substances are subject to review: if found unsafe, they are prohibited or a suitable management regime is imposed.

**Non-deliberate releases or contaminants** are 'by-product releases' from regular economic and industrial activity. Where the releases come from a product, such as cars or trucks, these can be controlled by product standards at EU level, including the Euro IV and V generation of vehicle emission controls. Releases from industrial processes can be controlled by point source requirements stipulating what sort and how much of certain pollutants are allowed to be released. The EC's Integrated Pollution Prevention and Control Directive and Urban Waste Water Treatment Directive are examples. Releases from diffuse sources (where the source is spread over a broad area, such as a field or a farm) are controlled by management practices, such as the EC Nitrates Directive.

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Accidental releases result from abnormal operating conditions, typically industrial spills and accidents. This type of release is controlled by legislation requiring appropriate safeguards to be put in place which minimise the chance of accidental releases occurring. The main example here is the EC Directive on the Control of Major Accident Hazards ('the SEVESO II Directive').

#### Preventing damaging exposures

Even if pollution does reach the environment, it can be kept away from direct contact with humans. 'Limit values' in the exposure medium (such as the air we breathe, the food we eat and the water we drink) are the main way to mitigate damaging exposure. The values are set taking into account the exposures or intakes at which effects are likely, appropriate safety factors, and normal 'background' concentrations. Today, they exist for ambient air, food, and for drinking and bathing water (e.g. the Revised EC Bathing Water Directive). Management plans are implemented to meet them, and systems ensure that the limit values are reviewed on the basis of developments in scientific evidence.

For food, the European Food Safety Authority carries out the risk assessment. For drinking water and ambient air, this role is performed by the World Health Organisation (WHO) and by the Scientific Committee on Health and Environmental Risks (SCHER), which provides scientific opinions on chemicals, biochemicals and biological compounds whose use may represent a risk for human health and the environment. Furthermore, the Scientific Committee on Consumer Products (SCCP) reviews the risks from consumer products,. Based on these risk assessments, the decision on risk management, based on a proposal from the Commission, lies either with the Commission itself (following consultation with Member States), or with the European Council and Parliament.



Based on scientific advice from the European Food Safety Authority, limit values are set to mitigate potential harmful exposure through food.



Clean water is not to be taken for granted. Scientific advice from SCHER and the WHO helps the EC to limit the risk of polluted drinking water.

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#### Meeting the limits

In most cases the limit values in Europe are set at the toxicologically- or epidemiologically-justified limits. But there are some cases where the existing contamination levels do not allow this, and so an intermediate target is set at a less strict level based on a scientific assessment of acceptable risk. This is the case for pollution burdens that are difficult to change quickly – for instance, where contamination of food or water continues even though a substance is banned, because of historical accumulation in the environment. The aim in such cases is to strike the best balance between the benefits of consumption, and the risks resulting from contamination.





# Risk management frameworks to protect human health from environmental releases

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From the above analysis:

- For deliberate releases, the existing risk assessment regimes perform their task well. As new threats arise, the existing regimes provide for follow-up monitoring, especially looking at persistent release, the possibility of bioaccumulation (or build up) and any potential irreversible health effects causing, for example, cancer or human cell mutations.
- HIA is not relevant for accidental releases which are controlled by specialised and up-to-date regimes, such as the SEVESO II.
- Where there is evidence that a limit value is inadequate, it should be revised downwards. Systems are in place for reviewing the scientific evidence and assessing existing limits in all routes of exposure – and feeding the results back into policy.

So the conclusion is that the **quantitative HIA approach is mainly applicable for non-deliberate releases, where people are over-exposed to a pollutant** (limit values are exceeded). This is true in practice as well, where HIA is used extensively for ambient air assessment, particularly in cases of persistent failure to meet safe levels – and where making progress towards meeting them is so expensive that the costs of measures are weighed up against the expected benefits. ۲

# Access to information: HIA and indicators

Health impact is in many ways the ideal indicator – both policy-makers and the public want to know how big a problem is, and whether it is getting bigger or smaller. But we live in the real, not the ideal world, and we have to make the best use of the information we have. And so a European Commission-funded project, called ENHIS, has put forward a core set of environmental health indicators for Europe that are feasible for implementation today. Involving agencies and organisations across Europe, ENHIS' indicators underpin development of the WHO's pan-European Environment and Health Information System (EHIS). In the follow-up project (ENHIS2), data should feed a new batch of indicators covering the whole WHO-European region.

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Of course, change is needed in the way data is collected and analysed at EU level, and is largely in progress. ENHIS2 has highlighted where the EU is 'data poor', and Eurostat, the Union's statistical service, will decide in 2007, as part of the European Community Health Indicators Project, which indicators it will pick up in the future.

The best way to look at the WHO and EU activities is as different stages towards the same goal, which is to provide publicly accessible information across Europe on the health impacts of environmental stressors, and to relate it to policy.



# Intervention to reduce nitrate exposure, Hungary example

How indicators can show policy effectiveness: as access to public water supply increases, the adverse health outcome decreases.



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# Possibilities and options for practical implementation

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# **NEW AND EMERGING ISSUES**

Emerging issues can be viewed from two main angles: what the Scientific Committees of DG SANCO and EFSA are doing; and whether the existing environment and health data can be combined or integrated across Europe.

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# The work of the Scientific Committees managed by DG SANCO and EFSA

Created in 2004, SCENIHR's mandate is to provide opinions on questions concerning emerging or newly identified risks, and on broad, complex or multidisciplinary issues requiring comprehensive assessment of the risk posed to consumers or public health. It also advises on related issues not covered by other Community risk assessment bodies. Examples of areas of activity include potential risks associated with antimicrobial resistance, new technologies such as nanotechnology and medical devices, physical hazards such as noise and electromagnetic fields, and other issues.

EFSA monitors procedures for collecting, collating and analysing relevant data regarding food safety. When the Authority has any information pointing to a serious emerging risk, it requests urgent additional information from Member States, other relevant Community agencies and the Commission. Once EFSA's scientific committee has evaluated it, the Authority passes on its findings to the European Parliament, the Commission and Member States.

# Linked up thinking from linked up data

#### The basic concept

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Using advances in geographically referenced data collection and analysis, experts may be able to find links between environmental contamination and health problems. The idea is to match data on the location of releases or high concentrations, with data on the geographical distribution of suspected health impacts, and check for associations. To minimise the chances of error, a good study should adjust for potential confounding factors – that is, other issues, such as smoking or socio-economic status, that can hide a real environmental effect or suggest a false one.

The technique ranges from sophisticated studies taking account of confounding factors at individual level, to rough-and-ready studies based on data at population level (not individual level). The latter can fail to pick up genuine impacts ('false negatives'), as well as generating doubtful associations ('false positives').

Additional benefits of data linkage include:

- possible new uses for existing data from creative thinking;
- significant improvements in the quality and/or comparability of individual data sets; and
- bringing various data-holders together, which develops contacts and networks which are useful beyond the narrow issue of data-sharing.



#### Did you know?

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#### Inspired to share

The **Shared Environmental Information System (SEIS)** is a Commission initiative that aims to improve the availability and quality of information in support of environment policy, while minimising, as far as possible, the burden on public administrations associated with reporting and monitoring.

**INSPIRE** aims to create a European Spatial data infrastructure covering both environment and health information and will ensure that the relevant public bodies make available and share their data. That would allow different types of data to be combined for integrated analysis, and would stimulate the development of analytical tools and applications.

# Data linking, the US and EU experience

Europe is among the leading regions in data linkage initiatives. France, the Czech Republic, Sweden, Austria, the Netherlands and the UK are among the EU Member States with experience. Internationally, the WHO is also a major player, and is involved in the Environment and Health Information System (EHIS) for the WHO-European region together with a number of EU Member States, the European Environment Agency and the Commission (through the ENHIS project).

The USA is also developing its own national system, called Environmental Public Health Tracking (EPHT). Its aim is the ongoing collection, integration, analysis and dissemination of data from environmental hazard monitoring, human exposure tracking, and health effect surveillance.

But there are questions about data linkage in the European context:

- while linking registers is simple enough, establishing realistic exposure models from the environmental data is very laborious and costly
- health problems associated with socio-economic differences can be so much greater than those from differences in environmental risks that the latter are masked
- there is limited access to data on environmental exposures and health status in specific geographic areas.

However, although there is no systematic assessment of the costs and benefits of such systems – or of the 'false positives and false negatives' issue – there has been some positive experience using them in Member States.

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## *E*&*H* tracking at the EU level?

At EU level, three initiatives will contribute substantially to modernising the collection, sharing, integration, analysis and dissemination of environment and health related data. These are the Shared Environmental Information System (SEIS, see box), the proposed INSPIRE Directive (Infrastructure for Spatial Information in Europe) which will underpin the SEIS, and the Public Health Portal which is working to make health data more readily accessible. This is a good basis, but more work is needed.

Before launching a full-blown EU-wide tracking scheme, further clarity is needed on its long-term benefits. These will be investigated in a pilot phase, along the lines of the US initiative, starting with tracking initiatives at Member State level and tool development at EU level. If they prove to be effective, then a coordinated EU-wide scheme can be considered.

The pilot phase will help iron out basic concerns, such as whether the data collection and processing is effective and sensitive enough, and whether definitions on exposure and diseases can be standardised and, thus, comparable between countries.

EU funding – under the LIFE+ scheme for better implementation, governance and communication of environmental policies, the Seventh Framework Programme (FP7) for research, and the Public Health Programme – is available for both pilot projects at Member State level, and for developing information systems to process the data at EU level. FP7 includes specific provision for developing Information and Communication Technology (ICT) aimed at environmental sustainability, and for geographical information systems, both with potential provisions for E&H. Loss in life expectancy attributable to exposure to fine particulate matter – Baseline 2000-2020





Advantage of spatial representation of data: maps showing how loss of life expectancy due to fine particulates changes between 2000 and 2020, as existing policy is implemented.

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**TASK 1:** Ensure that existing EU funding programmes enable pilot work on environment and health data linkage. Explore the possibilities for improving accessibility to, and harmonisation of, existing data on E&H. Based on this experience, draw conclusions on the future of systematic data linkage at EU and national level.



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# **IDENTIFIED PROBLEMS**

In this section we will consider health impact assessment (HIA) for each exposure route: how practical is it; where is it being applied already; how can it be improved; and what more information is needed to help prioritise, develop and implement E&H policy? If HIA is not being used, we assess whether, practically speaking, it could be, and if so, what information and/or action is needed to make it possible?

# Ambient air quality

HIA is most frequently applied for ambient air quality, and with considerable success. The most recent output at EU level is the Commission's Thematic Strategy on Air Pollution, which is supported by a very substantial analysis involving detailed HIA and cost-benefit work. But even for ambient air the assessment can be improved, and a continuous programme of development is underway in the context of the Clean Air For Europe (CAFE) programme. Some of the key areas being worked on are identified in Tasks 2 to 4:

**TASK 2:** Establish infrastructure: set up a network for combined monitoring of air pollution and related health effects across Europe to support detailed analysis of the short- and long-term effects of air pollution – in particular, which air pollution is affecting health.

**TASK 3:** Prioritise research on the long-term health impacts of air pollution and noise (and of other exposures and health impacts as far as possible).

**TASK 4:** Improve and harmonise health data for respiratory and cardiovascular disease. These are already broadly available at EU level on mortality, but morbidity data needs further work. The Commission services will examine the options and make concrete proposals.

# Indoor air

Indoor air quality is the E&H risk on which least work has been done. But studies indicate measurable effects on European health from poor air quality indoors. Among the offenders are tobacco smoke, indoor-generated particulate matter, carbon monoxide, carbon dioxide (which indicates poor ventilation), as well as nitrogen oxide, nitrogen dioxide, allergens (from dust mites, pets and cockroaches), mould, volatile organic compounds (VOCs), man-made mineral fibres, naphthalene and radon. Environmental tobacco smoke is the most significant issue in health terms.

HIA is possible for these exposures, and this has already been performed for chemical substances within the INDEX project (see panel). However, a high priority should be given to the development of a consensus on key indoor air pollutants across the EU.

The action that can be taken depends on whether we are discussing private or public spaces. For private homes, the potential actions are product regulation (on damaging products that are identified) and awareness-raising campaigns to reduce smoking and increase ventilation, for example. For public spaces, it is worth examining whether suitable standards could be established for a number of public places, such as schools and underground railway systems.

To identify whether risk reduction policy should be further developed, we need information on whether the indoor air concentrations across Europe are above the safe standards for the priority issues identified. Where no safe standards are currently set, that itself becomes the priority.

For private homes, it would be almost impossible to design a representative monitoring system given different personal behaviour. The two cases where monitoring of homes is likely to be useful are one-off measurements to get an idea of exposure levels of key pollutants; and monitoring where contamination levels might change for some reason (such as the introduction of a new product).

For public indoor spaces, monitoring may be possible, but further information would be required before deciding whether it is useful. A task is highlighted to help source this information.

**TASK 5:** Develop a consensus on key factors impacting on indoor air quality across the EU, based on health impact assessment (HIA), based on Member States' experiences. In particular, identify the key pollutants and if possible pollutant levels in transport-related indoor environments, schools and/or other public spaces with vulnerable groups, and in private homes.



We must prioritise research on the long-term impact of air pollution: outdoors but also indoors.

#### Setting the standard

The INDEX project - Critical Appraisal of the Setting and Implementation of Indoor Exposure Limits in the EU – systematically reviewed all available data (epidemiological and toxicological) to come up with standards for a range of indoor air pollutants. These are currently being reviewed by the Scientific Committee on Health and Environmental Risks, which has been asked to identify a Risk Assessment Strategy covering the whole indoor environment to support policy on indoor air quality, looking at technical issues such as combined effects and also at data gaps and uncertainties. The Committee will report by the end of 2006.



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# Drinking and bathing water

Analysis has shown that HIA is not practicable for drinking water in Europe due to the lack of European evidence of an impact at current population exposure levels. Thus changing monitoring to make it more suitable for HIA is not worthwhile – it should continue to be compliance based. But compliance monitoring itself can be improved, using the risk-based approach of the Water Safety Plans developed by the WHO, which are tools to identify potential contamination at any point in the treatment and supply chain.

For bathing water, the Commission is mandated under the revised Bathing Water Directive to carry out an epidemiological study on the health impacts, and to come forward with a report on the results of the study by 2008. Based on the outcome, we can decide what further assessment of health impacts is needed.

The information priorities in these fields are to safeguard compliance, and to ensure that the standards set are kept under review and adjusted where necessary. Although systems for doing this are in place, several areas for improvement are highlighted.

**TASK 6:** For drinking water, by far the most significant potential improvement is a move towards Water Safety Plans. This will be considered in the revision of the relevant Directive (98/83/EC).

**TASK 7:** Examine the possibility for a database of current raw monitoring data, which could be useful for analysing concentration trends and identifying new issues, and for a consensus at EU level on which data should be collected for drinking water.

**TASK 8:** Investigate the scope and value of developing an alternative indicator for drinking water (since exposure and health impacts are not feasible), such as the proportion of the population affected by non-compliance incidences, and the duration of non-compliance.

**Task 9:** The Commission is conducting an epidemiological study on the health impacts of bathing water required under the revised Bathing Water Directive and will present its results in 2008. Based on the results, the Commission will consider the need for further work.

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#### Food

As for drinking water, HIA is not practicable for food, and introducing it is not a high priority. Periodic monitoring exercises at European level give a rough assessment of exposure to particular contaminants in food and do not, in general, indicate a health problem from the kind of exposure levels common in the population.

However, substances like mercury do still present potential problems through food, and EFSA's Scientific Panels conduct periodic risk assessments using available information.

Information priorities are to monitor the residual health risk, to continue to ensure compliance, and to revise limit values where necessary. Responsibility for reviewing new information and carrying out the risk assessment lies with EFSA. Based on its scientific advice, the Commission can then propose revised values and adopt them after consulting Member States. Again, the basic system for health protection is adequate, but additional tasks would further support current compliance monitoring.



We are working to bring down the levels of contaminants in food, including seafood.

**TASK 10:** Develop a 'mutual alert' system for environmental monitoring experts to flag up issues which may have implications for food, while food experts identify priority cases of environmental contamination.

**TASK 11:** Improve the general coherence of environmental and food monitoring to ensure that mutual alerts use common terminology.

#### **Physical stressors**

#### Noise

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The Environmental Noise Directive (END) follows the HIA framework very closely, requiring 'noise exposure maps' to be drawn up for principal urban centres and transport routes distinguishing between 'night-time' and 'day-time' exposure. END also specifies certain dose-response relationships to be used (e.g. for relating noise to sleep disturbance) to assess the effect of noise on populations, in combination with the maps of noise exposure.

Recent studies confirm there is a genuine – though small – relationship between cardiovascular health problems and noise pollution, but with vast numbers of Europeans living in noisy urban settings, this 'small' association is not to be ignored. Cognitive effects are also potentially significant. The EU RANCH project (Road traffic and aircraft noise exposure and children's cognitive development and health.

Member States are obliged under the END to take account of major noise sources – namely, road, rail and aircraft – based on an assessment of the cost effectiveness of measures introduced to reduce harmful effects. EU legislation also covers noise



Tired of being woken up – noise is also pollution and, long-term exposure could cause health problems.





emanating from products, such as tyres and motorcycles, and the END will provide information on which measures are most effective in reducing exposure.

**TASK 12:** Collect, analyse and report noise exposure and related impacts across the EU (using noise maps produced under END). Integrate this information into findings from relevant EU projects to improve actions for boosting European health.

# Ionising radiation

There is a separate protection framework for ionising radiation established under the Union's Euratom Treaty, covering both health and ecosystem protection. The 'basic safety standards' on which protection is based are under review in 2006.

## Non-ionising radiation

In 2006, SCENIHR is finalising its update of an earlier scientific opinion of 2001 on the potential health risks of electromagnetic fields. It will consider all relevant information on exposure and health effects.

# The health impacts of climate change

The potential impacts of climate change on human health must be carefully considered. There are three main issues: extreme weather events (heatwaves and floods); the impact on vector-borne disease (that is, diseases borne by an agent such as an insect, an example being malaria); and the impact of climate change on the incidence of food- and water-borne disease. Under the second phase of the European Climate Change Programme (ECCP II) the Commission will present a Green Paper on adaptation to climate change, covering these and other issues on the basis of consultation with stakeholders.

#### The scope for HIA

HIA, using routine monitoring data, such as that done in CAFE for ambient air pollution, is not generally suitable for other exposures (with the exception of noise and some indoor air pollutants, e.g. radon). For exposures other than ambient air, one or more of the three main ingredients of HIA – population distribution of exposure; exposure-response relationships at the ambient levels of exposure; and baseline frequency of health impacts – is missing.

For exposures through food and drinking water, there is a lack of epidemiological evidence in Europe on dose-response relationships at current everyday exposures. The available data relate to extreme exposures, and finding ways to extrapolate these 'high-dose' relationships to learn something about the health impacts of lower doses is worth investigating.

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But by far the most important initiative in this field is further research on low-exposure health impacts and the impacts of cumulative exposure – a major topic in the Commission's Research Framework Programmes which is set to continue in the Seventh Framework Programme.

Efforts to develop HIA methodology and apply it to what are currently unworkable situations should also continue, on a Europe-wide basis where possible. Alternatives should also be examined, such as 'health risk assessments' (HRAs). However, HRAs are normally based on toxicological rather than epidemiological evidence, and so HIAs are preferable.

**TASK 13:** Harmonisation of HIA methodology, including standard guidelines on calculation, and consensus on the main elements to be included (e.g. exposure and health outcome indicators, standard procedures for expert judgement, and standard procedures for sensitivity and uncertainty analysis).

#### Wider scope for EU intervention studies?

Studies on particular interventions are widespread in Member States, and it is useful to consider the scope for a general programme to assess the effectiveness of European environment and health policy.

The US Environment Protection Agency (EPA) has useful experience in planning intervention studies. Predictably, air pollution is the hottest topic because of the size of the problem, the scale of the policy, and the comparative ease of demonstrating an impact. In Europe, a large-scale intervention study programme built around implementation of the Thematic Strategy on Air Pollution and the Environmental Noise Directive is worth pursuing. The scope for building such a programme into the study on long-term effects of air pollution is being considered (see Task 3).



# **Cross-cutting issues** and other matters

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# THE MAIN CROSS-CUTTING ISSUES

In this section, we consider three kinds of cross-cutting issue: **exposure to the same** stressor through different paths; the case where a single economic sector drives **exposure to a range of stressors** (e.g. transport driving exposure to air pollution and noise); and combined exposure to a number of different stressors.

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#### Same stressor, diverse routes

Many contaminants reach us through a number of different exposure routes – i.e. food, air, water. But in practice, one exposure route is often dominant. Even within a particular route, such as food, exposure from one foodstuff can be more significant than all others. Where cross-route exposure could pose a significant risk, it is taken into account in setting the limit values in the exposure medium.

Thus the current approach, focusing on the priority exposure route, or adjusting limit values to make allowance for exposure through other routes, is a sensible one for health protection. Where the limit values in question include reasonable safety margins, there is a fair degree of confidence that health is protected.

But sometimes the safety margins are narrower, because wide margins cannot be achieved in practice, normally because of historical contamination. Here, limit values must be continually kept under review – something the Commission does for both food and drinking water.

More research is useful into the extent of multi-route exposure, and the scale of the resulting impacts. The EU-funded INTARESE project, in particular, may provide information and tools to improve current protection regimes (for instance on cumulative exposure to household chemicals through a range of routes).

#### Multiple exposures, same sector

Integrated assessment modelling says what it does: it assesses the effects of a given economic sector via the whole range of stressors or pollution sources. Transport is the big source of multiple exposures, having substantial effects on both air quality and noise levels, and the EU's TERM project was set up to clarify the impacts. As in this case, the most fruitful approach is to identify key issues where multiple stressor effects are likely, and address them through specific projects.

Doubts have been raised about the suitability of integrated assessment modelling for smaller exposures and health impacts, such as those from heavy metals and persistent organic pollutants (POPs). For instance, for several of these substances a major exposure route is through eating fish, and it is extremely hard to link pollution emissions to concentrations in fish using environmental transport modelling.

The uncertainty around the dose-response relationships for these smaller exposures – the problem of extrapolating results from high exposures mentioned previously – is another problem. This makes the modelling results potentially less robust than those for ambient air and noise.

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What is more, modelling is unlikely to be useful in assessing to what extent exposure is driven by historical contamination versus current releases. This is a key question for heavily regulated pollutants, such as mercury and dioxins. To get any significant grip on such issues, alternative techniques may be more appropriate.

CAFE's modelling is a strong aid to environmental policy-shaping, but the use of integrated modelling approaches for smaller exposures – in particular, those that may be driven in large part by historical contamination – is subject to greater uncertainty which must be carefully quantified before the results can be used to justify policy action.

## Combined exposures, multiple stressors

This is a genuine but very complex challenge. At present, risk assessment considers stressors in isolation, and takes no account of the effects of simultaneous exposure to a combination of stressors. There are three potential combined effects: additive effects, where the effect is simply the sum of the individual effects; antagonistic effects, where the stressors 'cancel each other out' to a certain extent, thus producing a lower health impact than expected; and synergistic effects, where the combined impact is greater than the sum of the individual impacts.

Assessing how to take account of such impacts in risk assessment is a key research priority, the aim of which is to make practical proposals for handling combined effects in policy (see box).

The priority for the future is to highlight potentially vulnerable groups, such as pregnant women and children, identify sets of pollutants to which those vulnerable groups may be exposed, and propose ways to assess their combined effects.

# EU research on chemical mixtures and exposure to multiple stressors

#### Chemical mixtures

EDEN: Exploring novel endpoints, exposure, low-dose- and mixture-effects in humans, aquatic wildlife and laboratory animals (FP5)

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ACE: Analysing combination effects of mixtures of estrogenic chemicals in marine and freshwater organisms (FP5)

Devnertox: Toxic threats to the developing nervous system: in vivo and in vitro studies on the effects of mixture of neurotoxic substances potentially contaminating food (FP6)

Safefoods: Promoting food safety through a new integrated risk analysis approach for foods (FP6)

NewGeneris: Investigation of exposure to chemicals in food and the environment and their connection with childhood cancer and immune disorders (asthma, rhinitis, eczema/dermatitis) (FP6)

#### Exposures to multiple stressors

CEMFEC: Combined effects of electromagnetic fields with environmental carcinogens (FP5)

NOISECHEM: Noise and industrial chemicals: Interaction effects on hearing and balance (FP5)

Intarese: Integrated assessment of health risks from environmental stressors in Europe (FP6)

Nomiracle: Novel methods for integrated risk assessment of cumulative stressors in the environment (FP6)

PHIME: Public health aspects of long-term, low-level mixed element exposure in susceptible population strata (FP6)

More information on these is available on the Commission's research website: http://ec.europa.eu/research/index\_en.cfm





# THE POTENTIAL CONTRIBUTION OF HUMAN BIOMONITORING

One of the actions in the E&H Action Plan focuses on the development of a coherent approach to human biomonitoring (HBM) in Europe, and received strong support by the European Parliament and Member States.

# Body of evidence: HBM's role in policy

Human biomonitoring tracks environmental pollutants in the human body and how we react to them. For some pollutants, HBM can give a direct measure of total human exposure. This makes it potentially more relevant for risk assessment than using statistical extrapolations from chemical concentrations in soil, water, air or food.

Even where the health impacts of certain exposures cannot be identified, HBM can provide useful information, by determining reference exposure levels for whole populations. This can help to detect potential problems. If unusually high exposure figures appear during routine screening, this highlights the presence of unknown pollution sources or pollutants. HBM can also screen 'suspect' geographical areas, by comparing onsite biomonitoring data with reference levels, as done in the USA. In practice this can often alleviate concerns, by showing that the exposure is within the reference range. Screening HBM programmes are also useful for identifying bioaccumulation or 'build up' problems.

HBM can also be used to assess the effectiveness of policy once implemented, because it shows temporal trends in total exposure. For instance, breast milk monitoring programmes have shown a long-term decline of dioxins in people since dioxin legislation was introduced. Biomonitoring is also useful to indicate when a trend is reversed or when acute contamination is reduced.

# It's all in the research

Sound research and methodology is critical to ensuring HBM data is reliable and usable for policy-making. The research must be coordinated using validated criteria and methods, both for carrying out the HBM and interpreting the results. Recruitment of the study population, logistics, ethical issues, collaboration among disciplines, and adequate dissemination of results and reporting to the relevant authorities are also important.

HBM cannot be used in isolation to assess risks: findings must be cross-matched with toxicological, eco-toxicological and environmental (including monitoring) data to ensure that HBM results are translated into effective intervention strategies.

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## Preparing for take-off: EU pilot project

It is never easy to set up such a complex monitoring system, with technical, political, financial and communication all tackled in parallel.

The key technical need is a protocol outlining the environmental pollutants, related biomarkers and body tissues/fluids to be monitored, study population, analyses, research duration, etc. A series of recommendations are being developed on each of the various elements, to be completed by end 2006.

The pilot's success, politically and practically, rests heavily on Member State support and participation. Close contact with EU governments is a priority for achieving this. The EU's Seventh Framework Programme (FP7) for research will provide scope for integrating research activities on HBM – the science, methods and tools to develop a coordinated and coherent approach

Lastly, science-based communication should be an integral part of the programme. The Commission, in collaboration with the Member States, is considering how best to approach this issue so as to pass on information responsibly and avoid sensationalism.



We need to know which environmental pollutants, related biomarkers and body tissues/fluids to include in monitoring

#### **Testing HBM**

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In developing and testing an EU approach to HBM, three issues must be balanced:

- Capacity for biomonitoring must be enhanced across Europe, including 'biomarkers' to help identify, diagnosis and treat specific diseases, such as cancer.
- HBM will only gain and retain political support if it focuses on substances with a high potential regulatory impact. Substance selection should carefully consider regulatory priorities, such as Environmental Tobacco Smoke and the implementation of REACH.
- To boost its political relevance, the system must be designed to ensure HBM results are available fast good communication policy is essential.

# Priorities and conclusions

# WHICH ISSUES SHOULD WE FOCUS ON?

One immediate benefit of focusing on the health impact of exposure is the potential to prioritise among different environment and health issues. This helps analysts measure issues in relative scales of importance, not only in relation to each other, but also to other public health impacts. But a note of caution: the policy and priorities emanating from this approach are only as good as the impact data they are based on – data derived from a process (health impact assessment) that needs much more development.

Based on what is known, health risk from the environment is a relatively small part of the overall public health burden. Of the known environmental threats, ambient air quality has by far the largest health impact.

The relatively low impact of the environment on health is in large part due to the policies developed over the years, including regimes for controlling exposure through food, drinking water and bathing water. Also important are the systems for risk assessment of substances which may adversely impact human health, where the adoption of the REACH regulation is a major step forward. It is essential that this comprehensive network of measures stays in place to prevent and minimise damaging exposures so that the current (relatively small) environment and health problem is controlled and further minimised.

This assessment of relative priorities, and, indeed, this Review as a whole, starts very much from the exposure side – what pollutants we face – rather than from the health impact side – what disease problems we have. This is because many health impacts cannot be attributed solely to exposure to a particular environmental stressor, and so, to work out the contribution of the environment, you have to start from the point of exposure. But in identifying future priorities, we should start from the health impacts, and the key areas of concern are outlined on the next page.

Where both the problem and the role of the environment are clear, the Community is taking action already. Where the problem itself is not clear, more groundwork is needed (for instance on diagnostic techniques). But the most important issues are those where the problem is clear, but the role of the environment is not. Cases include the increase in asthma and allergies, and childhood cancer, which although it affects relatively few children, appears also to be increasing. Further research effort to find out what is driving such trends is the single most important action for the future.

Finally, it is important that the public has the maximum access to the information generated, and the major EU accessibility initiatives will be coordinated to ensure that this happens.



EU policy, research and action are working to provide a safer and healthier environment for all citizens – young and old, urban and rural.



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#### Health impacts: areas of concern

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There are roughly three categories of issue, each requiring a different approach:

- Diseases with clear diagnostic criteria, an identified problem (e.g. high or increasing prevalence), an environment-related risk factor, and also clear evidence on the scale of the environment's contribution. Examples are respiratory and cardiovascular disease linked to ambient air pollution and environmental tobacco smoke, and these are in general already being tackled.
- 2. Diseases with clear diagnostic criteria and an identified problem, but where the role of the environment is not clear. In the preparation of the Action Plan 2004-10, experts registered worrying trends in certain diseases (in particular asthma and allergies, and child cancer) but were unable to pin down the environmental contribution. If these diseases turn out to be driven by environmental factors, tackling them would become our major priority. But without better information on the extent of the environmental contribution, it is not possible to act effectively. Research at EU and Member State level, such as Newgeneris and GA2LEN, are already narrowing in on this.
- 3. Diseases where the diagnostic criteria themselves are controversial, and so even the scale of the problem is not obvious, such as neurodevelopment disorders (e.g. autism) or endocrine disruption which interferes with our hormonal system. The Action Plan address both of these disorders and calls for further research into potential effects, and improved diagnostic criteria. Examples of research projects are DEVNERTOX, which is working on neurotoxic food contaminants, PHIME (on the health impacts of heavy metals), and CASCADE (on various health effects of endocrine-disrupting compounds).

**TASK 14:** Ensure easy access by the public to comprehensive environment and health information, through coordination of tools such as the Commission's Public Health Thematic Portal, the Shared Environmental Information System and the Research E&H Portal.

# CONCLUSION

The main conclusion is that existing EU-wide monitoring and information systems and assessment strategies cover the range of known environmental impacts which can affect human health, as well as identification of potential threats. In many cases, these systems are in the process of further development to improve the level of protection.

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The Review has identified a list of Actions across the various exposure routes which could contribute towards better E&H information.

The work of the **SCENIHR and EFSA** on identifying emerging issues, in collaboration with other Scientific Committees, provides a comprehensive framework for the identification of new issues. The main task is to support its practical implementation while maintaining its independence from risk management decisions.

Other main tasks are to define better ways to **link current E&H data** to help identify relationships between environmental stressors and human health effects, and to make sure the results are accessible to all Europeans and stakeholders via streamlined **information systems**.

The Review suggests that integrated **health impact assessments**, using routine monitoring data, are most effective for ambient air, noise and perhaps indoor air pollution. But HIA is still a tool worth pursuing for other stressors (using more concrete guidelines and an agreed method). Exposure-related monitoring of air quality should be further developed, but is not considered cost effective for other routes of environmental exposure (food, drinking and bathing water), where compliance-based monitoring should be continued.

Of particular concern are **issues where the problem is clear, but the role of the environment is not**. Continuing the research effort to find out what is driving such trends is the most important action for the future. Finally, it is important that **public access to information** is maximised, and the major EU accessibility initiatives will be coordinated to ensure that this happens.

The Commission is keeping a close eye on E&H monitoring and future needs, including implementation of the 14 tasks highlighted in this Review. Regular progress reports will be presented to the main stakeholder body, the Consultative Forum on Environment and Health. The mid-term review of the Action Plan, brought forward in 2007, will provide an interim report, with final achievements reported at the end of the Action Plan's term in 2010.



The Commission's Public Health Portal (ec.europa.eu/health-eu/index\_en.htm) will be coordinated with the SEIS and the Research E&H portal so as to maximise public access to information.





# **MORE INFORMATION**

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The Commission's Environment and Health website: http://ec.europa.eu/environment/health/index en.htm

The Commission's website on Human Biomonitoring: www.eu-humanbiomonitoring.org

The Commission's Public Health Portal: http://health.europa.eu

The Commission's Research website: http://ec.europa.eu/research/index en.cfm

The Commission's Scientific Committees: http://ec.europa.eu/health/ph\_risk/committees/committees\_en.htm

The European Food Safety Authority: http://www.efsa.europa.eu/

The Commission's air quality website: http://ec.europa.eu/environment/air/index.htm

The Commission's water quality website: http://ec.europa.eu/environment/water/index.html

The Commission's INSPIRE website: http://www.ec-gis.org/inspire/

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