COMMISSION OF THE EUROPEAN COMMUNITIES

DRAFT Progress report on the implementation of the "European Environment and Health Action Plan 2004-2010"

13th November 2009

Content

1. INTRODUCTION

The "*Mid Term Review of the European Environment and Health Action Plan 2004-2010*"[1] reported on progress during the period 2004-2007 on the implementation of the European Environment and Health Action Plan (EHAP)[2].

This Progress Report aims (1) to present the progress on the activities carried out in the Commission in the framework of the EHAP after the Mid Term Review; (2) to assess the results since 2004 and (3) to prepare for the follow-up of the Action Plan post 2010 based on the conclusions, on brainstormings held with Member States[3] and with the Consultative Forum on Environment and Health[4], and taking into account the Council's and EU Parliament's views[5].

2. ACTIVITIES CARRIED OUT IN THE COMMISSION SINCE 2007 IN THE FRAMEWORK OF THE ENVIRONMENT AND HEALTH ACTION PLAN

The EHAP identified 13 specific actions which are jointly implemented by the Directorates-General for Environment, Health and Consumers, Research and the Joint Research Centre. Furthermore, the EHAP is an "*umbrella"* bringing together all the EU initiatives in the environment, health and research sectors designed to improve environmental health. Progress on health related environment policies since 2007 is reported in section 2.3.

2.1. Human bio-monitoring

The Commission continued its close collaboration with Member States and experts to prepare an EU pilot project[6] on human bio-monitoring (HBM) for testing out the feasibility of a coherent HBM approach in Europe.

– The technical preparations for the pilot project were done by the Implementation Group on HBM who prepared three Recommendations, by the ESBIO coordination action[7], and in the framework of the Administrative Arrangement between Directorate General for Environment and Directorate-General Joint Research Centre (JRC). The conclusions of the HBM Conference, organised by the French Presidency on 4th – 5th November 2008, also fed into the technical preparations.

– The political preparations for the pilot project were done via the established network of "*Political Back-Ups*"[8] and demonstrated to be efficient. The network has been encouraged to liaise with the responsible persons in the ministries for the European Health Examination Survey and for Inspire.

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1 COM(2007)314 - SEC(2007)777
2 COM(2004)416
3 17th December 2008 in Luxembourg
4 18th December 2008 in Luxembourg
5 Council Conclusions, 20th December 2007; EU Parliament Resolution on the Midterm Review of the Environment and Health Action Plan, 4th September 2008
6 www.http://www.eu-humanbio-monitoring.org
7 Project funded by the EU Sixth Framework Programme of Research (FP6) - Scientific Support for Policy programme, finished in October 2007.
8 persons responsible for HBM in the ministries

– Ensuring financing for the pilot project was difficult and the lack of appropriate EU funding hampered the start of the pilot project in 2008. The Commission launched several calls for proposals under FP7[9] and LIFE+ to fund the EU Pilot Project on HBM. Member States demonstrated strong interest and commitment by establishing consortia involving a high number of Member States and submitted different proposals in which co-funding was proposed.[10] The EU Parliament and the Council strongly supported the Commission HBM activities and urged the Commission to ensure adequate funding for the pilot project. The COPHES[11] project will kick-off on 1st December 2009. It includes 35 partners from 24 EU countries and Norway.

The pilot phase will focus on *capacity-building* and *harmonisation* of procedures, on *the future policy role* of HBM, and on *appropriate communication* at individual and at Community level.

For the post-pilot phase the Commission started to explore:

– the possibility to embed future HBM activities in an established framework such as the European Health Examination Survey[12] which SANCO aims to set up in 2011, provided that FP7 funding will be available;

– the possibility to integrate HBM activities with the harmonisation of indoor air quality monitoring requirements in EU;

– the possibilities for sustainable operational funding of a future HBM surveillance framework (LIFE+, European Environment Agency (EEA)) and who could play the role of a data centre to manage the data generated (EEA, JRC, European Centre for Disease Control (ECDC)).

– the links with and potential benefits for existing regulatory frameworks such as REACH[13], INSPIRE[14], Pesticides, Water Framework Directive[15].

2.2. Environment and health Information

The "*Environment and Health Information Review and Implementation Plan*"[16] made concrete recommendations for increasing linkage and integration between existing systems, enhancing efforts on research and improving data collection procedures. A detailed overview on the implementation of the recommendations so far is made in Annex I.

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9 http://cordis.europa.eu/fp7/home_en.html

10 COPHES proposal (1st FP7 call for proposals) was not selected for funding. COPHES II (3rd FP7 call for proposals) was selected for funding, DEMOCOPHES proposal (LIFE+) was not selected for funding and DEMOCOPHES II proposal (LIFE+, not yet evaluated).

11 Consortium to Perform Human Bio-monitoring on a European Scale – FP7

12 http://ec.europa.eu/health/ph_information/dissemination/reporting/ehss_06_en.htm A full-scale EU HES is scheduled for 2011-2013, if FP7 funding will be available

13 European Community Regulation on chemicals and their safe use – EC 1907/2006.

14 Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community

15 Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy

16 SEC(2006)1461 adopted on 8th November 2006

The ENHIS[17] projects started to collect comparable information on environment and health in the pan-European Region. The CEHIS[18] project identified directions for dynamic data flows between environmental and human health data and proposed how to integrate disparate information into a uniform system.

In the framework of INSPIRE[19], which will create an EU-wide harmonized database with geographical information to support environmental protection policies, health data are considered as well. The INSPIRE Directive includes in Annex III the data theme "*Human health and safety*" and work on this data theme started in 2009. By 15th May 2012 the Commission has to adopt Implementing Rules for the interoperability and harmonization of spatial data sets and services for human health data. Practical steps to involve the environment and health sector representation in INSPIRE Implementing Rules development were suggested at the Consultative Forum on Environment and Health in December 2008 in Luxembourg.

The proposed Shared Environmental Information System (SEIS) is a decentralised but integrated web-enabled information system based on a network of public information providers sharing environmental data and information. A SEIS portal will be developed and when ready (not within 2 years) it will be linked to the existing EU Health portal.

2.3. Health related environment actions

The Environment and Health Action Plan aims to ensure that human health aspects are duly taken into account in the different environment policies. A detailed overview on the initiatives since 2007, contributing to preventing adverse human health effects, is made in Annex II. The summary overview below shows that efforts have been made in the main environmental policies such as air quality, chemicals and climate change. Also, the issue of antimicrobial resistance has been addressed extensively.

In June 2008 the Directive on **ambient air quality** and cleaner air for Europe 2008/50/EC entered into force, streamlining the existing 5 legal instruments and introducing new objectives on fine particulate matter $PM_{2.5}$. These combine, for the first time, the $PM_{2.5}$ limit value with the specific target for public exposure reduction between 2010-2020. The latter should steer abatement actions that will maximize public health benefits. The Directive also includes specific requirements for $PM_{2.5}$ chemical speciation and background monitoring that should support better health impact assessments and identification of the specific properties (composition, size, surface area etc.) that make particulate matter the most toxic air pollutant. The Directive introduced also the possibility to gain, under specific conditions, more time for compliance with the existing limit values for PM_{10}, NO_2 and benzene. This provisions have until October 2009 been used by 18 Member States. Conditions are assessed by the Commission and though most have been objected to, the exercise creates important dynamics in better understanding air pollution situation in selected areas, development of more effective air abatement measures and raises awareness.

[17] http://www.enhis.org/

[18] **C**onnectivity **B**etween **E**nvironment and **H**ealth **I**nformation **S**ystems

[19] Infrastructure for Spatial Information in the European Union

The Directive also brought requirement for complete overhaul of reporting requirements; they are in final stages of preparation and should in future facilitate HIA and health related actions (such as information for vulnerable population) by adhering to SEIS/INSPIRE and introduction of near-real-time exchange requirements at EU level.

The **REACH** Regulation[20] entered into force in June 2007 and imposed gathering information on toxicological properties of chemicals through the EU Chemicals Agency (ECHA), which became fully operational on 1st June 2008. Companies submitted over 2 million pre-registrations by the deadline 2/12/2008. A first candidate list of 15 Substances of Very High Concern was established that may become subject of authorisation.

The new Framework Directive on the Sustainable Use of **Pesticides** aims to reduce the risks to human health and the environment from the use of pesticides with new measures that Member States will have to establish, such as access to training for professional users of pesticides, regular inspection of pesticide application equipment, a general ban of aerial spraying, and general principles of Integrated Pest Management becoming mandatory as from 2014. Under the revised Directive on the placing of plant protection products on the market new criteria for authorisation of plant protection products will be introduced that are expected to reduce possible risks of exposure to the most hazardous substances.

The Review Programme of the **Biocides** Directive continued evaluating active substances used in biocidal products[21] for their risks to human health and the environment. The revision of the Biocides Directive aimed to improve the protection of human health by including specific provisions related to the scope, product authorisation and data requirements. Several initiatives to address the concerns related to antibiotic resistance induced by biocides were undertaken.

Further to the **Mercury** Strategy[22] a number of proposals have been adopted with a view to banning mercury for certain uses within the EU, banning mercury exports from the EU from 2011 and imposing safe storage of unused mercury (see Annex II).

The Mid Term Review announced that the focus on **climate change and health** will be increased in the further implementation of the Environment and Health Action Plan. The Commission's "*White Paper on Adaptation to Climate Change*" - adopted on 1st April 2009 - includes a section on human health and is accompanied by a "*Commission Staff Working Document on Human, Animal and Plant Health Impacts of Climate Change*".

Further to the announcement in the Mid Term Review to increase the focus on **antimicrobial resistance** the Commission requested several scientific opinions[23] and

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20 http://ec.europa.eu/environment/chemicals/reach_intro.htm

21 that were on the market before 14th May 2000

22 COM(2005)20

23 *SCENIHR Opinion on the Assessment of the Antibiotic Resistance Effects of Biocides* http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=830 A *Joint EFSA/EMEA/ECDC/SCENIHR Opinion on Antimicrobial Resistance* is under preparation (adoption foreseen in October 2009).

has prepared a *Commission Working Document on Antimicrobial Resistance*[24] highlighting the need for an integrated cross-sector approach and laying the ground for future policy and research initiatives.

2.4. Environment and health research

The actions of the EHAP designed to fill the knowledge gap include (1) integration and strengthening of European environment and health research; (2) targeting research on diseases, disorders and exposures; (3) development of methodological systems to analyse interactions between environment and health; and (4) ensuring that emerging hazards on environment and health are addressed.

Integration and strengthening of European environment and health research

Research projects in the field of environment and health funded under the Fifth Framework Programme of Research (FP5) were analysed and their key findings together with an assessment of their relevance for EU policy were summarised in a 2007 publication[25]. Several relevant projects were funded under the Sixth Framework Programme for Research (FP6). Some were completed and a number of them provided reviews of the current state of knowledge on the potential health effects of factors such as electromagnetic fields, indoor air pollution and ambient air pollution. A project to strengthen networking between researchers, policy makers and stakeholders was funded[26]. The Seventh Framework Programme for Research (FP7), spanning the period 2007-2013, includes a sub-activity dedicated to supporting environment and health research under its Environment theme of the Cooperation Programme. This sub-activity had an initial annual budget of approximately 20 MEUR for the years 2007-2008. To date, 14 new research projects were launched under this sub-activity and additional 5 are planned to be launched by the end of 2009. Among the FP7 projects launched, there is also one dedicated to enhancing the coordination among national environment and health research programmes in Europe[27]. The Commission also continued to organise and to contribute to numerous research and policy-related events engaging a wide range of stakeholders including national and EU policy makers.

Targeting research on diseases, disorders and exposures

Under the EU Framework Programmes for Research, a number of projects have been designed to improve knowledge on the links between environmental exposures and four priority diseases (childhood respiratory diseases, neuro-developmental disorders, cancer and endocrine disrupting effects). For a more detailed account of the projects in question see ANNEX III.

Development of methodological systems to analyse interactions between environment and health

[24] Adoption foreseen in November 2009
[25] http://ec.europa.eu/research/environment/pdf/env_health_projects/env_health_brochure.pdf
[26] Health and Environment Network: http://henvinet.nilu.no/
[27] ERA-ENVHEALTH project: http://www.era-envhealth.eu

Under FP6, support has been provided to several projects devoted to the development of integrated risk assessment methodologies and of models for evaluating health effects of multiple environmental stressors or mixtures of pollutants (NOMIRACLE, INTARESE, HEIMTSA). In addition, other FP6 projects were devoted specifically to the valuation of environment-related health impacts on children (VERHI-CHILDREN) or to comparing the costs of emission reduction measures with their benefits in terms of reduced human health impacts (DROPS). Several major projects are still ongoing; once their results are available, suitable follow-up will be considered under FP7.

Ensuring that emerging hazards on environment and health are addressed

The World Health Organisation has recently identified **climate change impacts on human health** as a priority for global public health and there has been a growing recognition of the need for research on the linkages between climate, policies addressing climate change and health outcomes. In this context, DG Research has funded under FP6 the MICRODIS project dealing with impacts of natural disasters and the EDEN project investigating the impacts of environmental change on the spatial and temporal distribution of human pathogenic agents. Under FP7, two projects (ArcRisk, CLEAR) have been selected to examine the health risks resulting for Arctic populations from climate change induced changes in the distribution of environmental pollutants. A project on the health effects of changing surface UV radiation levels has also been launched in 2009. Starting from the third call for proposals under the FP7 Environment theme, an area dedicated to climate change induced human health effects has been introduced under the Environment and Health sub-activity as an acknowledgement of the importance of this issue. This means that one or two relevant topics will be annually opened for research proposals in the remaining FP7 calls. Another emerging area that has received substantial attention since 2007 concerns the possible **human health impacts of nanomaterials**. Under FP6, as many as 8 research projects have been supported in this area with a total EC contribution amounting to 20 million EUR. Significant support for research in this field is continuing under FP7 with 18 projects already selectedfor funding.

2.5. Training of professionals in environmental health

The Commission continues to promote the training of professionals. Following the completion of the INCHES project, the Commission is funding a European network for the training and development of public health environment physicians (PHEEDUNET)[28]. As the investigation of the environmental cause of ill health is highly complex due to knowledge gaps and multi-factorial causes, there is a need for specific training of physicians and other professionals on diseases caused by environmental factors. The goal of PHEEDUNET is to coordinate this training across Europe. The TRISK project[29] will recruit 25 experienced toxicologists to offer the risk assessment training modules.

28 http://www.pheedunet.eu/

29 European Toxicology Risk Assessment Training Programme, a programme co-financed by the European Commission under the Second Programme of Community Action in the field of Health (2008-2013). http://www.trisk-project.eu/

2.6. Indoor air quality

Improving indoor air quality (IAQ) in the framework of Action 12 is focussed around two key elements: (1) addressing environmental tobacco smoke (ETS) and (2) developing networks and guidelines on other factors affecting indoor air quality by using research and exchange of best practices.

The consultation initiated in 2007 by the Commission's Green Paper "Towards a Europe free from tobacco smoke: policy options at EU level" revealed significant support both for comprehensive smoke-free policies in all enclosed workplaces and public places and for further EU action to promote smoke-free environments throughout the Member States.

The European Commission adopted on 30 June 2009 a proposal for a Council Recommendation on smoke-free environments calling on all Member States to bring in laws to protect their citizens from exposure to tobacco smoke by 2012.

The second phase of the EU-wide HELP media campaign "For a life without tobacco" was launched on 31 May 2009 (World Tobacco Day). It targets young people both to help them quit smoking and to prevent them from starting.

In addition to environmental tobacco smoke, people are exposed to a multitude of indoor environmental factors which can influence respiratory health. A variety of biological, chemical and physical agents as well as ventilation rate influence IAQ and affect indoor human exposure. The Commission is using a comprehensive and integrated approach to tackle this complex issue and created an expert group in 2006 to coordinate work across policy areas.

The EHAP succeeded to create a number of preconditions necessary to close the knowledge gaps in order to prepare the launch of a coordinated action for the next action phase. Key achievements are (1) European and international agreement on a number of key pollutants based on health effects; (2) supporting the World Health Organisation to establish health based guidelines on key pollutants; (3) creating standardised procedures and criteria for monitoring indoor air versus health effects. This will be completed by end of 2009 and it will be followed up by a pilot phase to test newly established protocols and criteria with an ad hock project in 2010; (4) creating a tool for increasing public and professionals awareness: a dedicated website on IAQ is under preparation; (5) studying the feasibility of common criteria for existing labelling schemes in EU. An ad-hoc working group has been established that is drafting a proposal for a framework of harmonised criteria for labelling schemes for building materials. This proposal will be discussed with all Member States in 2010; (6) a construction material emission database and guidance has been developed trough a research project (BUMA). Final report and access to the database is expected by end of 2009; (7) special focus to most vulnerable groups (children, elderly). A pilot project is being launched on indoor air quality in schools. Given the substantial amount of resource available (4 m€) this project is expected to cover a large number of schools and Member States. Final output will be a guidance document for healthy environments in schools and a wide dissemination of this document at local (school) level. A similar project is ongoing on nursery homes; (8)

related research projects are supported under FP7. A project focusing especially on indoor microbial exposures[30] was launched in April 2008 and a topic on indoor air quality in office buildings is currently open for proposals; (9) specific projects are ongoing or under negotiation targeted at supporting Member States to implement measures on key areas. These include targeted project on radon, moisture and dampness, emission from consumer products, collection of best practises on maintenance) ventilation; (10) identification of main indoor sources, exposures routes and associated health effects and recommendations for research and policy actions (ENVIE project).

The next phase will have to put all these efforts into a policy coordinated framework based on health and focussing on the priority diseases identified by the 2003 European environment and health strategy.

2.7. Electromagnetic fields

The latest SCENIHR opinion[31] on the potential health effects of electromagnetic fields (EMF), adopted in January 2009, confirmed the conclusions of the previous assessments that current scientific evidence does not justify a change in the rationale used to set up the exposure limits proposed by Council Recommendation 1999/519/EC[32]. However, this opinion identified a number of areas characterised by insufficient and contradictory information as well as a number of knowledge gaps.

Following the publication of the SCENIHR opinion, the Commission organised on 11-12 February 2009 a workshop on "*EMF and Health: Science and Policy to address public concerns*". This workshop confirmed that the political issue of the possible health effects of EMF remains very sensitive, largely because of an ongoing scientific controversy kept alive by a small international group of scientists. The workshop concluded that more research is needed to resolve these scientific uncertainties and bring the controversy to a close.

As a result, the Commission asked the SCENIHR (i) to provide more details on the research recommendations presented in its opinion on the health effects of EMF adopted on 19 January 2009, (ii) to prioritize these research recommendations and (iii) to develop a research strategy based on studies which are feasible and able to deliver results within a reasonable time-frame. The result of this work was adopted in July 2009[33] and will be used as one of the sources of ideas for future research calls at EU level. Two research projects have already been launched in FP7, focused on potential risks of brain cancer in children and adolescents relative to mobile phone use[34], and on potential health risks of wireless technologies, respectively.

[30] Health Effects of Indoor Pollutants: Integrating microbial, toxicological and epidemiological approaches - www.hitea.eu
[31] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_022.pdf
[32] Council Recommendation (1999/519/EC) of 12 July 1999 on the limitation of the exposure of the general public to electromagnetic fields (0 Hz – 300 GHz)
[33] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_024.pdf
[34] http://www.mbkds.com/

2.8 Communication

In 2005, the European Commission and the European Environment Agency (EEA) published a joint report[35] which gave an overview of current environment and human health related issues in Europe. The report was followed in 2007 by a chapter[36] in the EEA report "Europe´s Environment – The fourth assessment" prepared for the 6th UNECE Environment Ministerial Conference in Belgrade 2007. Currently, the EC and the EEA are preparing a joint Reference Report due in 2010 summarising the current knowledge and advances in the Environment and Human Health area.

3. ASSESSMENT OF RESULTS SINCE 2004 – CONCLUSIONS

3.1. Human bio-monitoring

Both technical and political preparations for the EU Pilot Project progressed well since 2004. The lack of appropriate EU funding hampered the start of the pilot project in 2008. However, Member States demonstrated a persistent commitment by submitting new proposals and providing co-funding which resulted in the kick-off of the pilot project (COPHES) on 1st December 2009.

Prerequisites for a European HBM surveillance framework to be established after the pilot phase are: (1) sustainable funding; (2) a centre to manage the HBM data; (3) scientific support and decision-making structures at EU level for the establishment of European HBM limit values.

3.2. Environment and health information

Only limited progress has been made in the implementation of the "*Environment and Health Information Review and Implementation Plan*", mainly due to scarce human and financial resources. After the finalisation of the EHNIS projects, the major initiative addressing the issue of combining Environment and Health Information was the CEHIS[37] project, which was focusing on mapping data flows between environmental and human health data and proposed how to integrate them into a uniform system.

Progress on INSPIRE[38], the directive on a European spatial data infrastructure, and SEIS[39], the EU Shared Environmental Information System, provide a solid basis for the further development of the integrated European Environment & Health Information System.

Establishing a sound integrated European Environment & Health Information System is the cornerstone of the Environment & Health Action Plan and crucial for the long-term development of evidence-based environment and health policy. Past projects (e.g. ENHIS, CEHIS), while limited in scope and time, showed the usefulness of

[35] "Environment and Health" (EEA Report 10/2005)
[36] "Environment and Health and the Quality of Life"
[37] Connectivity Environment and Health Information Systems
[38] http://inspire.jrc.ec.europa.eu/
[39] http://ec.europa.eu/environment/seis/

such an infrastructure. It is important to keep in mind that the development of such a system is a complex taskand must be seen as a long-term process whose benefits grow exponentially with time while creating synergies and new uses in existing sources of data. Therefore, the modest but essential human and financial resources needed to develop this integrated European Environment & Health Information System should be made available to enable the efficient implementation of the "*Environment and Health Information Review and Implementation Plan".*

3.3. Health related environment actions

Policies related to air quality, water quality, noise, chemicals (REACH, endocrine disrupters, dioxins & PCBs, pesticides, biocides, mercury, nanotechnology), climate change, and biodiversity continued to include human health aspects aiming to contribute to the protection of human health. The Environment & Health Action Plan coordinates the ongoing health related environment activities and unites them under one single umbrella together with the environment related health activities and the environment and health research activities. This provides - together with the specific environment and health actions outlined in the Action Plan (human bio-monitoring, information system, etc.) - an integrated view on how environmental health is tackled at EU level and where we stand.

3.4. Environment and health research

During the first phase of the Action Plan, the Commission spent over €200 million on environment and health projects via the Sixth Framework Programme of Research (FP6)[40]. This represents an annual increase of around 10 million euro as compared to the Fifth Framework Programme of Research (FP5), which demonstrates that the adoption of the Action Plan has served as a catalyst to increase research spending at the Community level. It is important that this funding trend be maintained in the Seventh Framework Programme of Research (FP7).

The availability of extra funding has allowed the concentration and re-focusing of efforts to build up a European Research Area in specific areas of environmental health science as outlined in the European Environment and Health Strategy. The novel funding instrument of network of excellence was used in the area of environment and health to combat fragmentation of science and policy in specific areas such as allergy and asthma[41], environmental cancer risks[42] or health risks of exposure to endocrine disrupting chemicals[43]. These networks brought together a large number of scientists and other stakeholders from a variety of disciplines to carry out a joint programme of activity which included, in addition to research, activities such as training, dissemination of results, education, and exchanges of expertise.

[40] European Research on Environment and Health Funded by the Sixth Framework Programme: http://ec.europa.eu/research/environment/pdf/eur23460_en.pdf
[41] GA2LEN Global allergy and asthma European network: http://ga2len.com/
[42] ECNIS Environmental cancer risk, nutrition and individual susceptibility: www.ecnis.org
[43] Chemicals as contaminants in the food chain: a NoE for research, risk assessment and education: http://www.cascadenet.org/

The research/policy interface was enhanced during the first phase of the Action Plan by the introduction in the FP6 of a specific 'Scientific Support to Policy' programme[44], which allowed the close exchange of ideas between research and policy-makers and the discussion of policy options and implications of research undertaken. From this programme a number of smaller targeted research projects, addressing specific issues such as bathing water[45] or indoor air quality[46] were financed and information on these projects is available[47].

The additional availability of financial resources has also allowed the Commission to fund unprecedented large-scale integrated projects, the aim of which was to support objective-driven research to address major societal needs. This funding instrument was frequently used in the environment and health area in the past six years, for example, to fund projects and increase knowledge base on improving the methods, models and tools of integrated environment and health impact assessment[48]; on impact of environmental changes on the spread of infectious diseases[49]; on uncommon cancers[50]; or on genetic and environmental causes of asthma[51].

Efforts in the first period of FP7 have been directed towards strengthening the European Research Area in domains that are emerging or have been neglected in the past. A core of environment and health research will be funded from a specific Environment and Health sub-activity, embedded in the Environment theme of the Cooperation programme[52]. Unlike in FP6, policy aspects are embedded in all themes of the Cooperation programme, thus providing a close and natural link between research and policy where necessary and relevant.

Relevant policy-makers have been provided with progress or final project reports and have in some cases been briefed directly on the outcome of the results. In addition, they have attended numerous workshops and conferences on specific issues such as health impacts of endocrine disrupters, indoor air pollution or electromagnetic fields. They have also served in advisory functions for some projects. These contacts have allowed the transfer of results from science to policy and vice versa, and an exchange of ideas for prioritisation of issues for future research. Policy-makers involved in risk assessment and management issues at national or EU level have been engaged by the projects in a science-policy dialogue mostly via targeted workshops and participation in conferences and project meetings in order to ensure proper policy take-up of results generated.

[44] http://ec.europa.eu/research/fp6/ssp/index_en.htm
[45] EPIBATHE Assessment of human health effects caused by bathing waters: http://ec.europa.eu/research/fp6/ssp/epibathe_en.htm
[46] ENVIE Coordination action on indoor air quality and health effects: www.envie-iaq.eu/home.html
[47] http://ec.europa.eu/research/fp6/ssp/themes_en.htm
[48] INTARESE *Integrated assessment of health risks from environmental stressors in Europe*: www.intarese.org; HEIMTSA *Health and environment integrated methodology and toolbox for scenario assessment*: www.heimtsa.eu
[49] EDEN *Emerging diseases in a changing European environment*: www.eden-fp6project.net
[50] NEWGENERIS *Newborns and genotoxic exposure risks: Development and application of biomarkers of dietary exposure to genotoxic and immunotoxic chemicals and of biomarkers of early effects, using mother-child birth cohorts and biobanks*: www.newgeneris.org
[51] GABRIEL *A multidisciplinary study to identify the genetic and environmental causes of asthma in the European Community*: www.gabriel-fp6.org
[52] http://cordis.europa.eu/fp7/environment/home_en.html

3.5. Indoor air quality

One important achievement since 2004 is a strengthened cooperation between stakeholders on indoor air quality, and more broadly to improve respiratory health. These actions have been so far targeted on creating tools and preconditions necessary to support a more coordinated approach in this field as requested by the European Parliament in two Parliament Resolutions. Major achievements have been the prioritisation of a small pool of pollutants based on health effects and notably the collaboration with the World Health Organisation on developing health based guidelines value for those pollutants. Important steps have been also undertaken towards the creation of a common monitoring system for key pollutants and exchange of best practices-tools to prevent radon exposure and to improve ventilation practices in buildings on the basis of health criteria.

The next action plan needs to put more emphasis on the policy side. The issue of indoor air needs to be more prominent and to have momentum. This should become part of a broader strategy on healthy environments. Work and result on Environmental Tobacco Smoke have been quite satisfactory due to engaged resources and a youth-friendly EU wide media campaign. The creation of a thematic platform on "*Safe, Healthy, Energy Efficient and Sustainable Buildings in EU*" is envisaged which will assist towards the sustainable implementation of several EC policies affecting the built environment (e.g, indoor air quality, energy performance, noise, safety of constructions etc) in an integrated framework.

3.6. Electromagnetic fields

While the results of large past research efforts have provided the basis for the latest SCENIHR assessment of the potential health effects of EMF and are broadly reassuring, a number of uncertainties exploited by a small but vocal group of scientist maintain this issue as a very sensitive political subject. Limited additional research as recommended by the independent experts of the SCENIHR should be sufficient to resolve the main uncertainties feeding the current scientific controversy and anxious calls for the application of the precautionary principle.

3.7. Overall Environment and Health Action Plan 2004-2010

The Action Plan demonstrated its **added value** by:

(1) putting in place and maintaining *a strong process of coordination and collaboration* between the health, environment and research sectors at Member States and EU levels;

(2) consolidating *the progress made on well-defined inter-sectoral actions such as human bio-monitoring and indoor air quality* thanks to coordination and integration;

(3) providing *a broad and coherent framework for all the EU initiatives designed to address health issues related to the environment,* whether they originated under environment policy, public health activities or research activities. The

Action Plan ensured that health aspects are duly taken into account in environment policies, that environmental aspects are duly taken into account in health policies and that specific research addressing environment and health issues is funded[53]. It provided an integrated view on how the environment & health issue is addressed at EU level and on where we stand. Key EU environmental policies such as air quality, chemicals or climate change have explicitly taken health aspects into account and will deliver health benefits to EU citizens in the long-term.

The **difficulties encountered** during the implementation of the Action Plan relate mainly to:

(1) *Unavailability of appropriate funding*: as demonstrated above, there was a dependence on Research Framework Programmes (FP) funding for the implementation of several actions. However, the FP may not be the most suitable source of funding, especially when it comes to activities that require continuous funding over a long period of time. In addition, there is a strong competition for research topics to be funded under the FP and it is important to maintain a funding line dedicated to environment & health, especially as the evaluation process is done by independent evaluators and can never guarantee that a particular proposal will be selected for funding. This has the additional merit of maintaining the coordination and collaboration between the health, environment and research sectors at Member States and EU levels, identified above as a major added value of the Action Plan. The Commission should also consider creating an appropriate EU funding instrument for surveillance activities (such as for human bio-monitoring and air quality/health monitoring) and other technical non research projects for the future E&H Action Plan and other initiatives.

(2) *Science-policy interface*: relevant policy-makers were provided with progress or final project reports and have in some cases been briefed directly on the outcome of the results. In addition, they have attended numerous workshops and conferences. Nevertheless, the results of the many environment and health research projects funded under FP5, FP6 and FP7 and of other information gathering efforts could be better exploited at policy level. An efficient mechanism to ensure the science-policy interface should be identified.

4. REACTIONS FROM OTHER EU INSTITUTIONS

The Council Conclusions on Environment and Health[54] invited the Commission to ensure adequate funding for human bio-monitoring, to consolidate guidelines for indoor air quality, to develop the environment and health information system, and to increase funding for research. Furthermore, the Council urged the Commission and

[53] Following the adoption of the Action Plan the focus on *environment and health research* increased*:* Funding 2004-2008:=280M€ (€56M per year). This represents an average of 40% annual increase after the adoption of the Environment and Health Action Plan as compared to the funding level before.
[54] 20th December 2007

the Member States to develop tools for anticipating, preventing and responding to climate change and to continue to support research and to develop specific risk assessment for nanomaterials and nanoproducts.

The EU Parliament in its Resolution on the Mid Term Review of the European Environment and Health Action Plan 2004-2010[55] regretted the insufficient funding for human bio-monitoring, requested concrete measures on indoor air quality, expressed its concern about the lack of specific legal provisions to ensure the safety of consumer products containing nanoparticles, and requested stricter exposure limits for electromagnetic fields, and an adequate response to climate change.

5. INTERNATIONAL ORGANISATIONS

The Commission is supporting the World Health Organisation (WHO) and EU Member States to implement the Children's Environment and Health Action Plan for Europe (CEHAPE) and the Ministerial Declaration issued in Budapest in 2004. The work carried out in the framework of the EU's Environment and Health Action Plan is contributing to the implementation of the four Regional Priority Goals[56] identified in the CEHAPE. The Midterm Review has been presented in the Intergovernmental Midterm Review meeting on Environment and Health in Vienna in June 2007.

The Commission co-organised with WHO and the Spanish authorities a workshop in Madrid in October 2008 called International Public Health Symposium on Environment and Health Research: "Science for Policy, Policy for Science - Bridging the gap" to discuss how research findings can be translated into policy.

The Commission is involved in the preparation of the Fifth Ministerial Conference on Environment and Health "*Protecting Children's Health in a Changing Environment*" (March 2010, Italy) and attended four High Level Preparatory meetings (Milan, Madrid, Bonn, Parma). Climate change-related health issues will be one of the main pillars in the conference.

The Commission is also working in close collaboration with WHO concerning indoor air quality with the aim to produce health-based thresholds or guideline values for pollutants, and to gather best practices on remedial measures for moisture and mould.

6. FOLLOW-UP OF THE ACTION PLAN POST 2010

This progress report has been developed in view of the Fifth Ministerial Conference on Environment and Health, to be held in March 2010 in Parma. The disadvantage of issuing the report at this stage is that no clear commitments for the future can be included given the transition period between the old and new Commission.

[55] 4th September 2008 (P6_TA(2008)0410)

[56] RPG I: safe water and adequate sanitation; RPG II: injuries and physical activity; RPG III: respiratory diseases due to out- and indoor air; RPG IV: Hazardous chemicals, physical agents (noise), biological agents, hazardous working environment.

The assessment indicates that significant efforts have been done and that progress has been made in various areas since 2004. Building on this it is now proposed to continue and consolidate the present actions in the coming years, with emphasis on

- *continued coordination and collaboration* between the health, environment and research sectors at Member States and at EU level;

- *focusing on well-defined inter-sectoral actions in a number of priority areas*, such as human bio-monitoring, indoor air quality, the environment & health information system, climate change and health, etc. for which concrete activities, responsibilities, deliverables and funding will be identified;

- *providing a framework for all EU activities designed to improve the environment and health issue*: health related environment activities, environment related health activities and environment and health research activities and establishing an integrated state of the art.

Building on achievements so far and with these needs in mind, the Commission is considering to propose a new Action Plan in 2011. This progress report will be the basis for an in-depth debate with Member States and stakeholders preparing this new Action Plan.

ANNEX I
Detailed overview of progress on Environment and Health Information

Data linkage: Task 1 of the "Environment and Health Information Review and Implementation Plan" recommended to assess the feasibility of data linkage, as a basis for identifying emerging issues, by using existing funding programmes to enable pilot work.
Directorate-General Information Society funded a study on "*Connectivity between Environment and Health Information Systems: Supporting synergy between environment and health research and policies* "57. *[INFSO to complete]*

Two FP6 projects, "Health and Environment Network"58 and "Integrated Assessment of Health Risks of Environmental Stressors in Europe"59 were launched. The results will be available in 2010.

European advanced network for the combined monitoring of air pollution and related health effects: Task 2 of the "*Environment and Health Information Review and Implementation Plan*" recommended to set up and maintain a European advanced network for the combined monitoring of air pollution and related health effects.
The European monitoring network has not been set up because no funding was available under the FP7 Research Infrastructure initiative. An alternative solution (with a number of restrictions due to the limited budget) was proposed, notably to fund the network via a collaborative FP7 Project. Unfortunately this did not succeed either: the ANEMONE proposal[60] submitted by a consortium of European experts to the 1st call for proposals under the Environment theme of the FP7 Cooperation Programme (Megacities, air quality and climate) was not selected for funding. Following the third call under the Environment theme, the a TRANSPHORM project (Transport related air pollution and health impacts – integrated methodologies for assessing particulate matter) was selected for funding and is currently under negotiation. It addresses part of the objectives as it focuses on the effcts from transport. It will have close links with the ESCAPE project (see below).
Experts indicate that more sustainable EU Monitoring network is still needed and should be funded via Research Infrastructures.

Ambient air epidemiology: Task 3 of the "*Environment and Health Information Review and Implementation Plan*" recommended to develop a programme for long-term studies on ambient air pollution and health impacts across Europe.
"*The European study of cohorts for air pollution effects*"[61], launched under FP7, aims to measure fine particles and nitrogen dioxide at different locations in 40 areas spread over Europe and to study the relation between these pollutants and (1) low birth weight, asthma and allergy in children; (2) respiratory diseases in adults; (3) cardiovascular diseases in adults; (4) mortality and cancer in adults.
This study is only the start for setting up a programme for long-term studies. An operational budget for a future programme should be identified.

Ambient air, health data: Task 4 of the "*Environment and Health Information Review and Implementation Plan*" recommended to improve and harmonise baseline frequency data for health endpoints of interest across Member States.

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57 Contract duration: 12 months; budget: 200. 000 euro; study expected to start in April 2007
58 HENVINET, ending in April 2010
59 INTARESE, ending in October 2010 – www.intarese.org
60 Advanced Network for MONitoring airquality/climate and health Effects
61 *ESCAPE* http://escapeproject.eu (EC contribution €5.9M)

The proposed study related to an optimized data handling procedure was not launched due to the unavailability of funding under the Public Health Programme.

Indoor air Health Impact Assessment: Task 5 of the "*Environment and Health Information Review and Implementation Plan*" recommended to develop a consensus on key factors impacting on indoor air quality across the EU, based on health impact assessment; and based on Member States' experiences, identify the key pollutants and pollutant levels in transport-related indoor environments, schools and/or other public spaces with vulnerable groups; and evaluate Member States' current practice with regard to indoor air quality in private homes.
To this end DG ENV funded a study on "*Ranking indoor air health problems using health impact assessment*"[62], which finalised in November 2007. The study concluded that there is a consensus on priority pollutants to focus on, notably ETS, formaldehyde, CO, particles (PM2.5 and PM10), NO2, benzene, naphthalene, moulds and mites, dampness/moisture, CO2 and radon. The results of this study fed into the work of SANCO's IAQ Expert Working Group.

In 2008, the DG SANCO's experts group on indoor air quality assisted by DG JRC developed an EC Inter-service website on indoor air quality and health effects[63]. This website mainly aims at increasing public awareness on the health importance of air quality in indoor environments and giving advice on how to improve indoor air quality in the EU dwellings. The contents of the websitewill be completed during 2009.

In 2008, DG SANCO supported by the DG JRC launched a long term project for reviewing existing data on indoor air priority pollutants and their concentrations in EU Member States and establishing harmonised monitoring criteria and exposure assessment protocols which are necessary for obtaining comparable data on indoor air pollution in EU. As part of this project the INDEX exposure guidelines for indoor priority pollutants (i.e, formaldehyde, benzene, carbon monoxide, nitrogen dioxide and naphthalene) are being updated and the health effects due to exposure to indoor particulate matter are being evaluated.

With regard to construction materials (Council Directive 89/106/EEC) the Commission has established a preparatory working group led by DG JRC (and assisted by the German, French, Finnish and Danish labelling schemes for construction products) with the aim to establish common criteria between existing indoor emissions labelling schemes in the EU.
Another relevant project on building materials (BUMA[64]) was finalised in April 2009. BUMA created a database of emissions from commonly used construction materials through field and chamber measurements, and developed guidance for producers, constructors and end users.
Based on mandate M/366 (within the framework of the Construction Products Directive 89/106/EEC) CEN is working on developing horizontal technical assessment methods for the emission of dangerous substances emitting from construction products into indoor air, soil and water.

DG SANCO has recently launched a call for a project[65] to develop European health-based ventilation guidelines for homes, offices and public places such as schools and nurseries. These guidelines should help Member States in revising existing building codes and practices, also in the light of energy efficiency of buildings.

[62] http://ec.europa.eu/environment/health/news_en.htm
[63] http://iaq.jrc.ec.europa.eu/en/index.cfm
[64] http://ec.europa.eu/health/ph_projects/2005/action3/action3_2005_4_en.htm
[65] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:053:0041:0073:EN:PDF

The HITEA project[66] is an FP7 project focusing on the role of indoor biological agents in the development of respiratory, inflammatory and allergic health impacts among children. The project started in April 2008 and is scheduled to run for 5 years.

The EnVIE[67] Co-ordination Action on "*Indoor Air Quality and Health Effects*" funded by FP6 was successfully concluded in December 2008. EnVIE has identified key policies and research activities to fill existing gaps in knowledge which could contribute to reduce health effects from key indoor air pollutants.

The AIRMEX project (*European Indoor Air Monitoring and Exposure Assessment Project*) co-odinated by the Joint Research Centre was finalised in October 2008. This project started in 2003 aimed at identifying and quantifying the main air pollutants and their sources present in public buildings, schools and kindergartens in 11 European cities. An exposure assessment and evaluation of health risks of people spending time in these indoor environments due to chronic exposure to key air pollutants was also performed.

A new project (CLEAR-UP[68]) was also funded by FP7 for 2008-2012 that presents a holistic approach to ensuring a comfortable and healthy indoor environment based on resource efficient technologies. By development and novel use of nano-materials it aims to increase energy performance in heating, ventilation, air conditioning (HVAC) and lighting systems, and to improve indoor air quality using catalytic purification.

The four-year large-scale integrating NANODEVICE[69] project, launched in 2009, will aim at developing new and innovative concepts and methods for measuring and characterising airborne engineered nanoparticles with novel portable and easy-to-use device(s) for workplaces.

Drinking Water Safety Plans: Task 6 of the "*Environment and Health Information Review and Implementation Plan*" recommended to assess whether Water Safety Plans (WSPs) should be mandated in the context of the revision of the Drinking Water Directive. WSPs are based on 'Hazard Analysis and Critical Control Point' methodologies designed to identify contamination at any point in the treatment and supply chain.
The WHO study on WSPs[70] (finalised in October 2007) co-financed by a DG ENV funded grant gave support to the Commission in order to develop a framework for the implementation of water safety plans in the EU. The study concluded that WSPs should be included in the revision of the Drinking Water Directive. The Commission Proposal for a revision of the Drinking Water Directive is foreseen by the end of 2009 and one of the major changes[71] will be the inclusion of WSPs.

Drinking Water Data Base: Task 7 of the "*Environment and Health Information Review and Implementation Plan*" recommended to develop a database of current raw monitoring data.
The Commission has examined this possibility in the context of the Water Information System for Europe (WISE) and the Drinking Water Directive. The current priority is making available aggregated views on drinking water quality throughout the EU.

[66] Health Effects of Indoor Pollutants: Integrating microbial, toxicological and epidemiological approaches - www.hitea.eu
[67] http://www.envie-iaq.eu/
[68] http://www.clear-up.eu/
[69] Novel concepts, methods, and technologies for the production of portable, easy-to-use devices for the measurement and analysis of airborne engineered nanoparticles in workplace air. Website under construction.
[70] http://circa.europa.eu/Public/irc/env/drinking_water_rev/library?l=/dwd_2007_reportpdf/_EN_1.0_&a=d
[71] See Drinking Water website on europa: http://ec.europa.eu/environment/water/water-drink/index_en.html

Drinking Water Policy Effectiveness Indicator: Task 8 of the "*Environment and Health Information Review and Implementation Plan*" recommended to explore the possibility to develop an indicator of the effectiveness of drinking water policy in protecting health.
The ENHIS project[72] developed a qualitative health impact assessment on drinking water pollution. The aim is to develop a tool or guidance for policy makers how to understand currently available data on drinking water quality from national and international databases in terms of public health risk and health effects of drinking water pollution. [*SANCO to complete: what happened since 2007 ?]*

Bathing Water Epidemiology: Task 9 of the "*Environment and Health Information Review and Implementation Plan*" recommended to review the potential for health impact assessment of bathing water.
EPIBATHE and VIROBATHE - two FP6 projects on the health impacts of bathing water - were finalised in 2008. Based on the final reports[73] of the studies the Commission will in 2009 issue a document reporting on the outcome of the studies and concluding on the further work to be done on the health implications of bathing water at EU level.

Food Alert System: Task 10 of the "*Environment and Health Information Review and Implementation Plan*" recommended to develop a system of mutual alert between environment and health monitoring agencies.

Due to the lack of human resources nothing was done.

Food Monitoring Coherence: Task 11 of the "*Environment and Health Information Review and Implementation Plan*" recommended to improve the general coherence of environmental and food monitoring across Member States.

Due to the lack of human resources nothing was done.

Noise Health Impact Assessment: Task 12 of the "*Environment and Health Information Review and Implementation Plan*" recommended to assess the environmental noise exposure related health impacts on the population across Europe.

To date noise exposure data reported by Member States under the Environmental Noise Directive are collected and risk assessment guidelines for exposure to noise are being developed by WHO in collaboration with DG JRC.

Under the Environmental Noise Directive[74], Member States were obliged to provide noise maps by 31st December 2007 for all agglomerations with more than 250 000 inhabitants and for all major roads, railways and major airports. By 18th January 2009 Member States had to submit Action Plans.
The European Environment Agency is elaborating the noise maps. The first Quality Report was prepared in 2009. The collected data will be made available by the European Environment Agency in order to exchange information on noise exposure between Member States. The collected exposure data so far are not comparable in all cases. The revision of the noise directive will include the establishment of common noise assessment methods for road traffic, railway traffic, industrial and aircraft noise which will enable the collection of comparable data in the 2nd round of noise maps in 2012. These common noise assessment methods are currently being developed by DG JRC on behalf of DG ENV.

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72 ENHIS: Implementing Environmental and Health Information System in Europe http://ec.europa.eu/health/ph_projects/2003/action1/action1_2003_28_en.htm

73 For EPIBATHE the report is announced for Q1 2009.

74 2002/49/EC

In 2008, DG JRC assessed the equivalence of the national assessment methods used by the EU Member States for strategic noise mapping against the interim methods, as specified in Annex II of the Directive 2002/49/EC and the EC guidelines adopted on 6 August 2003.

In October 2009, WHO published the Night Time Noise Guidelines (NNGL) for Europe and is also preparing two other publications jointly with DG JRC on "*Practical guidance for risk assessment of environmental noise*" and on "*Aircraft Noise and Health*".

The Commission launched a coordination action under FP7 "*European Network on Noise and Health*"[75] related to the health impacts of noise. This network will review the existing evidence on the association of environmental noise exposure and health effects focussing on the consolidation of existing state of the art knowledge and the identification of gaps in the evidence and future research needs and hypotheses to be tested. Focus will be on noise exposure assessment in health studies in order to build more complex analytical models of noise and health effects that take into account moderating factors including the joint effects of air pollution and noise.

Health Impact Assessment and Burden of Disease Methodology: Task 13 of the "*Environment and Health Information Review and Implementation Plan*" recommended to progress towards the harmonisation of Health Impact Assessment (HIA) and Environmental Burden of Disease Methodology (EBDM).
HIA: the HEIMTSA[76] project funded under the Sixth Framework Programme for Research will develop a methodology for Health Impact Assessment by January 2011.
EBDM: The harmonisation work on Environmental Burden of Disease Methodologies has not yet started but will be included in one of the upcoming FP7 calls for proposals.

Enhancing public access to Environment and Health Information: Task 14 of the "*Environment and Health Information Review and Implementation Plan*" recommended to bring together environment and health information for scientists, policymakers and the public, through the EU Public Health Portal and the portal to be developed for the Shared Environmental Information System (SEIS), as part of an EU Communication Strategy on Environment and Health. The aim of this initiative is to maximise public availability of Environment & Health Information, give periodic feedback to stakeholders and to raise awareness.
The EU's Public Health Portal[77] was launched in May 2006 and contains under the subject "*My environment*" a sub-theme on "*Environmental Health*" where several links to similar EU initiatives are created: links with the European Environment and Health Action Plan, DG ENV's Endocrine Disrupter website, DG ENV's Climate Change information, EU reseach on Environment & Health, EEA's Environment & Health activities, WHO-European Environment & Health Committee, WHO-ENHIS website.
The Commission published a "Communication on a Shared Environmental Information System for Europe"[78] on 1st February 2008. A SEIS Task Force has been established to assist the Commission in preparing its policy proposals for the implementation of SEIS and met for the first time on 29th September 2008. The SEIS portal has not been developed yet and will not be finalised before 2011.

[75] ENNAH
[76] Health and Environment Integrated Methodology and Toolbox for Scenario Assessment (FP6 project) http://www.heimtsa.eu/
[77] http://health.europa.eu
[78] http://ec.europa.eu/environment/seis/index.htm and http://www.epractice.eu/community/seisnet

DG RTD has revamped its Environmental research website[79] and it now contains an Environment and Health section describing activities related to research. A dedicated website on endocrine disrupters is also available[80].

Summary overview: the shaded boxes indicate where progress is made.

Tasks	Description task	State of play	Problems encountered	Future
1	**Data linkage**	CEHIS project (Connectivity Environment and Health Information Systems) (DG INFSO and JRC)	Small scale feasibility study. Would need more resources for future development	Final report 2009. Pending on available human and financial resources further data linkage pilot projects could be launched. The Commission should then review overall progress and make recommendations for future data linkage activities at EU level.
2	**Ambient Air, Research Infrastructure**	EU Monitoring Network not set up. New project on air/health/transport has recently been selected under FP7 Cooperation Env that partially covers objectives.	No FP7 Research Infrastructure funding available. ANEMONE project not selected for funding. New project covers only transport related impacts, of limited duration.	The EU Monitoring Network is needed and should be funded via Research Infrastructures.
3	**Ambient Air epidemiology**	Started: FP7 project launched (ESCAPE[81]). The programme has not been developed yet.	Lack of operational budget.	Operational budget to be found.
4	**Ambient air, health data**	Study not launched.	No funding available under PHP.	Pending on available PHP funding.
5	**Indoor Air Health Impact Assessment**	OK	-	Will be continued by SANCO and its Expert Working Group.
6	**Drinking Water Safety Plans**	OK	-	Will be included in revision Drinking Water Directive.
7	**Drinking Water Data Base**	Examined, but not pursued.	-	-
8	**Drinking Water Policy Effectiveness Indicator**	?		
9	**Bathing Water Epidemiology**	OK	-	OK
10	**Food Alert System**	Not started	Lack of human resources.	Pending on available resources.
11	**Food Monitoring Coherence**	Not started	Lack of human resources.	Pending on available resources.
12	**Noise Health Impact Assessment**	Started.	-	Will continue in framework of Noise Directive

[79] http://ec.europa.eu/research/environment/index_en.cfm
[80] http://ec.europa.eu/research/endocrine/index_en.html
[81] European study of cohorts for air pollution effects: http://www.escapeproject.eu/index.php

13	**Health Impact Assessment and Environmental Burden of Disease Methodology.**	HIA: started. EBD: not started.	No FP7 call launched so far.	Results in January 2011. Pending on available FP7 funding.
14	**Enhancing public access to Environment & Health Information**	Started.	-	Will continue.

ANNEX II
Detailed overview of progress on health related environment actions

The Environment and Health Action Plan aims to ensure that human health aspects are duly taken into account in the different environment policies. In this respect, a number of new initiatives have been adopted since 2007 with a view to decreasing the risk to human health and gathering better information. These are summarised below.

Ambient air

In June 2008 the Directive on ambient air quality and cleaner air for Europe 2008/50/EC entered into force. It merges and streamlines the existing 5 legal instruments and introduces new objectives on fine particulate matter PM2.5. These combine, for the first time, the PM2.5 limit value (to be achieved throughout the territory) with the specific target for public exposure reduction between 2010-2020. The latter should steer abatement actions that will maximize public health benefits. Directive also includes specific requirements for PM2.5 chemical speciation and background monitoring that should support better health impact assessments and identification of the specific properties (composition, size, surface area etc.) that make particulate matter the most toxic air pollutant. The Directive introduced also the possibility to gain, under specific conditions, more time for compliance with the existing limit values for PM10, NO2 and benzene. This provisions have until October 2009 been used by 18 Member States. Conditions are assessed by the Commission and though most have been objected to, the exercise creates important dynamics in better understanding air pollution situation in selected areas, development of more effective air abatement measures and raises awareness. The Directive also brought requirement for complete overhaul of reporting requirements; they are in final stages of preparation and should in future facilitate HIA and health related actions (such as information for vulnerable population) by adhering to SEIS/INSPIRE and introduction of near-real-time exchange requirements at EU level.

A call for proposals on "*Transport related air pollution and health impacts"* was launched under FP7. This project will importantly contribute to better understanding of health effects of air pollution. A project called TRANSPHORM (Transport related air pollution and health impacts – integrated methodologies for assessing particulate matter) is under negotiation. It will have close links to the ESCAPE project (European Study of Cohorts For Air Pollution Effects).

FP7 funded the project "*HEalth Risk from Environmental Pollution Levels in Urban Systems"*[82] that will develop risk maps relating to human health, and O3 and PM concentrations in important and problematic large European urban areas such as Rome, Madrid, Dresden, Athens; Specific cardio-respiratory diseases, such as asthma, bronchitis, COPD exacerbation, ischemic heart disease, and the morbidity and mortality for these diseases, associated to O3 and PM, will be considered. HEREPLUS will produce the above mentioned risk maps starting from pre-existent environmental and health data, by development of new epidemiological and statistical approach, in support for the implementation of Global Earth Observation System of Systems (GEOSS) initiative and the Environment and Health Action Plan.

GMES – Global Monitoring for Environment and Security has since 2007 developed its Atmosphere service will support actions related to the reduction of public exposure to air

[82] HEREPLUS (From 1st call of FP7; EC contribution €1.4M)

pollutants by providing health-relevant data on air pollution. MACC project funded under FP7 is developing the pre-operational core service, while further downstream calls have also been initiated; PASODOBLE is currently under negotiation.

Noise

The revision of the Environmental Noise Directive is foreseen for 2010-2011. Health related issues will be duly taken into account in this revision. A European research network on noise and health (ENNAH), funded by FP7, was launched in September 2009.

Drinking water

A Commission Proposal for revising the Drinking Water Directive is foreseen for end of 2009. The main topics for the revision are the Water Safety Plans, the revision and adaptation to the state of the art of the microbiological and chemical parameters and an improved management of small water supplies as a cross cutting EU wide risk prone issue. Safe drinking water also from small supplies is an important issue. The Commission has therefore in January 2009 requested - based on article 10 of the Treaty – aggregated statistical information on the monitoring results for water supplies to which the Directive applies but which are not covered by the obligation to publish reports. From 2009, Member States will have the facility to deliver electronically the tri-annual report on drinking water quality as requested by the directive. From 2010 on, drinking water quality data will be available in an aggregated way and in graphical format on the Water Information System for Europe (WISE) website[83].

Bathing water

The Commission publishes in May of each year an EU-wide report covering all 27 Member States, both in a paper version and an internet version. Reports on individual Member States are published on the Internet. From June 2008 on the Bathing Water Atlas has been replaced by interactive maps on the Water Information System for Europe (www.water.europa.eu) which provide users with detailed information on the quality of bathing water in individual bathing areas in the WISE viewer.

REACH

The REACH Regulation[84] entered into force in June 2007 and imposed gathering information on toxicological properties of chemicals through the EU Chemicals Agency (ECHA), which became fully operational on 1st June 2008. Companies submitted over 2 million pre-registrations by the deadline 2/12/2008. A first candidate list of 15 Substances of Very High Concern was established that may become subject of authorisation.

Endocrine Disrupters

Legislative actions was taken to protect human health and environment from negative effect of substances having endocrine disrupting properties. The authorisation procedure for substances of very high concern under the REACH Regulation covers also substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of the CMRs, PBTs and vPvBs and which are identified on a case-by-case basis. This mechanism ensures that substances having endocrine disrupting effects after being identified as substances of very high concern can be used for a particular purpose, marketed as such or as a component of a product only after authorisation has been granted by the Commission. The newly adopted Regulation on plant protection products establishes criteria under which

[83] http://water.europa.eu/

[84] http://ec.europa.eu/environment/chemicals/reach_intro.htm

an active substance cannot be approved for use in plant protection products. One of these criteria in relation to human health specifies that an active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by the Authority, it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible. The criterion in relation to eco-toxicology states that an active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effect on non-target organisms unless the exposure of non-target organism to that active substance in a plant protection product under realistic proposed conditions of use is negligible. These provisions ensure protection of human health and environment from plant protection products having endocrine disrupting properties.

The first two test guideline for testing endocrine disrupting properties under the auspices of the OECD was agreed in 2007 and 2008. It is an in-vivo uterotrophic bioassay in rodents for screening for estrogenic properties (test No. 440) and extended repeated dose 28-day oral toxicity study in rodents (test No. 407). Other draft in vivo test guidelines like the Hershberger bioassay in rats, the amphibian metamorphosis assay, the 21-day fish assay or the stably transfected human estrogen receptor-α transcriptional activation assay are under development. Alternative non animal test methods for ED screening are also progressing under the auspices of the OECD. In particular, a draft OECD test guideline for agonist estrogenic assessment using an in vitro estrogen receptor transcriptional activation assay.

Funding of research on endocrine disrupters continued in FP7 for example under the theme 6 'Environment', activity "Environment and Health". Three projects were selected from the first call of FP7 dealing with long-term health impacts of endocrine-disrupting chemicals with an EU contribution of around 10 m€. The projects form a cluster called NECTAR (Network for Environment Chemical Toxicants Affecting Reproduction[85]).

JRC continued its work on development and validation of in vitro assays for testing of endocrine disruptors and started work on preparation of database of substances having endocrine disrupting properties.

Dioxins and PCBs

The Community Implementation Plan for the POP Regulation lists measures to be taken at EU level, including measures to address industrial and domestic sources for dioxin emissions. An important study on "*Information exchange on reduction of dioxin emissions from domestic sources*" was launched by the Commission in 2007. This study aimed to pool information and make it available to Member States to assist them in their efforts towards reduction of dioxin emissions and to ensure that knowledge is shared and awareness is conveyed across the EU. Key objectives of the project were (1) to improve the understanding of methods and practices to estimate dioxin emissions from domestic sources, as well as approaches to reduce these emissions; (2) to identify the main obstacles faced by Member States for accurate estimation and effective action; (3) to formulate recommendations based on findings, by identifying best practices or defining options for further action and (4) to ensure dissemination of the information. The study provided a critical assessment on the emission factors and activity

[85] http://www.nectarcluster.eu/

rates applied for the determination of dioxin emission inventories. It discussed the measures for reduction of dioxin emissions currently applied by Member States and analysed them in detailed case studies. Finally, conclusions and recommendations were summarized in a brochure targeting national authorities and decision makers. *[final text to be checked with Christian Wimmer]*.

Pesticides

The Thematic Strategy on the Sustainable Use of Pesticides[86] - adopted by the Commission on 12th July 2006 as part of the Sixth Environmental Action Programme[87] - aims to fill a legislative gap regarding the use-phase of pesticides at EU level through setting minimum rules for the use of pesticides in the Community, so as to reduce risks to human health and the environment from the use of pesticides. The Thematic Strategy resulted in four major pieces of legislation, bundled together as a "Pesticides Package". (1) the *Framework Directive on the sustainable use of pesticides*[88] aims to reduce the risks to human health and the environment from the use of pesticides with new measures that Member States will have to establish, such as access to training for professional users of pesticides, regular inspection of pesticide application equipment, a general ban of aerial spraying, and general principles of Integrated Pest Management (IPM) becoming mandatory as from 2014; (2) the *Regulation on the placing of plant protection products on the market, revising Directive 91/414/EEC*[89] includes several measures aiming at reinforcing the protection of human health and the environment. New criteria for authorisation of plant protection products will be introduced that are expected to reduce possible risks of exposure to the most hazardous substances. Particular emphasize will be given to the protection of vulnerable groups of the society. Furthermore, the Regulation obliges farmers to keep records on the application of plant protection products and to make this information available on request. Farmers can also be requested to give prior notice to neighbours before applying certain plant protection products which would allow them to take precautionary measures. (3) *The Regulation on the collection of statistics on plant protection products*[90]*; and (4) the revision of the Machinery Directive*[91].

The Thematic Strategy called for the establishment of a system of information exchange at Community level involving Member States and all other relevant stakeholders in order to continuously develop and update appropriate guidance, best practice and recommendations. The Thematic Strategy also announced that in the light of the outcome of this information exchange and the deliberations of the Expert Group, the proposed measures will be regularly reviewed and adapted to technical progress. Article 18 of the above-mentioned Framework Directive established the Expert Group on the Thematic Strategy on the Sustainable Use of Pesticides, which met the first time in June 2009 and will meet again in June 2010.

Biocides

86 COM(2006)373 final

87 Decision No 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme. It sets out the framework for environmental policy-making in the European Union for the period 2002-2012 and outlines actions that need to be taken to achieve them.

88 COM(2006)373 final

89 COM(2006)388 final

90 COM(2006)778 final

91 COM(2008)535 final

The Review Programme of the Biocides Directive continued evaluating active substances used in biocidal products[92] for their risks to human health and the environment. [… substances have been included in Annex I to the Directive]. The revision of the Biocides Directive aimed to improve the protection of human health by including specific provisions related to the scope, product authorisation and data requirements.
Antibiotic resistance is a major public health problem: it has increased worldwide, leading to treatment failures in human and animal infectious diseases. The frequency of antibiotic resistance has increased in parallel with the increasing use of antibiotics. The potential for biocides (disinfectants, antiseptics, preservatives, sterilants) to induce antibiotic resistance has been reported only relatively recently. Under the Review Programme of the Biocides Directive active substances used in biocidal products are currently being evaluated for their risks to human health and the environment. The potential risk of a biocide to induce antibiotic resistance is currently not addressed in the Review Programme. Directorate-General Environment requested the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to assess the antibiotic resistance effects of biocides. The Opinion[93] concluded that "*scientific evidence does indicate that the use of biocides may contribute to the increased occurrence of antibiotic resistance. To date, the lack of precise data makes it impossible to determine which biocides create the highest risk of generating antibiotic resistance. In view of the large and increasing use of biocides and the continuous increase of antibiotic resistance data and methodologies are urgently needed to clearly characterize the risk.*"
A joint SCENIHR/SCHER/EFSA Opinion on the antimicrobial resistance effects of 4 substances for the decontamination of poultry carcasses was adopted in April 2008.
The FP7 funded project "*Confronting the clinical relevance of biocide induced antibiotic resistance" (BIOHYPO)* started in June 2009 and results will be available in June 2012.

Mercury
Further to the Mercury Strategy[94] a number of proposals have been adopted with a view to banning mercury for certain uses within the EU, banning mercury exports from the EU from 2011 and imposing safe storage of unused mercury: (1) Directive 2007/51/EC of 25 September 2007 relating to restrictions on the marketing of certain measuring devices containing mercury. The restrictions concern fever thermometers (without any exception) and other measuring devices intended for sale to the general public; (2) Regulation (EC) No 1102/2008 of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury.

The SCHER and SCENIHR Opinions stated that on the basis of the current information it is not possible to conclude that mercury in dental amalgam constitutes a risk for human health.

The Directorate-General Environment funded study on "*Options for reducing mercury use in products and applications and the fate of mercury already circulating in society*"95" addressing Action 10 of the Mercury Strategy was finalised in December 2008 and available on http://ec.europa.eu/environment/chemicals/mercury/pdf/study_report2008.pdf.

Nanotechnology - Nanomaterials

[92] that were on the market before 14th May 2000
[93] SCENIHR Opinion assessing the antibiotic resistance effects of biocides adopted on 19th January 2009
[94] COM(2005)20
[95] http://ec.europa.eu/environment/chemicals/mercury/pdf/study_report2008.pdf

In the Nanotechnology Strategy[96] and Action Plan 2005-2009 the Commission proposes concrete steps towards a "*safe, integrated and responsible*" development of nanotechnology, which means that environment, health and social aspects of nanotechnology need to be considered at the earliest possible stage. One of the activities in 2006 was to review current regulatory frameworks to find out whether they adequately cover manufactured nanomaterials and provide sufficient protection against their effects.

Due to the increasing number of applications of nanomaterials on the market, there is an increasing demand for more data and information about them such as their identity, the identification of their use in various applications and their potential impacts to human health and environment. For the time being, reporting under the various existing regulatory schemes will constitute the main source of information on nanomaterials and their safety, but to satisfy the current needs on this issue, the Commission, industry associations, international organisations and private companies have conducted studies in this regard.

Scientific knowledge about environment and health safety aspects of nanomaterials has become a critical factor to assess and manage the risks of nanomaterials. In spite of a significant increase of the research efforts over the past 4-5 years at the EU level, in Member States and in third countries, large knowledge gaps remain. International collaboration has been intensified to speed up the work and to develop a common base of knowledge.

Although there has been significant progress, relatively little can today be said about the *actual short and long term risks* of nanomaterials for human health and the environment. To assess the risks of nanomaterials, potential *hazards* and *exposures* will need to be identified. A large number of experimental studies have been carried out to identify hazards, but data is patchy and has sometimes been contradictory. Big uncertainties are also involved when extrapolating the results to humans or the environment. For exposures there is a general lack of data for all steps in the life-cycle – from production and use (in different products) to recycling and disposal.

A major hurdle in the generation of data has been the lack of recognized methodologies to identify hazards and exposures. Many *test methods and test guidelines* for conventional materials and substances need to be modified to be fully applicable to nanomaterials. Methods for *exposure measurement* and *analytical methods* for characterisation of nanomaterials need to be further developed. High resolution and sometimes very costly instrumentation is needed. A specific difficulty is that nanomaterials readily undergo changes in contact with surrounding media (air, water, biological fluids etc.), which may change their properties and behaviour. Therefore, great effort has to be put into the *characterisation* of nanomaterials – whether it is for a laboratory experiment to find out about its toxicity, or whether it is in a consumer product to understand if and how it can be released from a product.

For regulatory and safety assessment purposes standardised and validated methods are needed.

The opinions of the EU Scientific Committees are key resources to identify the state of knowledge and define the knowledge gaps. Since 2005, the Commission has requested six opinions from various EU scientific committees in relation to the risk assessment of

[96] COM (2004) 338

nanomaterials. The EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR) has so far delivered four opinions on nanomaterials, the Scientific Committee on Consumer Products has published one (in cosmetics[97]), and the European Food Safety Authority one (in the food and feed area[98]). The first three opinions of the SCENIHR laid down the foundations for the risk assessment of nanomaterials[99][100][101]. The most recent SCENIHR opinion, from January 2009[102] is an update of the earlier opinions in response to the rapidly evolving state of the science in this area. It contains an overview of (1) potential environment and health hazards and risks of nanomaterials, (2) methodologies to establish hazards, exposures and risks of nanomaterials, and (3) further research needs to develop a robust and reliable way to establish risks with nanomaterials. In this last opinion, the SCENIHR stresses the need for the time being to assess the risk of each nanomaterial on a case-by-case basis and to be careful not to draw hastily any generalized conclusions about the risks of nanomaterials. They conclude: *"Health and environmental hazards were demonstrated for a variety of manufactured nanomaterials. The identified hazards indicate potential toxic effects of nanomaterials for man and environment. However, it should be noted that not all nanomaterials induce toxic effects. Arguably, some manufactured nanomaterials have been in use for a long time (carbon black, titanium dioxide) and show low toxicity. The hypothesis that smaller means more reactive and thus more toxic cannot be substantiated by the published data. In this respect nanomaterials are similar to normal substances in that some may be toxic and some may not. As there is not yet a generally applicable paradigm for nanomaterials hazard identification, a case by case approach for the risk assessment of nanomaterials is recommended."*

State of the research on the potential hazards and risks from nanomaterials

The SCENIHR (2009) identifies some areas where effects of different nanomaterials have been observed with potential relevance for human health and the environment. For the purpose of this report, a brief summary of these findings is given below.

- Free and low solubility nanomaterials remain a priority concern in the context of human and environmental risk.

- In spite of minimal amounts (approximately 1% or less of the administered dose) absorbed by the blood via the lungs or via the gastrointestinal tract, a considerable number of nanoparticles may be distributed in the body (translocation). Smaller nanoparticles have a much wider organ distribution than larger ones. The liver and the spleen are the major target organs, although for certain nanoparticles all organs may be at risk, including the brain and the reproductive system. For distribution to the foetus contradictory results have been observed. There are observations that nanoparticles may also penetrate into the brain if deposited in the mucosa of the nose.

[97] http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf
[98] The text of the opinion is available at http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf
[99] The first from March 2006 addressed *"the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies"* in general. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf
[100] The second from June 2007 dealt with "*the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials*". http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_010.pdf
[101] The third from November 2007 addressed *"the scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies. http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_012.pdf*
[102] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf

- When nanomaterials come in contact with biological fluids they become coated with proteins (protein corona), which may change their biological effects. Various types of nanoparticles may also affect the formation of protein clusters and fibrils. Whether the observed processes occur in vivo remains to be determined. However, as protein fibrillation has been connected with certain human amyloid diseases (Alzheimers, Parkinsons, Diabetes II and BSE belong to these), it is an area for which further research is needed.

- Long, non-degradable, rigid nanotubes (>20 micrometer) have in several experiments been found to have similar effects as hazardous asbestos, e.g. causing inflammatory reactions. Experiments also indicate that carbon nanotubes, with characteristics specified above, could induce a specific form of lung cancer (mesothelioma) observed in relation to asbestos exposure. Whether such nanotubes would pose a risk for humans is unknown but can not be excluded. SCENIHR recommends specific awareness when manufacturing nanotubes with these characteristics, possibly of any composition, and that the possibility for chronic inflammation and mesothelioma induction should be considered in the safety evaluation of that particular nanomaterial. SCENIHR further recommends that similar caution is taken with any long, thin biopersistent fibres, such as nanowires or nanorods.

- There is some evidence that the small size allows nanoparticles to penetrate into the cells and further into the subcellular compartments, including the nucleus. This opens the possibility for genotoxicity and direct interaction with DNA For some manufactured nanomaterials, in vitro genotoxic activity has been reported, but negative contradictory results were also obtained, and not all results could be confirmed by in vivo testing. One potential cause of inconsistencies is the difficulty in delivering the nanomaterials to the test systems appropriately.

- Based on the observations on the effects of particulate matter present in air pollution, some concern exists about the possible effect of manufactured nanoparticles on the cardiovascular system. However, this has not been clearly demonstrated to be the case for manufactured nanoparticles. Overall the information on the possible hazard of nanoparticles for cardiovascular effects is rather limited and needs expansion.

- In view of the increasing production, use and disposal of nanomaterials, there will be an increase in environmental exposure of these materials. There is no quantitative knowledge on the rates of release of nanomaterials to the environment. There is hardly any knowledge on the concentrations of nanomaterials in the ambient environment. For some nanomaterials (i.e. quantum dots) the transfer across environmental species was demonstrated indicating the potential for bioaccumulation via the food chain.

- Ecotoxic effects on environmental species have been demonstrated in test systems, especially using aquatic species. One of the major problems in these tests is the absence of consistent methods on how nanomaterials are to be suspended or dispersed in various exposure media commonly used in ecotoxicity testing.

<u>State of art of concerning development of methodologies needed to explore hazards and risks according to SCENIHR reports</u>

The points below summarize the SCENIHR recommendations concerning the methodological development for the different steps of risk assessment for nanomaterials:

- *Characterisation and measurement* of nanomaterials are important from many aspects. Nanomaterials require high-resolution analytical instruments and this is an area in rapid development. It is today possible to characterize airborne particles down to the nanometer range, and also in terms chemical composition. However, in biological or environmental media nanomaterials undergo changes easily, e.g. they agglomerate/aggregate or react with surrounding media in different ways. As this will change the properties and behaviour of the nanomaterial, characterisation of the "changed" nanomaterial will be needed in different situations relevant for the risk assessment. Although a consensus is emerging on which physical and chemical properties need to be determined for risk assessment purposes, there are not yet standardized and validated methods available. Also reference materials need to be developed and metrics established.

- Although existing *toxicity test methods* used for conventional materials may serve as a starting point for risk assessment of nanomaterials, they will likely not detect *all* aspects of toxicity. Nanomaterials may be transported to new target organs within the body, interact with proteins etc. Work to review current test methods and test guidelines has therefore been initiated More in-depth methodological problems are being addressed, like the ability of nanomaterials to agglomerate or interact with the media used in the test system, the "aging" of nanomaterials in test samples etc. All these observations require that proper characterisation of the nanomaterial in the test sample is made to control the experiment and ensure its reproducibility. For regulatory purposes standardised and validated test method will need to be developed, taking into account these factors.

- *Exposure assessment* needs to consider each stage in the life-cycle of products containing nanomaterials. One of the main limitations in the risk assessment of nanomaterials is the general lack of high quality exposure data both for humans and the environment. Although exposure measurements for laboratory test systems have been developed, there is a lack of general availability of robust and specific measurement methods. In particular, reliable and standardised measurement techniques and strategies, as well as screening/monitoring of nanoparticles in the work place need to be developed. For detection, measurement and exposure assessment of nanomaterials in the environment (ambient air, water, sediments and soil) the situation is even more difficult. Exposure estimates to consumers from food and consumer products remain also a particular difficulty, hampered by lack of information on product use. Suitable metrics need to be developed for exposure assessment and exposure limits for regulatory purposes.

- Understanding the *environment fate and behaviour* of nanomaterials is crucial for predicting the potential ecotoxic effects in various environmental species. There is today no quantitative knowledge on release rates or concentration of nanomaterials in the environment. There is therefore not possible to make quantitative predictions of environmental exposure and fate of nanomaterials in the environment. Well-established knowledge of distribution and fate of chemical substances, as it is applied in the current EU guidelines for environmental risk assessment of conventional chemicals, cannot be used for nanomaterials without modification. For example, the current method of determining dispersion in water should be different for nanomaterials. Whether a

nanomaterials will sediment or stay in the water (dispersed) will not only depend on the properties of the nanomaterial itself, but also on factor like pH, ionic strength, presence of organic matter in the water. This will influence the bioavailability of the nanomaterials. Also new methods to measure biodegradability needs to be developed.

- The common endpoints used in ecotoxicology such as mortality, growth, feeding, and reproduction can also be used for the evaluation of ecotoxicity by nanomaterials. Also here work is ongoing to review existing test methods and guidelines.

Conclusions on further research needs identified by the Scientific Committees

As a result of the various opinions of the Scientific Committees a number of research needs have been identified to address the gaps in knowledge and make a comprehensive risk assessment of nanomaterials possible. The main needs are:

- For the characterization of nanomaterials: development of harmonised methods for measuring and characterising nanomaterials, especially for measuring concentrations and characteristics of nanomaterials in biological and environmental media. This requires defining the metrics most appropriate for hazard characterisation and exposure and the development of reference nanomaterials.

- For assessing exposure: to improve exposure determinations/estimations and to develop more specific measurement methodologies to discriminate between background and manufactured nanomaterials. t,. To develop analytical methods to detect and measure ambient concentrations of free nanomaterials.. To develop a quantitative theory and models that predict residual concentrations of free nanoparticles from release rates, and implement such models in the current EU guidelines for environmental exposure assessment of nanomaterials.. To revise the standard OECD methods for measuring solubility in water to accommodate the measurement of the rate of dissolution of nanomaterials in the natural environment. This process is relevant to the environmental exposure assessment of nanomaterials.

- For the identification of human hazards: Further investigation of the effect of nanoparticles on protein behaviour as demonstrated in vitro is needed.. Additional research on the possibility for nanoparticles to translocate to the brain after deposition at the olfactory mucosa of the nose. Additional studies on the potential hazards of nanofibers/nanotubes.

- For the identification of environmental hazards: Studies on soil systems, marine species and terrestrial species in general, including primary producers are needed. Further work on the establishment of standard protocols. Investigation of the effects that the use of mechanical or chemical means to suspend nanomaterials for testing may have on any effects observed. Studies on a range of endpoints, with fate within the body and tissues assessed and depuration quantified and micro/mesocosms studies. Furthermore, dietary studies, the role of nanomaterials' coatings in uptake and translocation within the body, should be conducted, as well as the assessment of the role, if any, of their interaction with other environmental contaminants. Environmental fate and load assessment of nanomaterials. Finally, further information on the degradability (bio and abiotic) of nanomaterials should be derived.

Climate Change and Health

The Environment and Health Action Plan 2004-2010 announced in Action 8 that the Commission will work with Member States and the WHO to address climate change and health. The Mid Term Review reported that several EU projects on climate change and health have been funded under FP6, FP7 and under the Public Health Programme; it also announced that the focus on climate change and health will be increased in the further implementation of the Environment and Health Action Plan.

The Council urged the Commission and the Member States to develop tools for anticipating, preventing and responding to potential threats from climate change[103].

The European Parliament called for enhanced multi-agency cooperation '*in order to boost the early warning system and thus to curb the harmful effects which climate change has on health*'[104]; it also called on Member States and the Commission to respond adequately to the new threats posed by climate change such as the increased presence of emerging viruses and undetected pathogens and therefore implement new existing pathogen reduction technologies that reduce known and undetected viruses and other pathogens transmitted by blood[105].

Directorate-General JRC was involved in the *Global Air Pollution and Climate Change Action*[106] on linkages between air pollution and climate change to make policy makers aware of potential synergies and trade-offs that are imposed by the way the atmosphere and the climate system work; the *European Flood Alert System*[107], developed within the *Weather Driven Natural Hazard project*[108], will provide the Commission with information for the preparation and management of aid during a flood crisis; the *European Forest Fire Information System*[109] supports the services in charge of the protection of forests against fires in the EU and neighbours countries, and provides the Commission and the European Parliament with information on forest fires in Europe.

The Commission's "*White Paper on Adaptation to Climate Change*" - adopted on 1st April 2009 - includes a section on human health and is accompanied by a "*Commission Staff Working Document on Human, Animal and Plant Health Impacts of Climate Change*".

In the Fifth Ministerial Conference on Environment and Health to be held in Italy on 10-12 March 2010 climate change related health issues will be one of the main pillars. The Commission is actively involved in the preparations.

Biodiversity and health

The Commission (DG Environment) funded a "*Literature study on the impact of biodiversity on human health*". The aim is to provide an overview of existing information concerning the impacts of biodiversity loss and changes in ecosystem services on human health, with a particular focus on infectious diseases and medicines. Results will be available in March 2010.

Antimicrobial resistance

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103 Council Conclusions on Environment and Health - 20th December 2007

104 Paragraph 24 of European Parliament Resolution of 4 September 2008 on the mid-term review of the European and Health Action Plan 2004-2010 (2007/2252(INI))

105 Paragraph 26 of European Parliament Resolution of 4 September 2008 on the mid-term review of the European and Health Action Plan 2004-2010 (2007/2252(INI))

106 GAPCC

107 EFAS

108 WDNH

109 EFFIS

Scientific evidence suggests that during the last decade, antibiotic resistance by various mechanisms has increased worldwide in bacterial pathogens leading to treatment failures in human and animal infections. However, the bacterial resistance against different types of biocides (including disinfectants, antiseptics, preservatives and sterilants) has been studied only recently. Furthermore, research indicates that biocides and antibiotics may share some common behaviour and properties in their respective activity and in the resistance mechanisms developed by bacteria. One of the problems within Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products[110] and directives dealing with similar kinds of substances is that cumulative risks and impacts resulting from the use of the active substance outside the scope of the Directive are not addressed in the evaluation process. This is especially problematic in view of the possibility of cross-resistance.

In 2008 the Commission therefore asked SCENIHR to assess the antibiotic resistance effects of biocides. The SCENIHR opinion delivered in January 2009[111] confirmed that at least some resistance mechanisms are common to both biocides and antibiotics. Scientific evidence from bacteriological, biochemical and genetic data does indicate that the use of active molecules in biocidal products may contribute to the increased occurrence of antibiotic resistant bacteria. In view of the large and increasing use of biocides and the continuous increase of bacterial resistance to antibiotics, the SCENIHR identified a number of data and knowledge gaps to be filled, especially:

a) Quantitative data on exposure to biocides;

b) Standards and methods to evaluate the ability of a biocide to induce/select for resistance against biocides and antibiotics;

c) Environmental studies focussing on the identification and characterisation of resistance and cross-resistance to antibiotics following use and misuse of biocides.

In particular, the recommendation to develop standard protocols for the evaluation of antimicrobial resistance induced by biocides would be valuable in the review programme of the Biocides Directive where active substances used in biocidal products are currently being evaluated for their risks to human health and the environment. At present biocidal active substances are evaluated without taking account this issue systematically in the testing and assessment under the review programme. Steps should be undertaken to start developing these protocols in order to properly address the concern and recommendation stated in the above-mentioned Opinion and to take account of antimicrobial resistance at the product authorisation stage (within 4-5 years) or at the first renewal of the biocidal active substances (within 10 years).

As the issue of the possible health effects of AMR remains a very sensitive political subject, more research is needed to address the issues identified. The Commission, through the 7th Framework Programme for Research and Development (FP7), can finance such research through calls for proposals launched on a yearly basis. As a result, and in order for the Commission to be in a position to propose the most relevant research topics on this issue for future funding, the Commission has asked the SCENIHR to develop the research recommendations presented in the *SCENIHR Opinion on the Assessment of the Antibiotic*

[110] http://ec.europa.eu/environment/biocides/pdf/dir_98_8_biocides.pdf
[111] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf

Resistance Effects of Biocides and to propose a stepwise research strategy based on studies which are feasible and able to deliver results within a reasonable time-frame (5-10 years).

The Commission developed a policy discussion on antimicrobial resistance. In view of the failure of past sectoral actions, an integrated horizontal approach to antimicrobial resistance is being considered.

ANNEX III: Detailed overview of progress on environment and health research

1. Integrating and strengthening European environment and health research

Research projects in the field of environment and health funded under the Fifth Framework Programme of Research (FP5) were analysed and their key findings together with an assessment of their relevance for EU policy were summarised in a publication in 2007[112]. Several projects funded under the Sixth Framework Programme of Research (FP6) were completed and published reviews of the current status of knowledge and research results in particular fields such as health effects of electromagnetic fields (EMF-NET[113]), of indoor air pollution (ENVIE[114]) and ambient air pollution (CAIR4HEALTH[115]). In order to strengthen networking between researchers, policy makers and stakeholders, the HENVINET[116] project (Health and Environment Network) has been funded, bringing together over 30 partners from European as well as non-European countries.

The Seventh Framework Programme of Research (FP7), which started in 2007, includes under its Environment theme of the Cooperation Programme a sub-activity dedicated to supporting environment and health research, with an annual budget of approximately 20 MEUR. Among the projects selected in the first FP7 calls for proposals, the following ones focus particularly on research coordination and networking among actors in the environmental health domain:

- ERA-ENVHEALTH[117] encompasses 16 organisations involved in the funding of environmental health research at national or regional level. The objective of the project is to review relevant national research programmes, identify joint priorities and promote greater coordination and cooperation in environmental health research in Europe.
- HEREPLUS[118] seeks to promote greater coordination and cooperation among epidemiologists, biostatisticians, environmental scientists and GIS specialists in order to realise the full potential of GIS technology in environmental health research.
- ENRIECO[119] is designed to exploit the wealth of data generated in the past and ongoing studies in order to further elucidate the causal relationships between environment and health. To this end, the project is bringing together over 30 pregnancy and birth cohorts and information on some 250 000 newborns, infants and children from across Europe.
- NANOIMPACTNET[120], operational since 2008, is a multidisciplinary European network on the health and environmental impact of nanomaterials bringing together 24 institutes. It will create a scientific basis to ensure the safe and responsible development of engineered nanoparticles and nanotechnology-based materials and products, and will support the definition of regulatory measures and implementation of legislation in Europe.

During the second part of the Action Plan the Commission continued organising or otherwise contributing to numerous research and policy-related events engaging various stakeholders including national and EU policy makers. Examples include three research/policy workshops

[112] http://ec.europa.eu/research/environment/pdf/env_health_projects/env_health_brochure.pdf
[113] http://web.jrc.ec.europa.eu/emf-net/
[114] http://indoorairenvie.cstb.fr/
[115] http://www.cair4health.eu/
[116] www.henvinet.eu
[117] www.era-envhealth.eu
[118] www.hereplusproject.eu
[119] The project started in March 2009 and website is not yet available.
[120] http://www.nanoimpactnet.eu/object_class/nano_men_home.html

dealing with health risks related to indoor and ambient air quality or events dealing with the health risks related to exposure to electromagnetic fields, health risks of climate change and the cost/benefit and uncertainty analysis in the framework of environmental health research. Researchers from EU-funded projects presented numerous contributions at the International Public Health Symposium on Environment and Health Research (Madrid, 2008) of which DG Research was one of the co-organisers.

2. Targeting research on diseases, disorders and exposures

The aim of this action in the Environment and Health Action Plan has been to improve knowledge of the links between environmental exposures and four priority diseases (childhood respiratory diseases, neurodevelopmental disorders, cancer and endocrine disrupting effects). A number of targeted research projects has been launched under the EU Framework Programmes for Research, with the following overview highlighting only some major developments:

Childhood respiratory diseases

- Various aspects of allergy and asthma were addressed in 23 projects under FP5 receiving a total EC contribution of 30 million euro. The results were analysed and published in 2007.[121]
- In FP6, two large-scale projects focusing on asthma and allergy were funded (GABRIEL[122] and GA^{2}LEN[123]). GA^{2}LEN was completed in 2009.
- Since FP7 was launched in 2007, several projects have been started to study the effects of air pollution on the development of respiratory diseases. The ESCAPE project is combining health data available from European cohort studies with air pollution exposure assessment in order to investigate, among others, exposure-response relationships and thresholds for adverse perinatal health outcomes, and development of asthma in children. The HITEA project is focusing on the role of indoor biological agents in the development of respiratory, inflammatory and allergic health impacts among children.

Neurodevelopmental disorders

- Twenty-five projects investigating the neuroimmune, neurodevelopmental and neurotoxic effects of chemical contaminants were funded in FP5 with EC contribution of around 50 million euro. The results were analysed and published in 2007.[124] In FP6, additional 14 projects were launched at least partly addressing neurodevelopmental disorders as a health end-point, receiving a total EC support of some 60 million euro.
- As one of the health end-points under investigation, neurodevelopmental effects are studied in 7 projects already launched under FP7. One of the examples is the NEURONANO project studying whether nanoparticles induce neurodegenerative diseases.

Cancer

[121] http://ec.europa.eu/research/environment/pdf/env_health_projects/env_health_brochure.pdf
[122] www.gabriel-fp6.org
[123] http://ga2len.com/
[124] http://ec.europa.eu/research/environment/pdf/env_health_projects/env_health_brochure.pdf

- Ongoing large FP6 projects launched in 2005 and 2006 study how nutrition and genetic disposition affect susceptibility to cancer (ECNIS[125]) and investigate whether maternal exposure to dietary carcinogenic compounds results in *in-utero* exposure and molecular events in the embryo that may lead to increased risk of cancer in childhood (NEWGENERIS[126]).
- In FP7, the large-scale integrating COGS project will study the interaction between genetic susceptibility and environmental lifestyle factors in the development of several types of cancer and to this end it will follow 200 000 individuals. A more focused project MOBI-KIDS has been initiated to assess the potential effects of exposure to radiofrequency fields on the development of brain cancer in childhood and adolescence.

Endocrine disrupting effects

- Research on endocrine disrupting (ED) effects has been a high priority under FP5 with 25 relevant projects receiving a total EC contribution of 55 million euro. The results were analysed and published in 2007.[127] The projects included a cluster of four projects called CREDO (The Cluster of Research into Endocrine Disruption in Europe), which ended in 2008, receiving a Community contribution of nearly 20 million euro.
- In FP6, additional 19 projects were funded, which at least partially address endocrine disrupting effects, with a total EC contribution of 53 million euro, including the recently finished CASCADE[128] network of excellence, which investigated the mechanisms of action of food-borne chemical contaminants that interfere with hormone signalling.
- The support for ED related research has continued in FP7 with examples including a three-project, 10 million euro cluster called NECTAR (Network for Environment Chemical Toxicants Affecting Reproduction) and the OBELIX project testing a hypothesis that prenatal exposure to ED compounds in food plays a role in the development of obesity later in life.

3. **Research aiming at developing methodological systems to analyse interactions between environment and health**

Under the Sixth Framework Programme of Research (FP6), support has been provided to several projects devoted to the development of integrated risk assessment methodologies and models for evaluating health effects of multiple environmental stressors or mixtures of pollutants. They include the following integrated projects:

- NOMIRACLE[129], to be completed in 2009, is devoted to the development of methods for assessing the cumulative risks from combined exposures to multiple stressors including from complex mixtures of chemical, physical, and biological agents. The project also seeks to contribute to the integration of the risk analysis of environmental and human health effects.
- INTARESE[130] is developing a methodological framework and a set of tools and indicators for integrated assessment that can be applied across different environmental stressors, exposure pathways and policy areas.

[125] www.ecnis.org
[126] www.newgeneris.org
[127] http://ec.europa.eu/research/environment/pdf/env_health_projects/env_health_brochure.pdf
[128] www.cascadenet.org
[129] viso.jrc.it/nomiracle
[130] www.intarese.org

- HEIMTSA[131] is developing a methodology for health impact assessment (HIA) and cost benefit analysis (CBA), so that overall environment and health impacts caused by releases of substances into the environment from relevant human activities can be evaluated at the European level.The project is also contributing to the development of HIA/CBA capability in Europe.

In addition to the above, other FP6 projects were devoted specifically to the valuation of environment-related health impacts for children (VERHI CHILDREN[132]) or to comparing the costs of emission reduction measures with their benefits in terms of reduced human health impacts (DROPS[133]).

Several major projects are still ongoing. Once their results are available, suitable follow-up will be considered under the Seventh Framework Programme of Research.

4. **Research to ensure that potential hazards on environment and health are identified and addressed**

World Health Organisation has recently identified **climate change impacts on human health** as a priority for global public health and there has been a growing recognition of the need of research on the linkages between climate, policies addressing climate change and health outcomes. In this context, DG Research has funded under FP6 the MICRODIS project dealing with health, social and economic impacts of natural disasters and the EDEN project investigating the impacts of environmental change on the spatial and temporal distribution of human pathogenic agents (for more information see the boxes below).

The **MICRODIS** project aims to build up the scientific and empirical foundation on the relationship between extreme events and their health, social and economic impacts. The project is bringing together numerous partners from Europe and Asia and its overall goal is to strengthen preparedness, mitigation and prevention strategies in order to reduce the impacts of floods, windstorms and earthquakes on communities. http://www.microdis-eu.be.

The **EDEN** project is studying how changes in European environment and ecosystems, whether caused by altered human activity patterns or changes in climate, can influence the spatial and temporal distribution and dynamics of pathogenic agents causing diseases such as malaria, leishmaniasis or tick-borne encephalitis. It is focusing on human diseases that are sensitive to environmental changes and are either already present in Europe, can be expected to re-emerge or are spread on the fringes of Europe. http://www.eden-fp6project.net.

Under FP7, two projects (ArcRisk, CLEAR) have been selected to examine the health risks resulting for Arctic populations from climate change induced changes in the distribution of environmental pollutants. The projects are designed to contribute also more generally to the knowledge on how environmental contaminants are affecting human reproductive health. A project on the health effects of changing surface UV radiation levels has also been launched in 2009.

Starting from the third call for proposals under the FP7 Environment theme, an area dedicated to climate change induced human health effects has been introduced under the Environment and Health sub-activity as an acknowledgement of the importance of this issue. This means that one or two relevant topics will be annually opened for research proposals in the

[131] www.heimtsa.eu
[132] www.oecd.org/site/0,3407,en_21571361_36146795_1_1_1_1_1,00.html
[133] www.nilu.no/DROPS

remaining FP7 calls. The first topics opened for submission dealt with climate change and water-related health issues and with the quantification of climate change impacts on health in low-income developing countries. Following the evaluation of proposals in February and March 2009, it is likely that each of these topics will be covered by a research project which could start towards the end of 2009.

Another emerging area that has received substantial attention since 2007 concerns possible **human health impacts of nanoparticles**. Under FP6, as many as 8 research projects have been supported in this area with total EC contribution amounting to 20 million EUR. The supported projects include, for instance, CELLNANOTOX[134] investigating the correlation between the physicochemical characteristics of nanoparticles and their toxic potential for various organs or NANOSH[135] evaluating the inflammatory and genotoxic effects of engineered nanomaterials. Support for research in this field continues also under FP7 with six projects already selected and launched since 2007.

SUMMARY TABLE

1. Integrate and strengthen European environment and health research (Action 5)

Task	Description of task in the Technical Annex of EHAP and the midterm review report	State of play	Problems encountered	Future
2004-2007				
1	The Commission will analyse the final results of relevant Community funded research projects, and ask the Member States to provide an analysis of relevant national initiatives, with a view to ensuring that these research results are taken into account in policy making.	Final results of all 90 multicentre multidisciplinary research projects funded by the EU in the Fifth Framework Programme of Research (FP5) have been analysed and made public through a catalogue and on internet. Policy-makers have been provided with relevant final reports, have in some cases been briefed directly, and have attended numerous workshops and conferences on specific issues. The analysis of results of projects funded by the Sixth Framework Programme (FP6) has started although a majority of the projects are still ongoing. An impact assessment will be carried out in the latter half of 2009. Some analysis of national research activities has been or is being carried out by the EMF-NET coordination action and the ERA-ENVHEATH project.	Lack of human and financial resources has prevented the deep analysis of research activities at national level.	Final results of all FP6 results will become available by 2012. The Commission should then review overall progress and make recommendations for future research priorities, possibly to be implemented in the Eight Framework Programme (FP8).
2	The Commission will aim to consolidate ongoing research results in the priority areas (e.g. actions on allergies and on national endocrine disrupters test strategies).	The Commission has funded a large five-year network of excellence GA2LEN, which brought together 25 partners from the EU including the European Academy of Allergology and Clinical Immunology and patient organisations. In addition to research on the genetic basis, clinical treatment, environmental aspects and social causes of asthma and allergies, the project shared data and biological resources, trained young	The durable integration as foreseen for networks of excellence (NoE) has been problematic. Some NoEs are followed by coordination	In the Seventh Framework Programme of Research (FP7), allergy and asthma research is funded mostly by the Environment and Health themes. A joint or coordinated call for research proposals could be envisaged to pool resources to tackle a complex environmental health disease.

[134] http://www.fp6-cellnanotox.net/
[135] http://www.ttl.fi/Internet/partner/Nanosh/Main+Page/

		scientists, and exchanged staff between institutes. Research on endocrine disrupting chemicals has been a high priority in the Commission since the launch of FP5, during which 25 projects with EC contribution of €55M were funded including a cluster of four projects called CREDO (The Cluster of Research into Endocrine Disruption in Europe). Another three-project cluster, NECTAR (Network for Environment Chemical Toxicants Affecting Reproduction) is being funded in FP7, which will further fill in the gaps of knowledge. In FP6, additional 19 projects with a total EC contribution of €53M have been financed. Many of these projects have contributed to improved testing strategies of endocrine disrupters and have contributed to the OECD and ECVAM testing strategies. They contribute to the Community Strategy for Endocrine Disrupters and other chemicals policies.	actions in FP7.	As regards research on endocrine disrupters, a three-project cluster with EC contribution of €10M has been launched in FP7, which will elucidate the long-term health impacts of endocrine disrupting chemicals and mixtures.
3	The Commission will organise together with the Member States, European Conferences on Environment and Health to highlight the research results achieved in different priority areas and their relevance to policy development.	The Commission has organised or otherwise contributed during the six years of the Action Plan numerous events engaging various stakeholders including national and EU policy makers. For example: - endocrine disrupters: four international workshops to discuss testing strategies and current state of the art (2005, 2006, Brussels, Helsinki, Prague); - environmental cancer risks: one international workshop to highlight results of framework programme projects (2005, Warsaw) - health risks related to exposure to electromagnetic fields: a workshop highlighting the final results of the FP6-funded EMF-NET coordination action (Brussels, 2006) - climate change and health risks: workshop (Brussels, 2005), organisation of International Polar Symposium (2007); -health risks related to indoor and ambient air quality: three workshops with extensive stakeholder participation (Brussels, 2007, 2008, 2009) - risk assessment and cost/benefit analysis: workshop on harmonisation of risk analysis of food chemicals (Brussels, 2005), contribution to DG SANCO organised 1st international risk assessment conference (2008), two workshops on cost/benefit and uncertainty analysis (Brussels, 2007); - events with wide scope engaging a large number of stakeholders: Open Stakeholder Consultation: Priorities for Environment & Health Research in FP7 (2006); International conference on environmental epidemiology and exposure (Paris, 2006); International Public Health Symposium on Environment and Health Research (2008)		The Commission will continue organising targeted workshops on issues of policy relevance (climate change, endocrine disrupters, EMF…), sometimes in association with relevant projects. Many FP6 projects plan final end-user workshops or events, which will take place in the next couple of years. The Commission will organise a side event at the 2010 Interministerial Conference.
2007-2010				
5	The Commission will analyse the intermediary and final results of relevant projects for policy making from various Community	The final results of 90 FP5 projects have been published in a catalogue and on internet. An overview of ongoing 66 FP6 projects has	The publication of PHP projects is done by DG SANCO.	The final results of FP6 projects will be published once available (by 2012).

	programmes including the Fifth (FP5) and Sixth (FP6) Framework Programmes of Research and the Public Health Programme (PHP)	been published on the internet. An impact assessment will be carried out in the latter half of 2009, which will analyse also intermediary results.		
6	The Commission will organise workshops on targeted environment and health issues to highlight the research results achieved in different priority areas	See above		
7	The Commission will identify research needs for the future calls for proposals to be implemented in Community Programmes.	All workshops and events listed above have to some extent contributed to the prioritisation process. In particular, the workshop organised in 2006 (Open Stakeholder Consultation: Priorities for Environment & Health Research in FP7) contributed directly to the prioritisation process for the beginning of FP7. The Opinions of Commission's scientific committees have provided valuable inputs for priorisation, e.g., in the area of health impacts of EMF.		- Some projects such as ENNAH (European Network on Noise) will contribute to establishing priorities in a specific domain by carrying out reviews and organising end-user workshops - Targeted workshops on specific issues will be organised where deemed useful. - The Opinions of Commission's scientific committees will provide valuable inputs for priorisation - The 2010 Interministerial meeting on environment and health will help in establishing future priorities Climate and health workshop. Parma conference. Project end-user workshops (EDEN, NECTAR (?), SYSTEQ…)

2. Target research on diseases, disorders and exposures (Action 6)

Tasks	Description of task in the Technical Annex of EHAP and the midterm review report	State of play	Problems encountered	Future
2004-2007				
1	The Commission will support research on the causes of asthma and allergy focusing on complex interactions, such as changes in the environment and lifestyles	In FP5 23 projects addressing some aspects of allergy and asthma were funded with a total EU contribution of around €30 million. These projects are now finished and results have been analysed in 2007 and made publically available. These projects have greatly improved the database available for risk assessment as to environmental attributes of respiratory diseases such as air pollution and farming-related protective factors, wood dust, fragrances or ultraviolet radiation. In FP6 three major allergy/asthma projects were funded: EUROPREVALL, GABRIEL and GA2LEN. Taking into account smaller-scale projects, the EC contribution was close to €60 million. An ex post evaluation will be carried out in 2009/2010, which will analyse intermediary results of these projects. The results have provided and will provide in the	The results of ongoing FP6 projects are not yet available.	In the Seventh Framework Programme of Research (FP7), allergy and asthma research is funded mostly by the Environment and Health themes. A joint or coordinated call for research proposals could be envisaged to pool resources to tackle a complex environmental health disease.

		future scientific underpinning for EU public health policies pertaining to allergy and asthma including preventive measures. In FP7projects, allergy/asthma is one health endpoint that is being studied in numerous projects focused, e.g., on air pollution (ESCAPE, HITEA, TRANSPHORM), biomarker development (ENVIROGENOMARKERS), and GIS applications to health (EO2HEAVEN, HEREPLUS.		
2	The Commission will support research on the causes and mechanisms of neuro-immune disorders, identifying genetic and environmental risk factors, and identifying genetic and environmental factors leading to the development of dyslexia in children	25 projects with EC contribution of around €50 million were funded in FP5 investigating the neuroimmune, neurodevelopmental and neurotoxic effects of chemical contaminants. These projects are now finished and results have been analysed in 2007 and made publically available on the internet and via targeted workshops and other events. A majority of these projects have fed directly into EU legislation on chemicals and food contaminants, and have contributed to the overall goals of Community thematic strategies such as the Community Strategy on Endocrine Disrupters. Research on this continued to be a priority on this issue in FP6, 14 projects having been launched with a total EC contribution of around €60 million. A majority of the projects are ongoing. An ex post evaluation will be carried out in 2009/2010, which will analyse intermediary results of these projects. Neuro-developmental effects is one endpoint under investigation (among others) in 10 projects launched in FP7.	The results of ongoing FP6 projects are not yet available. No project on dyslexia has been funded. No dedicated project on neuro-developmental/ neurotoxic effects of environmental contaminants has been launched in FP7.	A dedicated project on neuro-developmental/ neuro-toxic effects of environmental contaminants could be considered as a topic for proposals in future calls of FP7.
3	The Commission will support research on the development of European networks to promote research into uncommon cancers, the identification of gene-environment interactions involved in the development of cancer in high-risk populations, and the definition of prevention strategies	IN FP6, two large-scale initiatives on environmental cancer risks have been launched: The ECNIS network of excellence and the NEWGENERIS integrated project. Both are identifying gene-environment interactions in the development of cancers and ECNIS is exploring prevention strategies. In FP7 a €12 million study called COGS (*Collaborative oncological gene-environment study*) is to be launched by the end of 2009.		A dedicated project on environmental cancer risks, e.g., focused on individual susceptibility and prediction biomarkers, could be considered as a topic for proposals in future calls of FP7.
4	The Commission will support research on the effects of exposure to metals in the environment and particularly those ingested from food related sources. Sources of human exposure to metals should be assessed, including via uptake by plants grown on contaminated sites. Research should also focus on individual susceptibility.	An integrated project PHIME (*Public health impact of long-term, low-level mixed element exposure in susceptible population strata*), launched in FP6, is continuing until 2011. It aims to establish how long-term exposure to low levels of metals influences public health, in this case diseases that affect the kidney, skeleton, nervous system, cardio- and cerebro-vascular disease and diabetes. It will also map levels of exposure across Europe and in the Seychelles, Bangladesh, Ecuador, China and Morocco. In order to find solutions to the problems, the project will also do research on plants, to develop species that take up less of the metals harmful to our health.		Analysis of the outcome of PHIME will allow to establish whether important knowledge gaps exist for future research
The analysis of results of finished projects has demonstrated that exposures of animals, especially in aquatic environments, to a number of				

industrial chemicals can cause severe endocrine-disrupting effects, of which the impact on reproductive functions has been studied most frequently. Due to the importance of the topic, two research clusters (CREDO and NECTAR), receiving an EU contribution of close to € 30 million, have been funded by the Framework Programmes. Exposure assessment of human populations to chemical pollutants or physiological stressors via food or the environment has revealed significant body burdens of contaminants in exposed populations, especially in children, and in some cases exposures to chemical or physical agents can be linked to negative health outcomes such as impairment in cognitive functioning and development..				
2007-2010				
5	The Commission will support research on the study causes of environment-related diseases via EU-wide epidemiological studies focusing on gene-environment interactions and to investigate long-term health impacts of exposure to environmental stressors such as chemicals, air pollution and noise and combinations thereof, taking advantage of existing cohorts or possibly starting new cohorts. By enhancing scientific basis of understanding of associations between exposures to especially chemicals and health impacts, these projects will contribute to many EU policies especially concerning assessment of risks of exposure to chemicals	In FP7, several projects have been launched, which will study causes of environment-related diseases via EU-wide epidemiological studies: -ESCAPE: on health impacts of ambient air pollution; - HITEA: on health impacts of indoor air pollution; - EFRAIM: on mechanisms of early protective exposures on allergy development - CONTAMED: on health impacts of endocrine disrupters; - OBELIX: on role of endocrine disrupters in obesity - CLEAR: on the role played by climate change in the distribution of environmental contaminants and their effect on reproductive health - MOBI-KIDS: on risks of brain cancer in children due to exposure to electromagnetic fields – COGS: on gene-environment interactions in cancer -ENRIECO: combining data from birth cohorts to improve the understanding of environment-health linkages..	Lack of funding precludes the launch of new large-scale cohorts studies	A feasibility study to explore the usefulness of launching a new large-scale cohort study in Europe will be launched by the end of FP7
In general, these projects have contributed to gaining a better understanding of the links between environmental factors and respiratory diseases, neuro-developmental disorders, cancer and endocrine disrupting effects. Targeted research actions to improve and refine knowledge of the relevant causal links have been set up, in addition to large-scale integrated projects and networks of excellence. Toxicological and epidemiological approaches employing biomarkers and cohort studies, among others, have contributed to the better understanding of both population exposures and health effects in all four priority domains concerned. A general focus has been on vulnerable groups such as children, focusing on early exposures and potential long-term health effects. A number of projects have also contributed to improved testing strategies for chemicals such as endocrine disrupters and alternative approaches to animal testing.				

3. Develop methodological systems to analyse interactions between environment and health (Action 7)

Tasks	Description of task in the Technical Annex of EHAP and the midterm review report	State of play	Problems encountered	Future
2004-2007				
1	The Commission will address the development of integrated risk assessment methodologies and models for evaluating cumulative effects, interaction between stressors and their influence on human health.	Four FP6 projects are ongoing on this topic: INTARESE (Integrated assessment of health risks from environmental stressors in Europe), HEIMTSA (Health and environment integrated methodology and toolbox for scenario assessment), NOMIRACLE (Novel methods for integrated risk assessment of cumulative stressors in Europe), 2-FUN (Full-chain and uncertainty approaches for assessing health risks in future environmental scenarios). Results will be available at the latest in 2012.		It should be ensured that relevant policy-makers are aware of the tools and methods under development.
2	The Commission will address the development of methodologies, techniques,	A majority of FP7 projects selected for funding from the first three calls address issues of low dose (e.g., NECTAR cluster on		By the end of FP7, the outcome of the projects launched so be analysed and

	and models to address complexity in environment/health interactions (multi-causality of disease, toxicogenomics, low dose, long-term exposure, combined effects, etc).	endocrine disrupters), long-term effects (e.g., MOBI-KIDS on health risks of exposure to EMF; ESCAPE on long-term health impacts on a number of health end-points of exposure to air pollution and noise). Toxocogenomic approaches to improve biomarkers are used, e.g., in the ENVIROGENOMARKERS (Genomics biomarkers of environmental health) project.		made public
3	The Commission will address the development of accounting frameworks incorporating externalities associated with various environmental stressors, the assessment of health related externalities, and definition of sustainability thresholds.	Four projects were funded in FP6: METHODEX (Methods and data on environmental and health externalities: harmonising and sharing of operational estimates), DROPS (Development of macro and sectoral economic models aiming to evaluate the role of public health externalities on society), ESPREME (Integrated assessment of heavy metal releases in Europe), and VERHI CHILDREN (Valuation of environment-related health impacts for children). The project results have been transferred to interested policy-makers.		
4	The Commission will address the extension and validation of methods and tools for environment and health impact assessment, cost/benefit analysis and the identification of sources of pollution.	The ongoing HEIMTSA integrated project (Health and environment integrated methodology and toolbox for scenario assessment) is creating a methodology that extends health impact assessment and cost benefit analysis, using the full-chain approach, to improve the evaluation of the environment and health impacts of policy scenarios in key sectors at the European level. It will develop health impact assessment/cost-benefit analysis capabilities in Europe.		
5	The Commission will address the health benefits of food assessed against the health risks of potential environmental contaminants.	Two projects have been funded: BENERIS (Benefit-risk assessment for food: an iterative value-of information approach) and QALIBRA (Quality of life – integrated benefit and risk analysis web-based tool for assessing food safety and health benefits). The two projects were cluster to enhance their synergies.		By the end of the first phase of the Action Plan, it should be ensured that relevant policy-makers are aware of the tools and methods that have been developed.
6	The Commission will address the reinforcement of European networks to foster co-operation and data exchange between environmental monitoring institutes and related regulatory bodies.			
7	The Commission will address the development and validation of technologies and diagnostic tools (e.g. biomarkers and biosensors) addressing real-life exposures.	At least 18 projects have been launched in FP6 and FP7 using toxicological and epidemiological approaches employing biomarkers and cohort studies to better understand real-life exposures and health effects. Exposure, effect and susceptibility biomarkers have been developed.		
8	The Commission will address the harmonisation and validation of risk assessment methodologies putting emphasis on exposure assessment and the production of standards and	The aim of the ongoing ENVIRISK (Assessing the risks of environmental stressors: contribution to the development of integrating methodology) project is to develop an integrated methodological framework to identify health risks caused by exposures to environmental factors.		

	reference materials.			
9	The Commission will address the facilitation of networking of researchers, policy-makers and other stakeholders to disseminate best practice and validate decision-support tools.	The aim of the ongoing HENVINET coordination action (Health and environment network), is, among others, to establish long-term cooperation between researchers, policymakers, and other stakeholders in the field of environment and health research and assessment. It will aim at the validation and exploitation of decision support tools, led by the joint efforts of environmental experts, experts on the modelling of environmental effects on physiology and health experts.		
2007-2010				
10	The Commission will analyse the policy relevance results of Community funded projects from FP5 and FP6 as regards (i) integrated risk assessment methodologies and models; (ii) methods and tools for environment and health impact assessment, cost/benefit analysis and the identification of sources of pollution; and (iii) risk/benefit analysis of foods affected by environmental pollution.	Most recent projects being funded address the complexity in environment/health interactions such as multi-causality of disease, toxicogenomics, low dose issues, long-term exposures, and combined effects. Review and validation of diagnostic tools such biomarkers have been carried out in a large number of projects, and the application of these to addressing real-life exposure situations have and will shed light on the multi-causality of environment-related diseases. An ex post evaluation will be carried out in 2009/2010, which will analyse also intermediary/final results.		

4. Ensure that potential hazards on environment and health are identified and addressed (Action 8)

Tasks	Description of task in the Technical Annex of EHAP and the midterm review report	State of play	Problems encountered	Future
2004-2007				
1	The Commission will work with Member States and international organisations, notably the WHO, to – explore how health sector planning and preparation can be improved for future extreme weather events, and actions can be better targeted and evaluated. – facilitate rapid assessment of emerging threats - launch a research action on the assessment of Global Change-driven factors linked to the risk of introducing and spreading emerging human diseases. – address topics such as a) climate change and health; b) water pollution (e.g. emerging pathogens in drinking water sources); c) possible environmental and human	A large-scale integrated project EDEN (Emerging Diseases in a changing European environment) has been launched with 49 partners from almost all countries in the EU and Africa. It is focused on elucidating how vector-borne infectious diseases, such as malaria, have (re)-emerged and are spread in Europe as a result of outbreaks, which could be linked to climate change, human-induced landscape changes or activities of human populations. Its final aim is to improve and validate risk maps for studying the spread and transmission of vector-borne diseases, which could integrate socio-economic and health data as well as modelling of vector behaviour. The MICRODIS integrated project (Health and socio-economic impacts of extreme events) aims at strengthening the preparedness, mitigation and prevention strategies that can reduce the health, social and economic impacts of extreme events on communities and is investigating the relationship between extreme	The issue of exploration of how health sector planning and preparation can be improved for future extreme weather events and the rapid assessment of emerging threats are not a research issues and therefore no research projects have been launched	

	health impacts of nanoparticles.	events and their health, social and economic impacts in Europe and Asia. Emerging water contaminants issues are being addressed by two FP6 projects: HEALTHY WATER (Assessment of human health impacts from emerging microbial pathogens in drinking water by molecular and epidemiological studies) and HIWATE (Health impacts of long-term exposure to disinfection byproducts in drinking water). The issue of environment and health risks related to exposure to nanoparticles has gained importance, with eight research projects funded both in FP6		
2007-2010				
2	The Commission will investigate the impact of global environmental change including extreme weather events and other effects of climate change on human health and animal health and to investigate potential risks posed by nanoparticles to human health, in synergy with the Nanotechnologies Action Plan.	To highlight the importance of potential health impacts of climate change, in FP7 Environment and Health sub-activity a specific area called 'Health impacts of climate change' has been introduced, from which research on this emerging public health issue has been (5 projects from the first three calls for proposals) and will be financed. After two calls for proposals, eight projects on risks posed by nanoparticles have been selected for funding in FP7.		

ANNEX IV
Overview of EU funded research project on indoor air quality

The most relevant projects include:

- The **INDEX** project[136] ("Critical appraisal of setting and implementation of indoor exposure limits in EU"), coordinate by the General Directorate Join Research Centre (2002-2004), identified a list of "priority compounds" on the basis of health impact criteria. Five compounds (formaldehyde, carbon monoxide, nitrogen dioxide, benzene and naphthalene) have been identified as high priority and suggestions and recommendations on potential exposure limits and risk management options have been formulated.
- The **THADE** project[137] ("Towards Health Air in Dwellings in Europe"), co-ordinated by the European federation of Asthma and Allergy (2001-2003), investigated the association among indoor air pollutants and respiratory diseases. Several recommendations have been formulated for international, national and local level to improve air quality in dwellings. The results of this project confirmed that air pollution in dwellings is a relevant health problem. It is a complex problem that must be addressed at European and international levels, and it involves the medical profession, scientific societies, patients' organizations, lawmakers, architects and the building industry.
- The **HESE** project[138] ("Health Effects of Schools Environment"), co-ordinated by the University of Siena (2002-2005), highlighted the high presence of particulate, moulds, and allergens related to poor ventilation, which appears to be extremely common in European classrooms. Poor ventilation is likely to increase airway inflammation and the risk of asthma in allergic children and could even increase the risk of sensitisation in healthy schoolchildren.
- The **AIRMEX** project[139] ("European Indoor Air Monitoring and Exposure Assessment Project"),, funded by the General Directorate Join Research Centre (2003-) aims at: (i) identifying and quantifying the main air pollutants in public buildings, including schools and kindergartens; (ii) identifying the main sources of these pollutants; and (iii) estimating people's exposure and evaluating possible health effects due to chronic exposure to these pollutants, especially for children.
- **Study** on "*Ranking indoor air health problems using health impact assessment*"[140] was coordinated by the VITO Institute (Belgium). This study has performed a review of existing information from science, from Member States and from stakeholders to inform the Commission on (a) the health impacts arising from indoor air pollution related issues, including uncertainties, and to make recommendations for filling any information gaps; (b) the key indoor air pollutants in homes and key public spaces across the EU, with an indication of the potential for intervention; and, based on the Member States' current practice, on (c1) the risks associated with the exposure to indoor air pollutants in public spaces; (c2) the existing surveillance monitoring schemes of public spaces and private homes and (c3) the implementation of exposure limits.

Other important projects are still ongoing. The most relevant are:

136 http://ec.europa.eu/health/ph_projects/2002/pollution/fp_pollution_2002_exs_02.pdf

137 http://www.efanet.org/activities/documents/THADEReport.pdf

138 http://www.hese.info

139 http://www.jrc.ec.europa.eu/project/airmex/index.htm

140 http://www.vito.be/VITO/EN/HomepageAdmin/Home/Homepage

- The **HITEA** project[141] (*Health Effects of Indoor Pollutants: Integrating microbial, toxicological and epidemiological approaches)* is an FP7 project focusing on the role of indoor biological agents in the development of respiratory, inflammatory and allergic health impacts among children. The focus is on microbial exposures due to dampness problems of buildings. In addition, the role of allergens, chemicals, cleaning agents, traffic exhaust and poor ventilation is studied. The study includes a cross-sectional and a longitudinal study in school buildings in three European countries as well as new analyses of already existing birth cohorts. Since some important aspects are difficult to study among children (e.g., invasive sampling), an adult cohort with similar exposures is also included. The project started in April 2008 and is scheduled to run for 5 years.
- The **BUMA** project[142] ("Prioritization of BUilding MAterials as indoor pollution sources"), co-ordinated by the University of Western Macedonia and the State General Laboratories of Cyprus (2006-2009). The project main objectives are: (i) the formation of a comprehensive database containing up-to-date quantified emitted compounds by construction products and other building materials; (ii) the classification and prioritisation of building materials from the developed database with respect to hazardous compounds emission factors and the relevant exposure levels; (iii) the creation of an Indoor exposure expert modelling system linked to the above mentioned data base; (iv) the production of relevant guidelines for policy-making actions.
- The **HealthyAIR** project, ("Network of actions and activities that address the effect of construction products on Indoor Air"), co-ordinated by the TNO Build Environment and Geosciences (The Netherlands) (2006-2009) aims at defining, initiating and developing activities that improve indoor air quality and reduce exposure to indoor air pollution sources, in particular of construction products.
- **GERIE** - *Geriatric studying Europe on health effects of air quality in nursing homes,* aims to the assess health effects of major indoor air pollutants and thermal conditions in elderly (> 70 years) living stably in nursing homes, to measure air quality and thermal conditions in these homes; in 8 European countries with contrasting lifestyle; and to explain health and environmental disparities in elderly in the EU and seek to identify best practices.
- **HESEINT,** *Interventions on Health Effects of Health Environment,* aims is to contribute to improve healthy growth and development of European children by improving the quality of the school environment and increasing the awareness and preparedness of European schools to cope with indoor air quality and with the special care required by children with asthma.
- **RADPAR** The general objective of this project is to assist in reducing the significant public health burden of radon related lung cancers in EU Member States (MS). The effectiveness of the various existing radon prevention and remediation strategies in the MS will be assessed with the objective of improving them. The assessment of potential conflicts between EU energy conservation objectives in buildings and radon control technologies will be an important objective of this project.

[141] http://www.hitea.eu/
142 http://www.buma-project.eu

- The **INTARESE**[143] project ("Integrated assessment of health risks of environmental stressors in Europe) is an ambitious project aiming at producing a new integrated risk assessment framework, based on the full chain approach (causal chain spanning sources of pollution, releases into various media, dispersion and transport, exposure medium inhalation/dermal contact/ingestion, intake, uptake, dose, health effects and impacts), based on three existing frameworks with differing approaches and aims. One policy area of concern included is housing: includes the effects both separately and in combination of environmental tobacco smoke, indoor air pollution (e.g., from cooking and heating, moulds, furnishings etc), noise and indoor climate (including temperature and dampness) on acute and chronic health (respiratory illness, cardiovascular illness, winter mortality and infant mortality).
- **The EnVIE project**[144] "Indoor Air Quality and Health Effects", co-ordinated by IDMEC (Portugal) (2004- 2008), has been supported under the 'Scientific Support to Policies' programme. EnVIE was designed to interface science and policy making in the field of indoor air quality and collected and interpreted scientific knowledge from on-going research, in particular from EU funded projects and the Joint Research Centre's activities. The major outcome of this coordination network was policy relevant recommendations based on a better understanding of the health impacts of indoor air quality.
- **INDOOR-EXPO project** coordinated by the General Directorate Join Research Centre. Scope of the project is:
    - to perform a systematic meta-analysis of publications and projects for selected health outcomes related to exposure to INDEX priory compounds.
    - to review and discuss exposure to and risks from indoor PM and prepare a draft report on exposure guidelines for Indoor PM.
    - to review existing data on indoor air pollutants and their concentrations in member state. This task aims at developing harmonised criteria on monitoring requirements and harmonized protocols for exposure measurements and assessment for a prioritized list of indoor air compounds in the EU.

143 http://www.intarese.org
144 http://www.envie-iaq.eu/