

Need for improved risk assessment in Europe

To support current and future European strategies, in particular for environment and health, there is an urgent need for 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 Integrated Project NoMiracle will help support the development and improvement of a coherent series of methodologies that will be underpinned by mechanistic understanding, while integrating the risk analysis approaches of environmental and human health. The project will deliver understanding and tools for sound risk assessment, developing a research framework for the description and interpretation of combined stressor effects that leads to the identification of biomarkers and other indicators of cumulative impacts. The IP will help increase knowledge on the transfer of pollutants between different environmental compartments, including how these processes are influenced by natural stressors such as climate, and on the impact of cumulative stressors, including chemical mixtures. This will facilitate the link information concerning the condition of air, water, soil and the built environment with human and ecosystem health monitoring data. By developing and using improved assessment tools and novel models, the project will quantify and aim at reducing uncertainty in current risk assessment and screening methodologies, e.g. by improving the scientific basis for setting safety factors. The new methods will take into account geographical, ecological, social and cultural differences across Europe. The IP consortium count leading scientists within human toxicology and epidemiology, aquatic and terrestrial ecotoxicology, environmental chemistry/biochemistry, toxicogenomics, physics, mathematical modelling, geographic informatics, and socio-economic science.

The interaction between environment and health is far more complex than commonly understood. In particular, little attention has been paid to the interaction of different pollutants in the human body as well as in the environment. Even low level exposure over a period of time to a complex cocktail of pollutants in air, water, food and consumer products is likely to contribute significantly to the health status of European citizens.

Within this project we will improve both human and environmental risk assessment procedures by addressing a series of major shortcomings that exist within the current approaches, namely that:

- they are based on direct effects of single compounds or products
- they apply uncertainty factors which are not strictly based on scientific principles
- they do not account for multiple stressors and indirect effects in a dynamic and heterogeneous environment
- they typically do not account for cumulative (integrated over time, space, substances) effects, and
- they do not allow for site specific and other spatially detailed evaluations.

Although it is generally acknowledged that chemical, biological, radiological, and other physical

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and even psychological stressors can cause a variety of human health or ecological health effects, assessing the risks associated with them is considerably more complex methodologically and computationally than current risk assessment practices. Given these lacunas there is an urgent need for "cumulative risk assessment" which can be defined as "an analysis, characterisation, and possible quantification of the combined risks to health or the environment from multiple agents or stressors".

Development of a framework for such complex risk assessments will greatly improve understanding of the effects of cumulative exposures occurring under the variety of field conditions within Europe and will provide a better scientific basis for forecasting risks and associated uncertainties. The understanding of the complexity of cumulative risks is a prerequisite for development of more efficient guidelines to provide data for future regulation of chemicals.

NoMiracle has seven major objectives

1. To develop new methods for assessing the cumulative risks from combined exposures to several stressors including mixtures of chemical and physical/biological agents.
2. To achieve more effective integration of the risk analysis of environmental and human health effects.
3. To improve our understanding of complex exposure situations and develop adequate tools for sound exposure assessment.
4. To develop a research framework for the description and interpretation of cumulative exposure and effect.
5. To quantify, characterise and reduce uncertainty in current risk assessment methodologies, e.g. by improvement of the scientific basis for setting safety factors.
6. To develop assessment methods which take into account geographical, ecological, social and cultural differences in risk concepts and risk perceptions across Europe.
7. To improve the provisions for the application of the precautionary principle and to promote its operational integration with evidence-based assessment methodologies.

NoMiracle Consortium organisation

NoMiracle work is organised in four research pillars and a management pillar. The four research pillars are linked in the way that they provide a flow of information through the pillars 1 to 4. The responsibility of the management pillar is to disseminate and report project results to the scientific community, the public and the EU Commission.

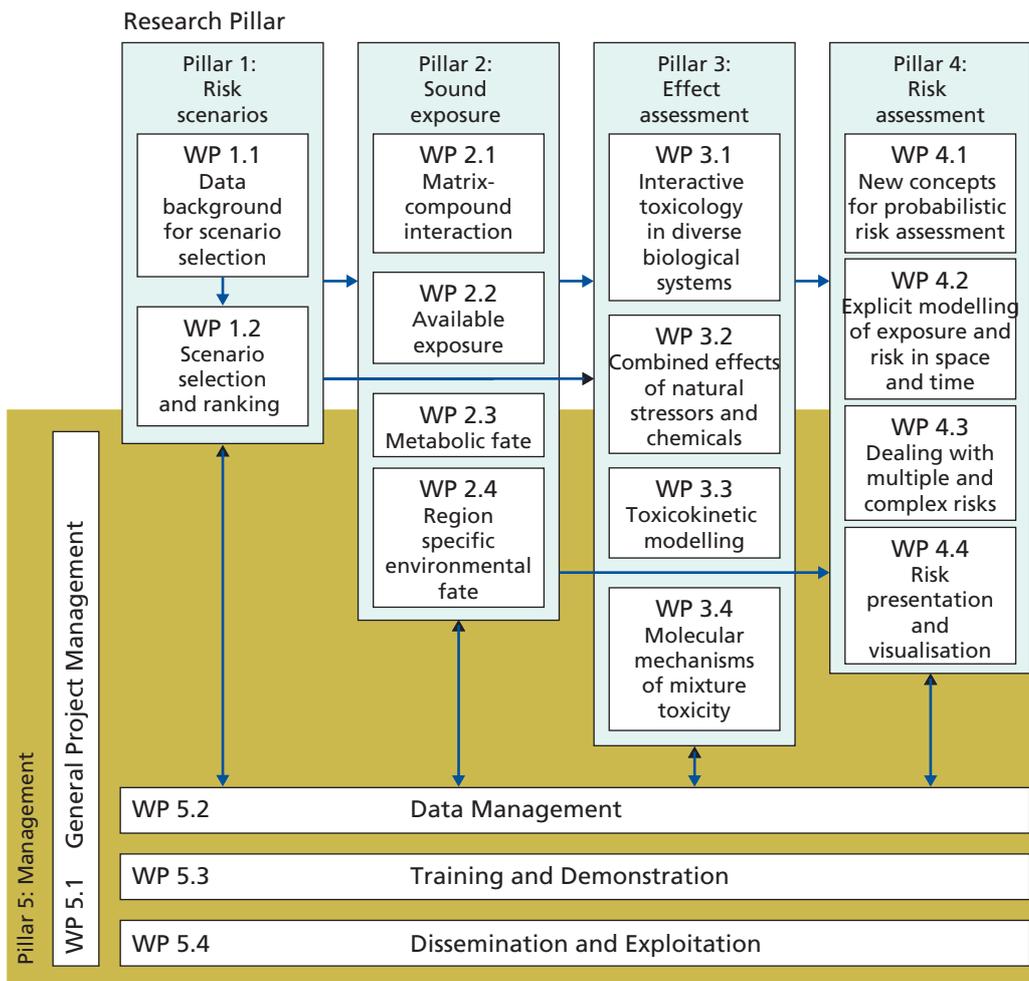


Diagram of NoMiracle activities and their components. NoMiracle consists of 4 main Research Pillars (RP) and a Management Pillar each containing a number of Work Packages (WP).

NoMiracle launched at kick-off workshop in Barcelona



From 18-22 January 2005, eighty scientists met at Institut d'Estudis Catalans in Barcelona to launch the new FP6 integrated project that will make a significant contribution to improving future human and environment health. The project takes an essential step toward better risk management of chemicals that are released into the environment and affect ecosystems and human health. NoMiracle will provide sound scientific risk assessment of pesticides, pharmaceuticals and other chemicals in dynamic and variable environments.

Thirty-eight institutions from 17 countries will work together for 5 years on the development of better methods to analyse, characterise and quantify the combined risks to health or the environment from multiple stressors. Examples of such cumulative stressors are mixtures of chemicals alone or in combination with biological or physical environmental factors such as pathogens and climatic conditions.

The research is of the highest relevance for the development of current and future EU risk management strategies and policies, and related research activities (e.g., Technology Platform for Sustainable Chemistry, Environment and Health Action Plan 2004-2010, Environmental Technologies Action Plan, and REACH).

NoMiracle aims at the creation of a basis for fairer and more efficient chemical risk management. The project will focus on specific scenarios detailing major pollutants and other environmental stres-

Will our health and the environment in which we live improve all by themselves?

Or do we need *Novel Methods for Integrated Risk Assessment of Cumulative stressors in Europe?*

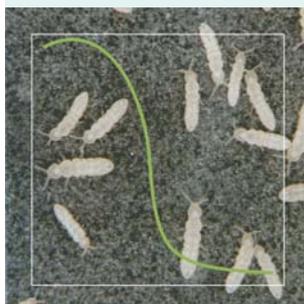
sors as actually found in selected European regions. These represent the range of real situations found in Europe in terms of major pollutants, environmental conditions, exposure to multiple chemicals, which vary today because of different chemical regulation policies, land use practices, distributions of industrial activities and economical and social conditions.

During the Barcelona meeting, the scientists defined the initial scenarios and selected priority chemicals. In the first phase the crosscutting experiments will deal with four different insecticides representing 3 different modes of action, a metal, and a volatile organic compound. The work also involves larger training sets of chemicals for calibration of specific experimental methods and mathematical tools. The scenarios provide baseline situations allowing NoMiracle scientists to simulate the consequences of chemical compounds or mixtures in the environment and close to humans.

The project will promote strong interactions among interdisciplinary research lines, and the consortium calls for collaboration with related research. The NoMiracle scientists wish to establish real communication with other academic and industrial scientists as the project results would significantly benefit from additional data provided by industry or other stakeholders. Therefore, interested industries, administrations and research institutions are strongly encouraged to contact the project co-ordinator or the co-ordinators of the research pillars (see addresses under NoMiracle co-ordination).

Presentation

The NoMiracle project is managed and co-ordinated by Hans Løkke, Director of Department of Terrestrial Ecology at the Danish National Environmental Research Institute.



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The department focuses on how plants, animals and their habitats are affected by natural conditions (climate and soil) as well as human activities (air pollution, pesticides, genetically modified plants and various agricultural management systems).

This knowledge is used by national and international authorities and private stakeholders and supports the national monitoring programme NOVANA.

Visit the Department at:
<http://www.dmu.dk/International/About+NERI/Departments/Terrestrial+Ecology/>

The department collaborates with a number of international partners and has the overall responsibility for several large international research and development programmes in EU, Africa, and Vietnam. The work is organised in two sections:

Section for Plant and Insect Ecology

- Risk assessment of genetically modified plants, pesticides and air pollution.
- Management of the subprogramme for terrestrial habitats within the Danish monitoring programme NOVANA.
- This section runs a genetic laboratory.

Section for Soil Fauna and Ecotoxicology

- Research on how stress from chemical substances, climate and different cultivation systems affect soil living animals and the ecosystem they are a part of.
- This section runs a GLP ecotoxicology laboratory.

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Activities

- Training workshops in ecotoxicology and toxicology, Barcelona 20 January 2005.
- SENSE course S131, Topics in Ecotoxicology, Wageningen, 15-18 February 2005, with contributions from NoMiracle

Future activities

April/May 2006 - A combined workshop on (1) risk mapping, scenario ranking, risk presentation and visualisation and implications for the precautionary principle, and (2) mixture toxicity.

Links

<http://europa.eu.int/comm/environment/health/pdf/com2004416.pdf>
<http://www.credocluster.info/>

NoMiracle co-ordination

Visit NoMiracle at:
<http://viso.jrc.it/nomiracle/>

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