

Editorial



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Dear friends of HEROIC,

The previous newsletter featured opportunities for integrated risk assessment of chemical mixtures and gave an update on existing approaches and methodologies to assess mixture toxicology.

In this issue we provide some information on two expert meetings: the expert workshop on expert elicitation held in Chatou, France, on October 1-2, 2013, and the expert meeting on extrapolation for hazard assessment, held in Leipzig, Germany, November 7-8, 2013. We also report preliminary findings on the stakeholder consultation survey, which aim to collect new insights on potential socio behavioural factors influencing the effectiveness of the risk analysis procedure.

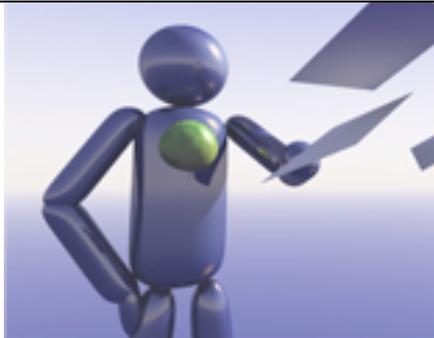
HEROIC enters the third and final year of the project, and we would like once again to encourage all interested parties to support us in our endeavour and to constructively collaborate in achieving our objective for the benefit of society as a whole.

We hope that you find this information useful, and we are looking forward to hearing your feedback.

Prof. Martin F. Wilks
Project Coordinator

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HEROIC consultation workshop on expert elicitation



To assess how human and environmental exposure assessments can benefit from each other, the HEROIC Consortium organized an expert workshop in Chatou, France, on October 1-2, 2013 to analyse expert decision rules and to identify recommendations for improving the robustness of WoE approaches in decision making processes. The general objective was to test integration frameworks based on concrete case studies for early Proof of Consistency (PoC).

Twenty-one experts participated to the workshop, coming from academia (e.g. EPFL, Switzerland; Paris Sud University), health agencies (e.g. Austrian Agency for health and Food safety) and industry (e.g. Yves Rocher)

Evaluating how human and environmental risk assessors cross-evaluate and integrate toxicological data to come to a decision is an important element to illustrate how, where and why human and environmental RAs are done differently to identify the main drivers in integration and decision-making. As part of Work Package (WP) 4 '*Integrated decision-making framework for the future*', the objective of the expert consultation was to analyze the level of agreement and disagreement between experts on decision processes, and to identify the main drivers for deviations in expert decision, based on two selected case studies (skin sensitization and endocrine disruption).

Case studies were used to make explicit these inter-expert subjective choices and value-laden assumptions that significantly contribute to the uncertainty of the final decision. Uncertainty is then reflected by the degree of disagreement between experts at each level of the process (relevance, individual strength of evidence, integrated strength of evidence) as well as missing information in the form of truncated datasets.

The workshop featured two breakout group sessions which provided in depth discussions about decision rules followed by experts for data integration, based on how they weighted different lines of evidence such as non-test data, in vitro tests, in vivo tests on wildlife, in vivo tests on mammals.

As a follow up to the workshop recommendations for a more transparent, structured and robust framework to integrate various sources of information for hazard and risk assessment will be drafted.

All participants are grateful to P. Ciffroy for the hospitality and organisation of the meeting.

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Expert Workshop on Extrapolation for Hazard Assessment, Leipzig, November 7-8, Germany



An expert workshop was organized on November 7-8, 2013, at the Helmholtz Centre for Environmental Research (UFZ) in Leipzig, Germany, to explore and evaluate approaches to extrapolate the hazard assessment of chemical substances across environmental and human endpoints as well as within environmental toxicology across different species, aiming at the systematic exploitation of toxicological information between different species and endpoints as well as for mixtures. There were 28 participants in total. The majority of them were academic: 22. In addition there were 3 from industry and 2 from regulatory

The workshop was structured in three breakout group sessions to explore three areas of potential opportunities for species-species, endpoint-endpoint and single-compound-to-mixture extrapolation, within the scope of the REACH legislation. In depth discussions took place to evaluate: i) how information available for one species or endpoint can inform the hazard assessment of another species or endpoint; ii) how non-animal information can inform about adverse outcome pathways as basis for a predictive environmental and human hazard assessment; iii) how pharmacological models can be used for extrapolating from single-compound effects to mixture toxicity.

As a follow-up to this workshop recommendations on opportunities for a mechanism-based approach to extrapolate across human and environmental endpoints will be published in the peer-reviewed literature. This will serve as an input to draft guidelines on extrapolation for hazard assessment.

All participants are grateful to Gerrit Schürmann and Ralph Kühne for the hospitality and organisation of the meeting.

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Stakeholders consultation on potential socio-behaviour factors influencing the effectiveness of the actual risk analysis procedure



Taking the outcome of WP2 SWOT analysis of current risk assessment practice (HEROIC newsletter n.2) as a starting point, we selectively expanded this initial work for more in depth analysis of the socio-behavioural factors that have a potential influence on the effectiveness of the overall risk analysis procedure.

Our objective was to outline how socio-behavioural factors influence and contribute to shape current policy priorities, protection goals and perception among different societal groups, on how knowledge in risk assessment is interpreted by risk managers and translated into risk management options, influencing the final decision making process.

To explore these aspects, we selected the sector-specific regulatory framework for plant protection products. The web-based stakeholders consultation was launched in June and was closed at the end of September 2013.

The survey confirms there are factors limiting the effectiveness of the risk assessment phase. These are mainly linked to how the knowledge is produced and how the knowledge produced in the risk assessment phase then is interpreted and used for establishing monitoring programs and/or mitigation measures. The survey also highlighted the strong influence of socio-psychological factors and the cultural quality of pesticide risk evaluations.

Principles guiding the evaluation are not solely the national environment, spatial framework and economic aspects, which are still considered important, but also those related to the ethical issues and social behavioural aspects linked to responsibility, trust, reliance, that can strongly influence the choice of the approach to be taken.

Stakeholders clearly indicate that education level influences the attitude towards risk and pesticide use education is a societal need that we have to take into consideration but also that attitude toward risk is not properly considered in the risk assessment phase.

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The results indicate that there is an interest in an interdisciplinary approach in risk analysis that involves also other different scientific disciplines, but also that this aspect have not yet been fully explored and the role of socio-behavioural factors have not been fully recognised among all stakeholders. The survey highlighted the importance of the qualitative component of “chemicals risk analysis” that should be practically relevant but also ethically acceptable. These qualitative components could help to produce better economic estimate, more faithful to human psychology, and to support risk managers to better communicate on risks and mitigation measures.

We wish to thank all the stakeholder participants for being part of this consultation process and for providing important information and useful comments and we will consolidate and evaluate all contributions to prepare for a follow up roundtable discussion with a panel of selected experts. The insights gained from this process will help to improve and promote the integration, where useful and possible, of the human and environmental RA in a manner suitable for its coupling with Socio Economics Analysis (SEA).

Focus On Heroic Partners

Our newsletter also gives us the opportunity to introduce the HEROIC partners.

We started in the first issue with the Swiss Centre for Applied Human Toxicology which coordinates the HEROIC project. In the following issues we presented the Catholic University of Sacred Heart (UCSC), Italy, the Spanish Council for Scientific Research (CSIC), the National Institute for Industrial Environment and Risks (INERIS) in France, the Benaki Phytopathological Institute (BPI) in Greece and Faust and Backhaus Environmental Consulting (F+B) in Germany.

The present issue features the Helmholtz Centre for Environmental Research (UFZ) in Germany.

	<p>The Helmholtz Centre for Environmental Research - UFZ (www.ufz.de) was established in 1991 and has more than 1,100 employees in Leipzig, Halle/S. and Magdeburg. They study the complex interactions between humans and the environment in cultivated and damaged landscapes. The scientists develop concepts and processes to help secure the natural foundations of human life for future generations. UFZ is (co)-responsible for various tasks in WP3, WP4 and WP6.</p>
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The project work is allocated to the Department of Ecological Chemistry, which undertakes research into environmental chemodynamics and molecular toxicology. Its focus is on structure-activity relationships, employing chemoassays, bioassays, computational

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chemistry, chemoinformatics and biomimetics to study compound toxicity, reactivity, partitioning and degradation.

UFZ, belongs to the Helmholtz Association of National Research Centres, an interdisciplinary institution that contributes to solving major challenges facing society, science and the economy with top scientific achievements in six research areas: Energy, Earth and Environment, Health, Key Technologies, Structure of Matter, Transport and Space. With about 34,000 employees in 18 research centres the Helmholtz Association is Germany's largest scientific organisation.

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News

HEROIC second SAB meeting

The second Scientific Advisory Board (SAB) meeting took place at INERIS, Paris, France, on October 3, 2013. The purpose of this joint meeting was to analyse and reflect on the progress of the project and evaluate the results of each WP.

The members of the Science Advisory Board provided valuable input for the continuing work of the project and gave the opportunity to the HEROIC Consortium to reflect on the challenges as HEROIC enters the final and third year of the project. Further discussions will take place to evaluate the opportunity for some SAB members to more specifically share their expertise with regard to certain activities of project, including a third PoC case study and guidelines on extrapolation for hazard and exposure assessment.

EUROTOX 2013



HEROIC participated to the 49th Congress of the European Societies of Toxicology (EUROTOX, <http://www.eurotox2013.com/>) that was held in Interlaken, Switzerland, September 1-4, 2013 dedicated to 'New Frontiers in Safety Sciences', with a serie of lectures, poster and the chairing of a symposium on integrated risk assessment.

In the Symposium on 'Integration of human and environmental risk assessment – is it the future?' chaired by L. Aicher (WP2 leader), M. Wilks (HEROIC Coordinator) introduced the HEROIC project and P. Ciffroy (WP4 leader) presented some further insights in decision-making using weight of evidence approaches in human and environmental RAs. "The poster 'Extrapolation of toxicology endpoint data in developing integrated human and environmental risk assessments' by A. Dalzell and R. Glass, described with a case study how data could be better used in human and environmental RAs to promote the use of IRA.

The Congress provided an excellent opportunity to bring the HEROIC project and its objectives to a wide audience.

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Events

Expert workshop on extrapolations in integrated exposure assessment, Paris, January 21-22, 2014

Today, exposure assessment has been established through extensive cumulative experience of scientists from many disciplines (transport modeling, biogeochemistry, multimedia modeling, pharmacokinetics, etc) and can be both directed towards biota or human for further RAs. Exposure assessment is challenged by increasing scientific complexity (e.g. multiple stressors, mixtures) and resourcing, the availability of data and the increasing need to evaluate substances due to revised legislations (e.g. REACH). Altogether, these points create the need for better exploitation of all currently existing data, experimental approaches and modeling tools and it is assumed that a more integrated approach to RA may be part of the solution. An “Integrated exposure assessment” is defined in the frame of HEROIC project, and in the context of this workshop, as the possibility of combining information (content) generated for different purposes, in particular from information generated for human exposure assessment to information dealing with environmental exposure and vice-versa.

To go a step further towards a common understanding of integrated exposure assessment, and to assess how human and environmental exposure assessments can benefit from each other, the HEROIC project is organizing in Chatou and Paris, France, on January 21-22, 2014 a specific workshop gathering several experts in exposure assessment.

The workshop will feature a plenary session and two breakout sessions, on exposure scenario and waving (lead: Philippe Ciffroy, WP4 leader) and on metrics and biokinetics (lead: A. Péry, WP3 leader). The workshop has been designed to maximize the interactions between the participants and stimulate discussions, based on the identification of best- and worst-case scenarios.

In the next issue a feedback of the workshop will be provided. For more detailed information please contact: philippe.ciffroy@edf.fr or alexandre.pery@ineris.fr.

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Publication

The position paper ***“Perspectives for integrating human and environmental risk assessment and synergies with socio-economic analysis”*** is now published on *Science of the Total Environment*, 456-457 (2013) 307–316.

This paper describes the scope and prospects of the integrated assessment and of including socio-economic analysis in this risk assessment. From this analysis a number of recommendations for the next research steps can be derived.

The abstract is available on the HEROIC website in publications section of Documents.

Next Issue

The next issue will feature other news and documents developed by the HEROIC Consortium and a feedback of the Expert workshop on extrapolations in integrated exposure assessment organized in Paris.

Contact us

For more info

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HEROIC is a project funded by the European Community's Seventh Framework Programme under grant agreement n° 282896. All rights reserved.

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