

n.2

Editorial



In this issue:

- Editorial
- Strengths, Weaknesses/limitations, Opportunities, and Threats(SWOT): analysis of the "As Is" situation in risk assessment practice
- The accessibility of available data: the Tox-Hub platform
- Focus on HEROIC partners
- Events
- Next Issues

Dear friends of HEROIC,

In the previous newsletter we introduced ourselves and our project, provided you with some background material, explained our ways of working and updated you on the activities which have taken place so far.

In this issue we would like to share with you some outcomes of our first year of work. In particular, we provide an overview of the analysis of existing gaps and needs of current risk assessment processes. This will be part of the first HEROIC position paper which will soon be submitted for publication.

We also take the opportunity to introduce to you the Tox-Hub platform through which HEROIC intends to close some of the gaps and remove impediments linked to the accessibility of the data.

Most importantly, we would like 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. Let me also take this opportunity to wish you all a peaceful Christmas and a very happy and prosperous New Year 2013.

*Prof Martin F Wilks
Project Coordinator*

n.2

Strengths, weaknesses/limitations, opportunities, and threats (SWOT): analysis of the "as is" situation in risk assessment practice.



The main objective of HEROIC Work Package 2 (WP2), led by UNIBAS, is to identify common methodological and data needs in current risk assessment practices for chemicals, pesticides, pharmaceuticals, food additives and cosmetics at European level as an input for the development of an integrated risk assessment. Based on the initial results of the landscaping exercise that identified key partners and major processes for risk assessment, management and communication at EU level, we performed a SWOT analysis through structured expert interviews to identify weaknesses in the current risk assessment process and to specify the necessary requirements to change the "as is" situation.

Structured telephone interviews were conducted with subject matter experts in the area of risk assessment and risk management within regulatory bodies and the private sector at EU level. The experts were asked to characterise weaknesses/gaps in the current risk assessment process and to specify what changes would be needed to facilitate improved risk assessment practice. Consolidation and refinement of our initial evaluation was achieved through expert consultation during the first HEROIC workshop, held at INERIS, Verneuil-en-Halatte, France, April 12th-13th, 2012, which convened 60 experts from public institutes, academia and business sectors. Results from the gaps and needs analysis are briefly summarised below.

Infrastructure and organisational set-ups

The separation of human health and environment risk assessments is deeply rooted in the culture and practices of many risk assessment or management institutions and organisations at the EU level and beyond. This is mainly considered a consequence of the allocation of the risk assessment of different chemicals categories to distinct regulatory authorities and scientific disciplines. The lack of exchange between disciplines and authorities, and also between risk assessors and risk managers, hampers more efficient working relationships.

Capacity was unanimously recognised as another issue for risk assessment. Despite human resource constraints, the demand for risk assessment remains high, regulatory timeframes remain ambitious and assessments are getting increasingly complex. This growing complexity and the interdisciplinarity of risk assessment sciences also result in major capability issues which are amplified by the lack of adequate training programmes.

n.2

Science and policies


Risk assessors recognised the need for sufficient data as being the most critical success factor to carry out proper risk assessment. Exposure assessment and cumulative assessment of mixtures were identified as the weakest points in current risk assessment practice. Risk assessors are challenged by the growing complexity of regulatory sciences and acknowledged the need for continuous training and up to date information on the latest developments in their field.

From the standpoint of risk management, the need for more informative risk assessments was recognised. These need to translate the technical expression of risk characterisation parameters into human health and ecological criteria, such as the impact on morbidity and mortality or human welfare and ecosystems services. Since risk management decisions are not purely science-driven but must also include political, economic and social factors, risk managers need to consider cost-benefits which put into perspective the human health and environmental risk implications of different alternative approaches to risk management.

Risk perception and communication requirements differ among stakeholders, and risk managers need to be able to respond to those different needs. These requirements highlight the importance of problem formulation at the onset of the risk assessment process. Distinct national protection goals, priorities and differences in risk perception among different societal groups, or with respect to different categories of chemicals, influence risk management decisions. Therefore, risk assessors and risk managers need to find a common understanding of the priorities and protection goals from the outset of the risk assessment process.

Based on the results of the initial landscaping exercise and the SWOT analysis, an action plan has been drafted with recommendations which will be further developed in the framework of the HEROIC Project. For more details, please contact Lothar Aicher, (lothar.aicher@unibas.ch) or Nicolas Roth (nicolas.roth@unibas.ch). As next steps, HEROIC WP3 (“*Data and Models for Exposure and Effects Assessment*”) and WP4 (“*Integrated Decision Making Framework for the Future*”) will address the issue of translating data into knowledge.

The accessibility of available data: the Tox-Hub platform

| | |
|---|--|
|  | <p>Accessibility to available data was one of the main gaps identified by the experts limiting current risk assessment processes.</p> <p>A great deal of useful data is generated in the private sector, e.g. as part of the product authorisation process or within scientific consortia, but these are generally not accessible to a broader scientific community.</p> |
|---|--|

Scientific data cannot be easily exchanged or accessed on a broader scale because they are stored in very heterogeneous environments. There is no harmonised terminology used to categorise data, they are often available in different formats in both human and environmental disciplines and the respective databases have different structures. Consequently, it can be difficult to navigate through various data bases, to extract the desired information and to pool the data. It is one of the major objectives of HEROIC WP5 to develop the Tox-Hub platform which will facilitate the exchange of information and the better use of existing data for risk assessment.

The proposed platform will serve as a ‘Google-like’ search engine but highly specialised for integrated ecotoxicology and toxicology fields of science. The Tox-Hub will serve as a centralised platform which combines ecotoxicological and toxicological databases, thereby narrowing a web universe to a very specialised search. The user will be able to get much more specific references and a more efficient way to find information avoiding unnecessary search results. Creation of the searching preferences is followed by analysis of external references and will be executed with a corresponding algorithm which enables a highly specialised search.

Tox-Hub Architecture

The task is to implement a web services platform devoted to toxicological and ecotoxicological data, able to retrieve data from different databases (DBs). Therefore, an XML language (ToXML) is being developed to standardise and enable the dialog with the different databases.

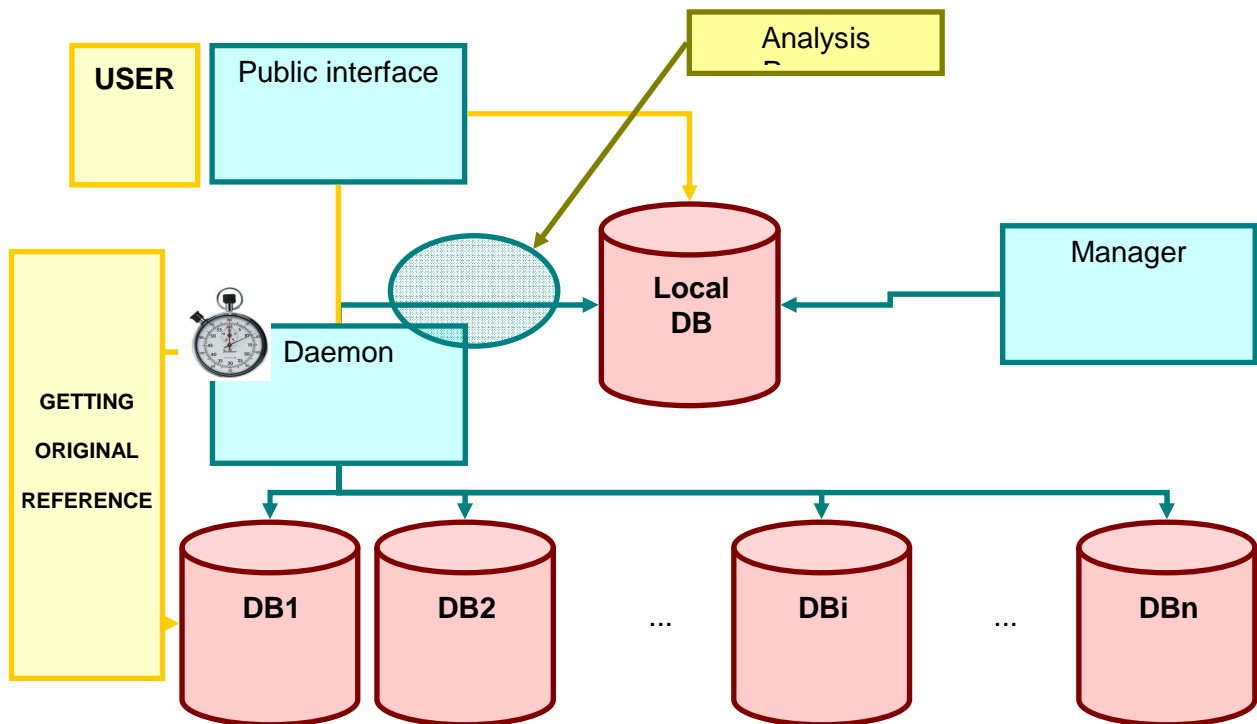
Roles and Actors We need to distinguish three actors (or roles, colored in blue in the scheme) interacting with the system:

User: A person who interacts with the system to retrieve useful information from the human or ecotoxicological point of view.

Manager: Maintains the performance of the system tuning its performance with the general needs.

Daemon: This is a process that executes the tasks of maintenance incorporating the new information and updating the old one.

n.2



Through the Tox-Hub platform HEROIC will share the existing knowledge in a conceptual framework of data, methods and processes and make it available to all partners in the risk assessment value chain. The knowledge platform will provide a better overview of data availability. Tox-Hub also represents the e-learning platform where training materials will be made available in order to improve the capacity building in risk assessment across EU member states.

n.2

Focus On Heroic Partners

Our newsletter also gives us the opportunity to introduce the HEROIC partners. We started in the first edition with the Swiss Centre for Applied Human Toxicology which coordinates the HEROIC project. In this issue we introduce the Catholic University of Sacred Heart (UCSC) (WP6) and the CSIC (WP5).

| | |
|---|--|
|  | <p>The Spanish Council for Scientific Research (CSIC) is the largest public institution dedicated to research in Spain and the third largest in Europe. Belonging to the Spanish Ministry of Economy and Competitiveness through the Secretary of State for Research, Development and Innovation, its main objective is to develop and promote research that will help to bring about scientific and technological progress, and it is prepared to collaborate with Spanish and foreign entities in order to achieve this aim. According to its Statute (article 4), its mission is to foster, coordinate, develop and promote scientific and technological research, of a multidisciplinary nature, in order to contribute to advancing knowledge and economic, social and cultural development, as well as to train staff and advise public and private entities on this matter.</p> <p>The IDAEA (Institute of Environmental Assessment and Water Research) of Barcelona is part of the CSIC. It is led by Prof.Dr Damiá Barceló Culleres.</p> |
|---|--|

CSIC plays an important role in scientific and technological policy, since it encompasses an area that takes in everything from basic research to the transfer of knowledge to the productive sector.


The IDAEA group carries out its activities in the areas of: Environmental research, environmental risk assessment, food quality and chemical safety area, human exposure and risk assessment. The main focus of its work is the assessment of origin, transport and evolution of natural and anthropogenic organic inputs to the environment, including the atmosphere, the water column, soils, sediments and organisms. Other relevant topics involve the study of fossil molecular compounds as traces of climate change in the past and the toxicity of organic pollutants in organisms such as fish, shellfish and human beings. Main research lines are: Environmental chemistry, organic and analytical chemistry, ecotoxicology, paleoclimatology and chemometrics.

CSIC is the leader of WP5 which has the goal to create the web platform **Tox-Hub**.

n.2

Main objectives of WP5 are:

- to facilitate data access and data search, and thereby create a better mutual understanding of data, methods and procedures used in toxicology and ecotoxicology,
- to create an interactive internet platform to connect toxicological and ecotoxicological data bases (previously created under different research projects),
- to facilitate efficient data mining and distance learning contributing to capacity building, a key aspect in WP6.

| | | |
|--|---|---|
|  | <p>UNIVERSITÀ CATTOLICA del Sacro Cuore</p> | <p>Università Cattolica del Sacro Cuore (UCSC) - with >25'000 students - is the largest private non-profit university in Europe. It is recognised by the Italian law and the EC as public body with the main scope in higher education and research.</p> |
| | | <p>UCSC participates in HEROIC with two institutes: the Institute of Agricultural and Environmental Chemistry (ICAA) and OPERA Research Centre.</p> |

The **Institute of Agricultural and Environmental Chemistry (ICAA)** is based in Piacenza and directed by Prof Marco Trevisan,. Thanks to half a century of research, teaching and training activities in the areas of agri-environmental risk assessment and human health safety protection from pesticides, ICAA is now involved in EU, national and global projects on pesticides fate modelling and environmental and human risk assessment.

The institute organises numerous national and international conferences, and most notably among them, the Symposium on Pesticide Chemistry, launched in 1979, has had its fourteenth edition in 2011.

The **OPERA Research Centre** (www.operaresearch.eu) was set up in 2010, with the specific objective of involving the stakeholders in a think tank to achieve the correct implementation and transposition of the new regulation on risk assessment in the broad context of the sustainable economic, social and agriculture development of the EU society. It is headquartered in Piacenza, Italy and hosted by the Università Cattolica del Sacro Cuore (UCSC), which provides the necessary resources and support. It is bound by the principles and procedures of UCSC. As a fully independent body, OPERA's vision is to be transparent to all the relevant stakeholders and the public.

Main objectives of WP6 are:

- to involve all relevant stakeholders and end-users and take full account of relevant socio-economic issues for a sustainability assessment and development of the new and improved methods and policy tools and to develop technical programmes as a new conceptual model of skills and competence for upgrading of performance ability in the EU member states.
- to conduct surveys of stakeholders and end-users to obtain data on factors influencing the outcome of their activity, including socio-economic factors.

n.2

Events

Second HEROIC Consortium meeting

The second HEROIC Consortium Meeting was hosted by SCAHT, and held on September 20, 2012, in Basel, Switzerland.

The Consortium Meeting gives to all HEROIC partners involved in the different work packages the opportunity to meet and exchange on a regular basis. The current status of the milestones and deliverables were addressed for each work package. Next steps were discussed as well as the timelines, objectives and contents for HEROIC related meetings and events which are planned over the course of the next 2 years. Strategic decisions were made with respect to the HEROIC Project and the way forward.

First HEROIC Science Advisory Board meeting


The first Science Advisory Board (SAB) Meeting was hosted by SCAHT and held on September 21, 2012, in Basel, Switzerland. The SAB consists of internationally renowned experts from different stakeholder groups who have a longstanding involvement in EU risk assessment activities. The SAB will be consulted at critical stages of the HEROIC Project throughout its life cycle.

Members of the SAB are: *Prof. J. Bridges* (University of Surrey, UK) (chairman); *Prof. A. Boobis* (Imperial College, UK); *Dr M. Jacobs* (EFSA); *Dr G. Loizou* (Health and Safety Laboratory, UK); *Dr M. Montforts* (RIVM, NL); *Prof. P. Wiedemann* (Kaiserslautern Institute of Technology, D); *Dr J.Tarazona* (ECHA).


The Board was introduced briefly to the HEROIC concept and the different work packages, and was given the opportunity to comment on the status and progress of work. The scale and scope of the HEROIC Project were discussed in depth to ensure overall relevance and feasibility of its objectives. In particular, discussions took place on the selection of the most appropriate case studies to illustrate the benefits of integrated risk assessment; the role of socioeconomic aspects for HEROIC; the challenges to access non-publicly available data; and potential integration of mixtures assessment. The SAB gave a valuable input on the current stage of the Project and on future actions to be taken to make HEROIC a success.

n.2

SETAC meeting

| | |
|---|--|
|  <p>23rd SETAC Europe Annual Meeting 12-16 May 2013 • Glasgow.setac.eu</p> | <p>HEROIC will participate in the 23rd Annual Meeting of the Society of Environmental Toxicology and Chemistry (SETAC Europe) “<i>Building a better future: Responsible innovation and environmental protection</i>” that will be held in Glasgow on 12th - 16th May 2013 .</p> <p>The meeting will also be the occasion for the next Consortium and Scientific Advisory Board meetings.</p> |
|---|--|

EUROTOX 2013

| | |
|---|--|
|  <p>eurottox 2013 Interlaken Switzerland 49th Congress of the European Societies of Toxicology</p> | <p>HEROIC will participate in a symposium at the EUROTOX 2013 Congress on ‘Integration of human and environmental risk assessment – is it the future?’</p> |
|---|--|

Publication

A position paper on the identification of the opportunities in integrated human and environmental risk assessment and synergies with socio-economic analysis will soon be submitted for publication.

Next Issue

The next issue will feature other news and documents developed by the HEROIC Consortium.

Contact us

For more info

<http://www.heroic-fp7.eu>

info@heroic-fp7.eu

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

The EU does not take over any responsibility for the contents of this newsletter, that reflect only the partner authors views