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Perspectives for integrating human and environmental exposure assessments

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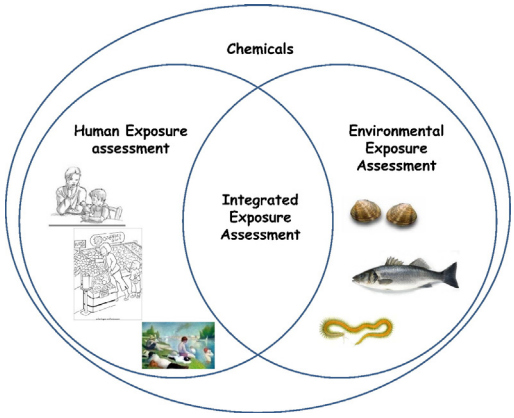
HIGHLIGHTS

- Opportunities to integrate human and environmental exposure assessment are identified.
- Perspectives to harmonize exposure assessment data, models and methods are presented.
- Use and sharing of emission and exposure data are a prerequisite for integration.
- Developing a common model for exposure assessment is a key point for integration.
- This work may serve as an input to develop guidelines for exposure extrapolation.

GRAPHICAL ABSTRACT



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ABSTRACT

Integrated Risk Assessment (IRA) has been defined by the EU FP7 HEROIC Coordination action as "the mutual exploitation of Environmental Risk Assessment for Human Health Risk Assessment and vice versa in order to coherently and more efficiently characterize an overall risk to humans and the environment for better informing the risk analysis process" (Wilks et al., 2015). Since exposure assessment and hazard characterization are the pillars of risk assessment, integrating Environmental Exposure assessment (EEA) and Human Exposure assessment (HEA) is a major component of an IRA framework. EEA and HEA typically pursue different targets, protection goals and timeframe. However, human and wildlife species also share the same environment and they similarly inhale air and ingest water and food through often similar overlapping pathways of exposure. Fate models used in EEA and HEA to predict the chemicals distribution among physical and biological media are essentially based on common properties of chemicals, and internal concentration estimations are largely based on inter-species (i.e. biota-to-human) extrapolations. Also, both EEA and HEA are challenged by increasing scientific complexity and resources constraints. Altogether, these points create the need for a better exploitation of all currently existing data, experimental approaches and modeling tools and it is assumed that a more integrated approach of both EEA and HEA may be part of the solution. Based on the outcome of an Expert Workshop on Extrapolations in Integrated Exposure Assessment organized by the HEROIC project in January 2014, this paper identifies perspectives and recommendations to better harmonize and extrapolate exposure assessment data, models and

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methods between Human Health and Environmental Risk Assessments to support the further development and promotion of the concept of IRA. Ultimately, these recommendations may feed into guidance showing when and how to apply IRA in the regulatory decision-making process for chemicals.

1. Introduction

The assessment of risks from chemicals to the environment and human health is traditionally based on a four steps common paradigm: hazard identification and dose (effect)-response assessment (i.e. hazard characterization), exposure assessment and risk characterization. Exposure assessment is a central pillar of the risk analysis process, which involves the estimation or measure of the magnitude, frequency and duration of exposure to chemicals, along with the number and characteristics of the target exposed. Yet exposure assessment is generally considered as a weak point in risk assessment; this is due to the fact that exposure assessment is often hampered by a general lack of exposure data and by the complex landscape of different pattern of uses and combined exposure (ranging from single exposure to multiple exposures from a single chemical or from multiple chemicals), the use of the many different exposure assessment models (area, concentration, species, life cycle analysis), and the inherent natural variability in exposure levels, leading to uncertainty in the estimates. Exposure assessment can be directed towards non-human living organisms (called hereafter "biota") (for further Environmental Risk Assessment — ERA) or humans (for further Human Health Risk Assessment — HHRA). So far, Environmental Exposure Assessment (EEA) and Human Exposure Assessment (HEA) have generally used and developed their own data, methods, scenarios and models in parallel, with poor linkage between them. There is a rationale behind such differences. One the one hand, for historical and practical reasons, the separation of ERA and HHRA is deeply rooted in the culture and practices of many risk assessment or management institutions and organizations at the European Union (EU) level and beyond, which is mainly a consequence of the allocation of the risk assessment of different chemicals categories to distinct regulatory authorities and scientific disciplines. On the other hand, from a scientific standpoint, scenario building must indeed account for different pathways: while 'on site' exposure (i.e. local exposure to chemicals that are emitted into the environment under non intentional or controlled conditions) is mainly of concern for biota, exposure to humans can be extended to chemical production (occupational exposure) or application (e.g. pesticides exposure for operators, bystanders and residents), regional and global use of resources (imported products) and intentional and/or non intentional use of products by consumers (e.g. cosmetics).

The protection goals in EEA and HEA are also clearly different: except in case of endangered species that must be protected in their own right, environmental protection is expressed in terms of protection of ecosystem structure (biodiversity) and functions (life support) and thus targets populations and their interactions within ecosystems. Human protection instead is targeted towards individuals with the objective of preventing any adverse effect on each human being health. But despite such unavoidable differences, EEA and HEA also overlap in several instances. Fate models used in EEA and HEA for predicting the distribution of chemicals among physical and biological media are essentially based on properties of environmental compartments (soil, plants, etc) and on common properties of chemicals (e.g. partitioning and degradation in environmental media). Given the limited number of species for which experimental data is available, bioconcentration, biodegradation and metabolism data and models used to estimate the internal concentration in biological media are by necessity based on inter-species extrapolations, including biota-to-human extrapolations. Species that are assessed in the frame of EEA can also form part of the human food chain (e.g. fish). Beyond these scientific overlaps, EEA and HEA are also facing common challenges, in particular with regard to increasing scientific complexity and resources. The different categories and amount of substances for which EEA and HEA are required will continue to increase substantially due to revised legislation (e.g. the REACH [Registration, Evaluation, Authorisation and Restriction of Chemicals, EC/1907/2006; EC, 2006] Regulation, risk assessment for emergent chemicals such as pharmaceuticals, nanomaterials, etc). Finally, the desire to assess the impact of multiple stressors and the exposure to mixtures adds additional complexity in exposure assessment.

Altogether, these points create the need for a better exploitation of all currently existing data, experimental approaches and modeling tools and it is assumed that a more integrated approach of both EEA and HEA may be part of the solution.

Integration of EEA and HEA was already evaluated in pioneer activities as part of a framework on Integrated Risk Assessment (IRA) developed under the auspices of the International Program on Chemical Safety (IPCS) of the World Health Organization (WHO), the European Commission (EC), the Organization for Economic Cooperation and Development (OECD) and the US Environmental Protection Agency (US EPA) (WHO, 2001). Opportunities for integration were identified in the modeling of chemical transport, fate, and exposure, in particular for environmental exposure models, where concentrations in water, soil, air and different food items must be estimated (Vermeire et al., 2007). Key elements to be integrated in the exposure characterization were outlined, i.e. sources and emissions, distribution pathways, transport and fate models, external and internal exposure models, measures of exposure related parameters (metrics), analytical tools such as methods for sensitivity and uncertainty analysis (WHO, 2001). Critical research recommendations were formulated, including: i) harmonization and improvement of exposure characterization, human health and environmental surveillance methods and exposure models; ii) incorporation of multiple sources and pathways into models of exposure that include both human and wildlife receptors; and iii) integration of monitoring data including measures of exposure and effect (Munns et al., 2003).

Building on this legacy, new opportunities to better integrate EEA and HEA were evaluated by the EU FP7 HEROIC (Health and Environmental Risks: Organization, Integration and Cross-fertilization of Scientific Knowledge, Grant Agreement no. 282896, www.heroic-fp7.eu) Coordination action (Péry et al., 2013a), as an input to promote the concept of IRA, as outlined in a recent White paper (Wilks et al., 2015). HEROIC defines IRA as "the mutual exploitation of ERA for HHRA and vice versa in order to coherently and more efficiently characterize an overall risk to humans and the environment for better informing the risk analysis process". Accordingly, in the frame of the present paper, 'Integrated Exposure Assessment' is defined as the possibility of combining information generated for different purposes, in particular from information generated for HEA to information dealing with EEA and vice-versa.

Because of the need to develop a common understanding of Integrated Exposure Assessment, and to assess how EEA and HEA can benefit from each other as an input for IRA, the HEROIC project organized on January 21–22, 2014 in Paris, France, a dedicated workshop gathering several experts from academia, regulatory authorities and industry involved in the risk or exposure assessment area. This paper reflects experts' views on current gaps and needs as well as new opportunities and recommendations for extrapolating across human and environmental exposure data, models and methods, to support the further development and promotion of the concept of IRA. Four topics were covered in specific breakout group sessions: i) exposure scenario building, exposure waiving; ii) exposure scenario, temporal and spatial scales; iii) metrics; and iv) toxicokinetics for biota and humans.

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