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A Multi-Criteria Decision Analysis based methodology for quantitatively scoring the reliability and relevance of ecotoxicological data

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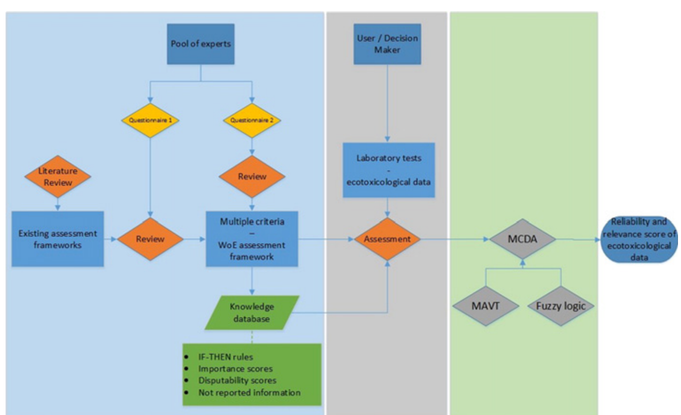
HIGHLIGHTS

- Quantitative scoring of the reliability and relevance of ecotoxicological data
- MCDA based methodology, which handles uncertainty and uses fuzzy logic.
- Innovative Weight of Evidence (WoE) assessment framework
- Assessment framework based on three solid Lines of Evidence (LoEs)

GRAPHICAL ABSTRACT



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ABSTRACT

Ecotoxicological data are highly important for risk assessment processes and are used for deriving environmental quality criteria, which are enacted for assuring the good quality of waters, soils or sediments and achieving desirable environmental quality objectives. Therefore, it is of significant importance the evaluation of the reliability of available data for analysing their possible use in the aforementioned processes. The thorough analysis of currently available frameworks for the assessment of ecotoxicological data has led to the identification of significant flaws but at the same time various opportunities for improvement. In this context, a new methodology, based on Multi-Criteria Decision Analysis (MCDA) techniques, has been developed with the aim of analysing the reliability and relevance of ecotoxicological data (which are produced through laboratory biotests for individual effects), in a transparent quantitative way, through the use of expert knowledge, multiple criteria and fuzzy logic. The proposed methodology can be used for the production of weighted Species Sensitivity Weighted Distributions (SSWD), as a component of the ecological risk assessment of chemicals in aquatic systems. The MCDA aggregation methodology is described in detail and demonstrated through examples in the article and the hierarchically structured framework that is used for the evaluation and classification of ecotoxicological data is

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shortly discussed. The methodology is demonstrated for the aquatic compartment but it can be easily tailored to other environmental compartments (soil, air, sediments).

1. Introduction

Ecological risk assessment (ERA) is defined as the estimation of both the magnitude and the probability of environmental harm caused by human activities (Barnthouse and Suter, 1986). Ecological risk assessment usually focuses in the estimation of negative effects on specific ecosystems (Breitholtz et al., 2006) and according to the European Commission (2003) it is completed in four steps: hazard identification, dose–response assessment (effect assessment), exposure assessment, and risk characterisation. Many international organisations have developed frameworks for ERA, such as the US Environmental Protection Agency (US EPA, 1998), the World Health Organisation (WHO, 2001), the European Commission (EC, 2003) and others (OECD — Organisation for Economic Co-operation and Development, EPPO — European and Mediterranean Plant Protection Organisation, ECETOC — European Centre for Ecotoxicology and Toxicology of Chemicals). These frameworks have been evaluated, advanced and adapted in order to meet the needs of the assessors in various countries (e.g. European Union, United States, Japan, Canada, South Africa, Australia and New Zealand), as identified by Suter (2006) and Bradbury et al. (2004).

ERA can be divided in two main tiers: Screening ERA and site-specific ERA (Critto and Suter, 2009). While screening risk assessment aims at identifying chemicals and agents that do not pose hazards at the ecosystem under analysis, and thus could be excluded from the assessment process, site-specific risk assessment aims at providing estimations of risks to support decision-making processes (Critto and Suter, 2009). The definition of Environmental Quality Criteria (EQC) is included in the context of screening ERA. EQ criteria (or standards) are threshold numerical values that indicate a level beyond which there is a significant risk that the associated environmental quality objective has not been achieved and for which the assessors should adopt actions for the preservation of the ecosystems, including the development of a site-specific risk assessment (EPA, 2005). The way environmental standards are derived, and the frameworks within which they are used, differ between countries and regions. The EQ criteria can be derived either through deterministic or probabilistic approaches, with the latter being preferred in the recent advances in the field as they allow to take into consideration uncertainty as well as the spatial and temporal variability of the data (Verdonck et al., 2002). In the recent years, various international frameworks and legislation have been developed to tackle important issues regarding the water related EQC, such as the establishment, the derivation methods and the implementation. These include the Water Framework Directive (EC, 2000), followed by the REACH regulation (EC, 2006), the Environmental Quality Standards Directive (EC, 2008) of the European Commission and the related Technical Guidance Document (TGD-EQS) for Deriving Environmental Quality Standards (EC, 2011), the standards of the European Chemicals Agency (ECHA, 2008b), the Water Quality Standards Regulation of the US Environmental Protection Agency (US EPA, 1983) and the related Water Quality Standards Handbook (US EPA, 1994). The advances in the field of risk assessment have urged scientists to develop methodologies that are strongly connected with the decision-making processes and specifically develop high-quality assessment that address the needs of decision makers. Ecotoxicological data are used in the derivation of EQC and in the risk assessment processes, therefore it is of high interest the analysis of their reliability and relevance that will allow the derivation of more significant and relevant EQ criteria, as well as more reliable risk assessments.

Ecotoxicity data can be obtained through many different approaches and conditions, e.g., the protocol can be standardized or not; for non-standard tests, experimental design and/or analytical methods can vary among laboratories; time duration can vary among experiments, leading to chronic or acute data; different physiological endpoints can be observed, e.g. mortality, growth, reproduction and more; statistics used for interpreting data can differ, leading to e.g. NOEC or ECx and more. Each ecotoxicity datum must then be evaluated to rank its acceptability for being used in the further risk assessment process. This is possible through the incorporation of ecotoxicity data in the building of Species Sensitivity Weighted Distribution — SSWD (Duboudin et al., 2004), which can be used as a component of the ecological risk assessment of chemicals in aquatic systems. So far, such evaluations of individual data were often done on a case-by-case expert judgement. This results in a poor transparency, reproducibility and predictability of the risk assessment process because each expert may have his own implicit set of criteria and rankings for rejecting or not an ecotoxicity datum.

To improve ecotoxicity data evaluation, several structured frameworks based on lists of pre-defined criteria were proposed. A first attempt to classify ecotoxicological data, according to a systematic approach, and to harmonise data evaluation processes was proposed by Klimisch et al. (1997), who proposed four qualitative reliability categories (i.e. Reliable without restriction, Reliable with restriction, Not reliable and Not assignable). In order to help the assignment of a study to these categories of reliability, Klimisch et al. (1997) proposed to screen several elements, such as the description of the test procedure, the data on the measured parameters, test species, exposure period, the statistical evaluations and more. Warne et al. (1998) proposed a more detailed scheme for assessing the quality of aquatic ecotoxicological data. It is based on a series of questions and a score is given to the answer of each question; the scores of all questions are then summed in order to obtain a 'total score' for each datum, expressed as a percentage of the maximum possible score. The data are classified as being unacceptable, acceptable or high quality, depending on whether the quality score is $<50\%$, between 51 and 79% and $>80\%$ respectively. Hobbs et al. (2005) submitted Warne's scheme to a panel of experts and refined the set of questions in order to modify/clarify ambiguous or poorly written questions, to reduce assessor variation and thus improve the consensus level among experts. Similarly, Schneider et al. (2009) developed a tool (called ToxRTool) for assessing reliability of toxicological data (both in vitro and in vivo data and rather dedicated to human health risk assessment). The process followed by Schneider et al. (2009) is similar to those of Hobbs et al. (2005), i.e. based on a set of questions, refined after consultation of a panel of experts. One innovation of Schneider's framework is the introduction of 'red criteria': non-compliance with at least one red criterion leads to the 'Not reliable' category, irrespective of the total score achieved. Breton et al. (2009) developed a Quality Assurance system (called eco-QESST) specifically dedicated to three of the most common tests used in ecotoxicology, i.e. the *fish acute toxicity test* (OECD, 1992), the *Daphnia acute immobilization and reproduction toxicity test* (OECD, 2004) and the *algae growth and inhibition effects test* (OECD, 2002). The eco-QESST system is based on a set of questions, most of them being answered as either by 'Yes', 'No', 'Not applicable' or 'Not reported'. A scoring process is included in the eco-QESST system: a 'Yes' answer is given a specific weight, depending on the relative importance of the factor addressed by the question, while a 'No' or a 'Not reported' answer is given a zero weight. The overall study quality score (OSQS) is calculated as a percentage of maximum sum of weights. Finally, Ågerstrand et al. (2011) reviewed criteria for reporting and evaluating ecotoxicological tests dedicated to pharmaceuticals. A framework allowing a comparative assessment of standard and non-standard tests was then developed. A main innovation of Ågerstrand's framework was the explicit subdivision of the analysis criteria in reliability and relevance criteria.