Integrated Environmental Assessment and Management — Volume 19, Number 4—pp. 913–919
Received: 10 March 2022 | Revised: 20 June 2022 | Accepted: 22 June 2022

Special Series

Ecological risk assessment for contaminated sites in Italy: Guidelines and path forward

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EDITOR'S NOTE:

This article is part of the special series, "Remtech Europe 2021: International Approaches to Contamination Management." The series documents and advances the current state of the practice, with respect to the sustainable management of contaminated sites, high resolution techniques for characterization, disrupting technologies for remediation of soil and groundwater, and risk assessment frameworks.

Abstract

Ecological risk assessment (ERA) is defined as an iterative process that evaluates the likelihood of adverse ecological effects resulting from exposure to one or more stressors. Although ERA is recognized as a valuable procedure to better address efforts and strategies for site remediation, in Europe a common framework for the implementation of ERA in the management of contaminated sites is lacking. In Italy, there are no legally binding provisions regulating the direct assessment of potential likelihood of ecological risks. In this context, the main objective of this article was to develop a guideline to facilitate ERA application in support of an effective and sustainable management of contaminated sites in Italy and to facilitate a multistakeholder dialogue. The work was based on a critical review of existing ERA guidelines in the international context, as well as other regulatory documents and technical approaches dealing with the evaluation of ecological effects of chemical contaminants in different environmental compartments. Approaches and tools available in these documents were then used to prepare a proposed guideline for the Italian context; the proposed ERA guideline is meant to represent a flexible but robust approach that can be useful in evaluating existing data (e.g., from past investigations) as well as in the planning of site-specific investigations. To facilitate the direct application of the ERA procedure, the guideline was prepared including several templates of summary tables, checklists, and examples. The proposed ERA guideline could facilitate the decision-making process for contaminated sites with ecological values, although its application would necessarily require, at least in the initial phase, testing of its suitability to the Italian context and setting-up of a close dialogue and collaboration with local authorities and other stakeholders. *Integr Environ Assess Manag* 2023;19: 913–919. © 2022 SETAC

KEYWORDS: Contaminated sites, Ecological risk assessment, Ecological risk assessment guidelines

INTRODUCTION

Ecological risk assessment (ERA) is defined as an iterative process that evaluates the likelihood that adverse ecological effects are occurring or may occur as a result of exposure to one or more stressors (US Environmental Protection Agency [USEPA], 1992). The ERA framework aims to provide a structured approach to assessing risks to ecosystems from chemical contamination and, in several countries, it is used as a site management tool at contaminated sites (Environment Agency UK, 2008a; Federal Contaminated Sites Action Plan [FCSAP], 2012; USEPA, 1998, 2018). Specifically, ERA provides a basis for determining whether remediation or other risk management measures are warranted (i.e., are there unacceptable ecological risks?) and to what extent (e.g., which parts of a site should be remediated?) (FCSAP, 2012). Although ERA is recognized as a valuable procedure to better address and optimize efforts for site remediation and to inform long-term management strategies, in Europe a common

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Published 6 November 2022 on wileyonlinelibrary.com/journal/ieam.

framework for the implementation of ERA (and, in general, of risk-based management procedures) in the management of contaminated sites is lacking. In Italy, there are no legally binding provisions regulating the direct assessment of potential likelihood of ecological risks posed by contaminated sites to ecological receptors, and the few examples of ERA applications in this context were driven by proactive actions of local authorities and stakeholders (Guzzella et al., 2016; Marziali et al., 2015) or triggered by environmental research initiatives (Semenzin et al., 2009). In this context, the main objective of this article was to develop a guideline to facilitate ERA application in support of effective and sustainable management of contaminated sites in Italy and to encourage multistakeholder dialogue. The ERA process, indeed, allows the structured incorporation of additional elements in the decision-making process, such as consideration of ecological values to be protected and their relationship with contamination and human activity. Further, it ensures that a broader range of considerations and interests are tackled in the discussion among involved actors about site remediation and reuse.

The task of ERA guideline development was based on a critical review of existing ERA guidelines in the international context, as well as other regulatory documents and technical approaches dealing with the evaluation of ecological effects of chemical contaminants in different environmental compartments.

METHODOLOGY

A critical review of existing ERA guidelines was performed to identify and evaluate available frameworks and common approaches and tools. The analysis focused mainly on best practices specifically defined for the assessment and management of contaminated sites (e.g., Environment Agency UK, 2008b; FCSAP, 2012; USEPA, 1992, 1997, 1998, 2018). However, considering the need to address the effects of contamination reaching different environmental compartments, especially for extended and complex megasites, the review also included technical documents released in Europe (European Commission [EC], 2018) and in Italy related to the implementation of the Water Framework Directive (WFD; European Commission [EC], 2000) and daughter directives (European Commission [EC], 2008a; European Commission [EC], 2013) and of the Marine Strategy Framework Directive (MSFD; European Commission [EC], 2008b), because they can offer methodological approaches and quality standards possibly of great utility in the implementation of ERA for inland, transitional, or coastal water bodies.

The approaches and tools presented in these documents and evaluated as appropriate and effective for the context of interest were then used to prepare a proposal of a guideline for the ERA of contaminated sites suitable to the Italian context.

RESULTS AND DISCUSSION

ERA and the EU perspective

In Europe, there is no specific framework to guide the evaluation of historical or recent contamination resulting from industrial activities and to assess risks for ecological receptors, although the EU legislation defines several policies that directly or indirectly contribute to the protection of terrestrial and aquatic ecosystems (European Commission [EC], 2021). For example, regarding contaminated soil, the same EU Soil Strategy for 2030 recognizes the lack of strategic coordination to tackle soil-related concerns (including issues related to historical contamination) at the EU level. It highlights the need for significant progress on identifying contaminated sites, restoring degraded soils, and introducing restoration objectives.

Similarly, the evaluation of historical contamination affecting aquatic ecosystems is not specifically addressed in the European legislation: The remediation of contaminated sediment is typically conducted under national law, although the WFD and other general regulations offer some basic principles for the evaluation of aquatic ecosystems (European Chemical Agency [ECHA], 2014). The WFD and daughter directives set the criteria to achieve the "good surface water status" (defined based on ecological and chemical status), including Environmental Quality Standards (EQS) for a series of contaminants in water and biota; regarding sediment, there are no EU-wide EQS values, and sediment EQS are typically defined by member states at the national level to protect generic aquatic ecosystems (Tornero et al., 2019). However, the same WFD recognizes that sediment EQS are useful only for the first-tier assessment; if the measured concentrations exceed the sediment EQS, site-specific assessments of the benthic community should be conducted to assess the ecological status (ECHA, 2014; EC, 2018). Similarly, the MSFD aims to coordinate policies of EU Member States to improve the marine environmental status; however, there is currently no comprehensive and robust method of assessing the effectiveness of adopted measures and their contribution to reaching Good Environmental Status (Gorjanc et al., 2022), defined as the environmental status of marine waters where these provide ecologically diverse and dynamic oceans and seas, which are clean, healthy, and productive within their intrinsic conditions, and the use of the marine environment is at a level that is sustainable. Definitions and criteria set by the MSFD and WFD are broad in the overall scope because they are meant to ensure general protection of water ecology on a wide scale (e.g., river basins, marine regions and subregions); although informative for generic protection goals, these approaches provide little information for the evaluation of site-specific case studies. The lack of a common approach to site assessment and remediation has resulted in substantive differences between different member states, leading to national differences in the remediation sector (EC, 2021). With special regard to Italy, the legally binding procedure to assess contaminated sites

(Legislative Decree 152/2006, 2006) requires the evaluation of risks to human health posed by contaminants in soils and groundwater, whereas the consideration of ecological receptors potentially linked to relevant exposure pathways is not required. If the contamination affects surface water and sediments, the approach generally adopted in Italy required the comparison of measured concentrations with EQS (Ministerial Decree 260/2010, 2010; Legislative Decree 172/2015, 2015). Additionally, for sediment to be dredged, there are national regulations establishing criteria and thresholds for the classification of seabed sediments and the technical requirements for the management of dredged sediment and disposal in the marine environment (Decree 173/2016, 2016; Decree 172/2016, 2016). However, these approaches are not specifically meant to determine ecological risks on a site-specific basis to inform decision-making or to optimize site management strategies as they relate to ecological values. In this context, the use of screening standards (set by WFD or adopted from other legislations) is not sufficient to address and inform the decision-making process because they are based on the protection of generic aquatic environment and on conservative assumptions (EC, 2018; Wenning & Ingersoll, 2005). Additionally, the use of sediment quality standards in risk assessment is challenging because the bioavailability and toxicity of contaminants can be strongly influenced by a variety of site-specific parameters and conditions. The lack of a regulated and officially recognized approach in Italy to the application of ERA in contaminated sites has led, in some cases, to the elaboration of assessments that have proved to be biased or unsatisfactory with respect to the remediation objective and reuse of sites.

In this sense, the ERA guideline presented in this paper, and resulting from a proactive collaboration between academic and industrial partners, aimed at identifying useful approaches and tools for the definition of environmental assessment strategies for contaminated sites with ecological value.

Determining environmental risk affects management decisions and cleanup costs and can cause unintended consequences following well-intentioned, but inappropriate or unnecessary, actions. If ecological attributes are to be used to characterize a contaminated site, it is strongly suggested that tools that are sensitive and representative of these attributes are used to inform environmental management decisions. This will facilitate a clear comprehension of the site contamination without overestimating risks and impacts. In this context, we used existing approaches to develop an ERA guideline to inform decision-making for contaminated sites in Italy.

Developing ERA guideline for Italy

The scope of the work was to provide a method to assess risks to ecological receptors; this evaluation, which is intended to supplement but not replace the human health risk assessment, can provide useful information to guide environmental management strategies of contaminated sites presenting an ecological value (or linked to area[s] deemed to have important ecological values). The proposed ERA guideline is meant to represent a flexible but robust approach that can be useful for the evaluation of existing data (e.g., organizing and evaluating environmental data from past investigations) but also to guide the planning of site-specific investigation. In this context, the proposed ERA guideline relies on the joint evaluation of structured lines of evidence (LoE) through appropriate weight of evidence (WoE) methods rather than on the application of individual mathematical indexes and algorithms, to allow for a comprehensive and transparent evaluation of all available data and information from distinct "domains" (e.g., chemistry, ecology, ecotoxicology).

Specifically, the proposed guideline details the ERA procedure, including tools and approaches to each assessment step, and it is composed of a main text and four annexes focusing on different aspects of the ERA (Figures 1 and 2).

The first step of the ERA—the problem formulation—is essential to address and develop the scope of the ERA and should clearly detail the tools to be used and specify how the results will be evaluated. Early in this phase, it is important to establish a dialogue between risk assessors and involved stakeholders (e.g., site owner and manager, environmental agencies and local authorities, site users) to define the protection goals and level of protection to be considered in the ERA. As with any risk assessment, the selection of protection goals (and related level of protection) is a management matter more than a scientific issue (ECHA, 2014). These aspects should be defined on a shared basis among the stakeholders, considering socioeconomic, human health, and ecological concerns, as well as the aesthetic value of the ecosystems and the future use of the area (Burger, 2019; Cundy et al., 2013). In the problem formulation, the risk assessors should also evaluate existing data and site-specific information to identify the contaminants of potential concern (CoPCs; defined as any contaminant that is shown to pose possible ecological risk to a site), the ecological receptors and the exposure pathways to be evaluated, and to define the conceptual site model. Additionally, the problem formulation should indicate the LoE that will be evaluated for the ERA, defined as any pairing of exposure and effect measures that provides evidence for the evaluation of a specific assessment endpoint (FCSAP, 2012). To guide the assessor in the direct application of the ERA procedure, Annex 1 of our guideline includes several templates of summary tables, checklists, and examples, to be used in the problem formulation but also in the subsequent steps: analysis of exposure and effect data and the risk characterization (Figure 2).

In the analysis phase, available environmental data are evaluated and structured to characterize exposure and effects. The exposure assessment is aimed at characterizing the mechanisms by which receptors are exposed to CoPCs. Typically, this evaluation considers chemical concentrations in environmental matrices, such as water, sediment, soil, but also, for bioaccumulative compounds, biotic matrices (e.g.,

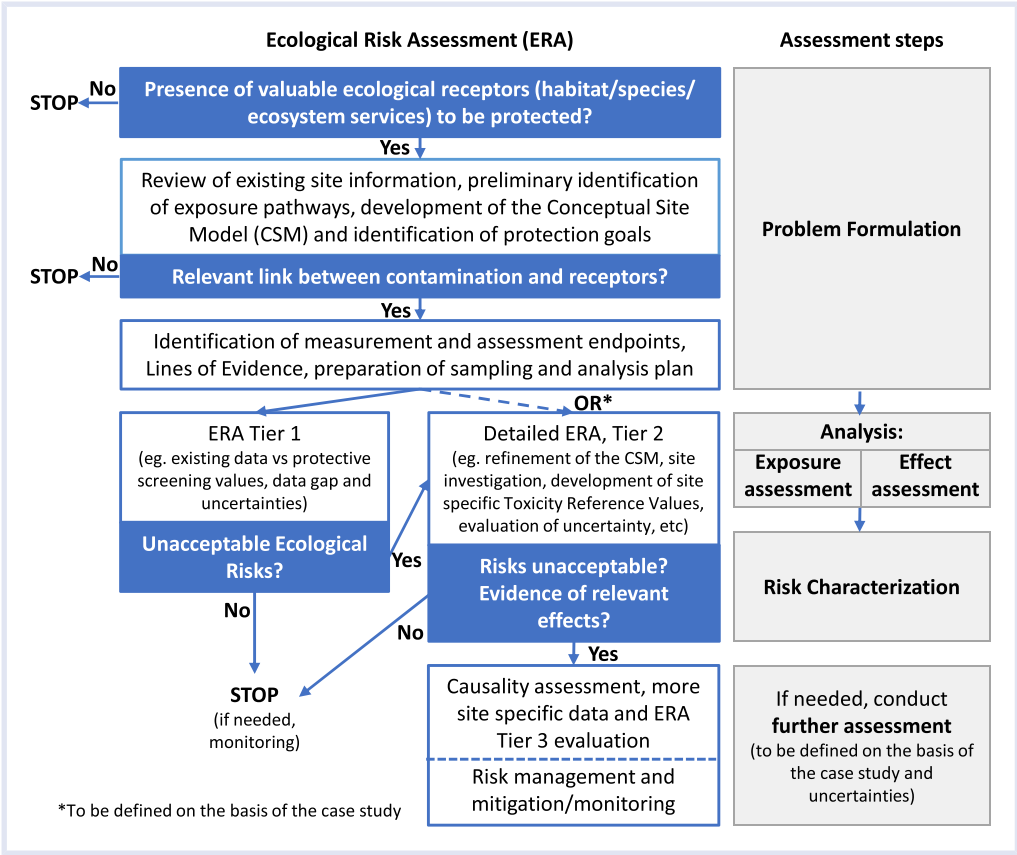

FIGURE 1 Overview of the proposed ecological risk assessment (ERA) procedure. The ERA guideline relies on a tiered approach, with levels (tiers) of increasing complexity; in this sense, the level of details (Tier 1, screening phase, vs. Tier 2, detailed ERA) can be defined considering the site characteristics, available data, and the ERA's overall scope. The screening phase may be avoided if enough information indicates the need of a more detailed ERA

biological tissue) and, for wildlife, estimates of the total ingested dose. To ensure that a critical review of available site-specific data is performed and to identify sources of uncertainty, the proposed ERA guideline summarizes methods and tools typically used for the exposure assessment and describes advantages and limitations of the most common metrics measured during the characterization of contaminated sites.

The effect assessment is meant to characterize the nature of effects caused by each contaminant under exposure conditions relevant to the agreed protection goals and related ecological receptors. This evaluation is typically conducted considering scientific literature and site-specific data, such as toxicity tests performed on field-collected samples and results of site-specific ecological surveys meant to evaluate whether environmental quality has been affected by CoPCs. Typically, ERAs are conducted adopting a tiered approach, with levels (tiers) of increasing complexity depending on the complexity of the project and the level of certainty needed for risk management decisions (Allard

ERA Steps	Main text, ref. chapter	Annex			
		1. Checklist and templates	*2. Screening values and Toxicity Reference Values (TRV)*	*3. Toxicity testing*	*4. Causal link*
Problem Formulation	2-3	√	√		
Exposure assessment	4	√			
Effect assessment	5	√	√	√	
Risk characterization	6	√			√

FIGURE 2 Structure of the proposed ecological risk assessment (ERA) guideline

et al., 2010); in this sense, we summarized the main methods generally used for effect assessment in the screening phase or in a more detailed ERA.

The effect assessment requires the evaluation of concentration–response (or dose–response) relationships, to estimate effect levels for CoPCs measured in the environmental matrices of the contaminated site; evaluation of exposure–response relationship facilitates the interpretation of the potential effects (and probabilities) associated with certain CoPC concentrations. The effect assessment, essential to risk characterization, is often performed at the screening level considering environmental quality criteria and existing benchmarks (hereafter generally referred to as toxicity reference values [TRV]); however, the use of generic values is recommended only for a screening evaluation and presents several limitations (Allard et al., 2010), whereas a more realistic and detailed effect assessment should be defined, if feasible, based on site-specific evidence (toxicity testing and ecological survey, if properly conducted) or adapting dose–response relationships documented in the literature to the site-specific context. In this context, Annex 2 summarizes methods and approaches to conduct site-specific effect assessment based on studies from scientific literature or considering site-specific studies. Additionally, Annex 2 includes a list of screening values and existing benchmarks considered protective toward ecological receptors, selected from international literature and regulations. Emphasizing toxicity testing, Annex 3 of the ERA guideline details criteria and proposes a structured procedure for the selection of the bioassays to be used in the site-specific ERA, considering protocols and organisms most commonly used in Italy for toxicity testing (Figure 3).

The last step of the ERA is the risk characterization, when information obtained from exposure and effects assessments (organized as LoE) are evaluated jointly to estimate probability, magnitude, and extent of adverse ecological impacts, as well as to perform uncertainty assessment. These results should be shared and discussed among involved stakeholders, so that the decision-making process for the contaminated site can be fully informed, science-based, and more likely successful. The ERA also represents a communicative tool; thus, a participatory approach and an active stakeholder engagement represent added values for the ERA, because a multistakeholder dialogue would promote the transparency, objectivity, and communication of the risk assessment (Munns et al., 2019). From a technical point of view, for risk characterization, the existing guidelines (FCSAP, 2012; Organisation for Economic Co-operation and Development [OECD], 2019; USEPA, 2016) recommend a WoE approach, considering for each LoE magnitude, ecological relevance, reliability, and causality of the observed effects. In this context, the guideline reports several examples of frameworks and templates, to be adapted to the case study and available data. Finally, to better support the risk characterization and the subsequent risk management actions, Annex 4 of the proposed ERA guideline focuses on the evaluation of the causal link in ERA (Cormier et al., 2010; Environment Agency UK, 2008a,b;

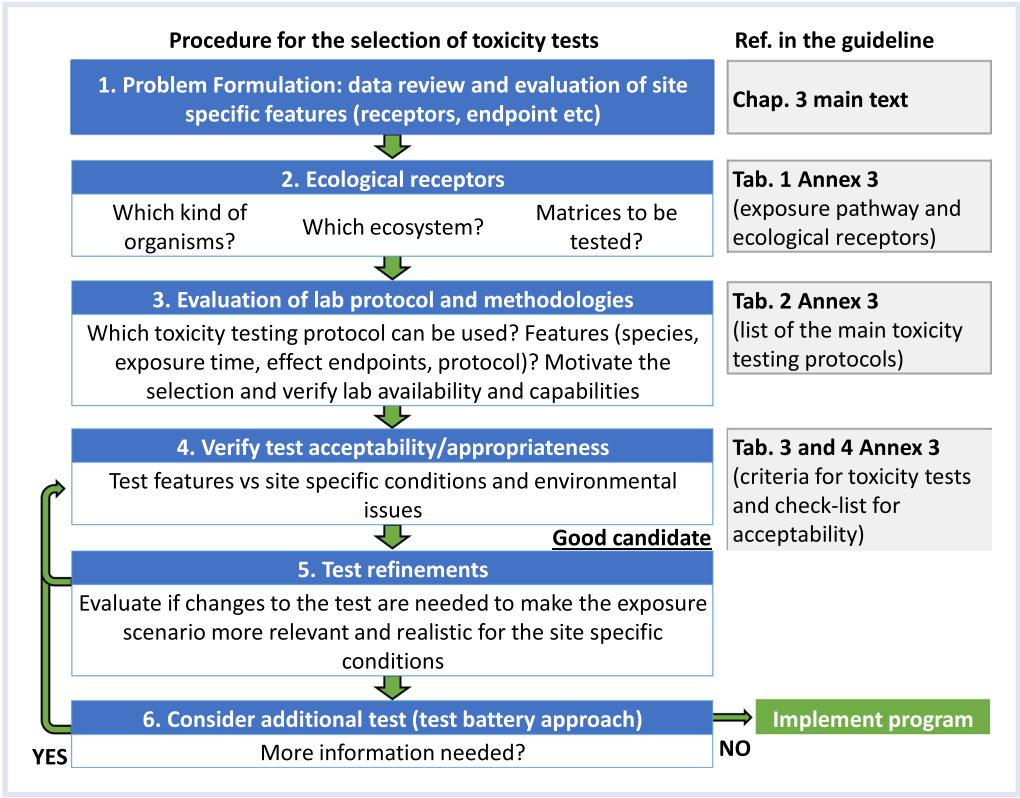

FIGURE 3 Procedure for the selection of toxicity test

 DOI: 10.1002/ieam.4654

FCSAP, 2013; USEPA, 1997). This evaluation is relevant because, if causality of the observed effects is not clearly determined, actions aimed at reducing ecological risks (such as remedial activities) may prove ineffective, resulting in a waste of used resources. In this sense, if available data suggest the need for a causality assessment (e.g., in case of observed severe biological impairment), the ERA evaluation would benefit from additional insights and specific consideration aimed at investigating other physical, chemical, and biological stressors that may act in concert with contaminants.

CONCLUSIONS

We believe that the application of the guideline presented in this paper could suitably guide the management of contaminated sites that present an ecological value, allowing a balance between environmental protection and remediation strategy and facilitating a multistakeholder dialogue. For this reason, we propose it as a supporting means to facilitate the consideration of ERA in the management of contaminated sites in Italy. In this context, the ERA guideline was prepared including several templates of summary tables, checklists, and examples, to guide the assessors in the direct application of the ERA procedure and to facilitate critical review of available site-specific data and identify sources of uncertainty.

The ERA outcomes can largely inform risk managers, providing a basis for actions aimed at limiting exposure to the ecological stressor and at reducing adverse effects for ecological receptors; additionally, the ERA procedure can also provide a transparent process for communication with interested parties and stakeholders and can serve as a basis to negotiate remediation options and to develop monitoring plans to confirm risk reduction and ecosystem recovery.

The proposed ERA guideline could facilitate the decision-making process for contaminated sites with ecological values, although its application would necessarily require, at least in the initial phase, testing of its suitability to the Italian context and setting-up of a close dialogue and collaboration with local authorities and other stakeholders.

We believed that sharing this guideline with the main stakeholders of the remediation sector, especially Environmental National Authorities, could represent a significative step in starting a debate to regulate the ERA as a legislative requirement in the environmental procedures.

ACKNOWLEDGMENT

The work was done entirely by the listed authors, with no assistance of other individuals or organizations. The work was funded by Eni Rewind through an agreement with Fondazione Università Ca' Foscari (FCF).

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

All data and information analyzed during this study are included and/or referenced in the article.

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