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Environmental risk assessment of chemicals and nanomaterials — The best foundation for regulatory decision-making?

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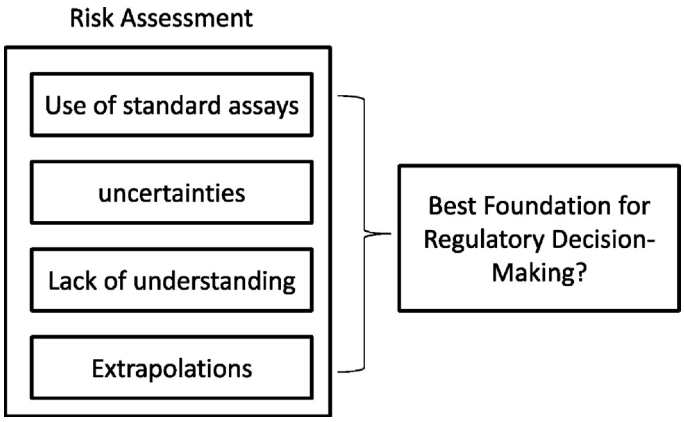
HIGHLIGHTS

- Environmental risk assessments are preferred for informing chemical risk management.
- The analysis show that ERAs are not as scientifically well-founded as often perceived.
- ERAs are a pragmatic decision-making tool and should be applied as such.

GRAPHICAL ABSTRACT



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ABSTRACT

Environmental risk assessment (ERA) is often considered as the most transparent, objective and reliable decision-making tool for informing the risk management of chemicals and nanomaterials. ERAs are based on the assumption that it is possible to provide accurate estimates of hazard and exposure and, subsequently, to quantify risk. In this paper we argue that since the quantification of risk is dominated by uncertainties, ERAs do not provide a transparent or an objective foundation for decision-making and they should therefore not be considered as a "holy grail" for informing risk management. We build this thesis on the analysis of two case studies (of nonylphenol and nanomaterials) as well as a historical analysis in which we address the scientific foundation for ERAs. The analyses show that ERAs do not properly address all aspects of actual risk, such as the mixture effect and the environmentally realistic risk from nanomaterials. Uncertainties have been recognised for decades, and assessment factors are used to compensate for the lack of realism in ERAs. The assessment factors' values were pragmatically determined, thus lowering the scientific accuracy of the ERAs. Furthermore, the default choice of standard assay for assessing a hazard might not always be the most biologically relevant, so we therefore argue that an ERA should be viewed as a pragmatic decision-making tool among several, and it should not have a special status for informing risk management. In relation to other relevant decision-making tools we discuss the use of chemical alternative assessments (CAAs) and the precautionary principle.

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1. Introduction

An environmental risk assessment (ERA) is often championed as the preferred decision-making framework for regulators looking to ensure that the regulation and risk management of chemicals and nanomaterials are enforced in the most transparent, objective and reliable way for society (van Leeuwen and Vermeire, 1995). An ERA, in many aspects, is regarded as the "holy grail" for addressing risk, one of the major reasons for which is that it is considered the best approach to ensure scientific and evidence-based regulation (Löfsted, 2011). In a world where risk perception is believed to be a strong driver of risk management (Slovic, 1999), some argue that it is increasingly more important that policymaking is driven by evidence rather than political dogma (Holmes and Clark, 2008). ERAs are considered to be a cornerstone in regard to ensuring such evidence-based foundations for regulation, and they now provide the backbone of many pieces of European legislation, such as the water framework directive, biocidal product legislation and chemical legislation known as REACH (EC, 2000, 2006, 2012).

The fundamental hypothesis on which the ERA paradigm is based is that risk is a function of hazard and exposure. When an ERA is conducted, the hazard and concentration–response assessments, based on the principle that toxicity is concentration-dependent, form the foundation for determining a toxicity threshold. This assessed potency is thereupon used to assess risk by comparing the derived threshold for toxicity with exposure concentrations (EC, 2003). This implies that accurate measurements of the hazard and concentration response relationship can be provided, where uncertainties ideally should be negligible or at least well-quantifiable. These experimentally derived assessments thus form the very foundation of ERAs and thereby the "evidence-based" foundations with which they are supposed to provide decision-makers. The four steps of risk assessment (i.e. hazard identification, dose–response assessment, exposure assessment and risk characterisation) were originally proposed by the US National Research Council of the National Academy of Sciences (NRC-NAS) in their landmark 1983 publication "The Red Book" (NRC, 1983). During the 1990s, the US EPA adapted the RA framework to ecological risk assessment for assessing risk where human health is not the primary focus. For instance, in 1992, the US EPA published the report *Framework for Ecological Risk Assessment*, which proposed principles and terminology for this process (US EPA, 1992), which was summarily adopted in the EU via the Technical Guidance Documents (TGDs), although no references are provided within these guidelines (EC, 1993a). While its intentions have always been good, the ERA framework has increasingly come under critical scrutiny and has been criticised for not being able to provide the input that risk managers need, and so modifications are currently being discussed in the EU (Scientific Committees, 2013).

One of the key limitations of the ERA seems to be that risks can only first be truly assessed after an adverse impact has been firmly established scientifically, which is unfortunate when it comes to protecting the environment (EEA, 2001, 2013). Article 191 of the Lisbon Treaty states that the protection of the environment 'shall be based on the precautionary principle and on the principles that preventive action should be taken' (EU, 2007). An important question is therefore whether an ERA can provide sufficient knowledge for decision-makers to, on the one hand, ensure "evidence-based" regulation and on the other hand provide them with enough decision-making support in time to take precautionary preventive actions. In this paper, we argue that the answer to this question is "no." In order to explain our conclusion, we first analyse how the first two steps of the ERA framework, namely hazard identification and dose–response assessment, are used to inform decision-making in two specific cases. We do this in order to illustrate some of the challenges that ERAs face when it comes to assessing the hazardous nature of chemicals and nanomaterials. The first case considers one of the most comprehensive environmental risk assessments ever performed in the EU, namely in respect to nonylphenol, while the second case examines engineered nanomaterials (ENMs).

Based on the nature of the identified challenges, we would argue that they cannot be addressed solely by revising ERAs in the future; rather, they are a reflection of the fundamental limitations of the ERA framework. Via a historical analysis of the development of ERAs, we discuss how these limitations, related to hazard identification and dose–response assessment identified in the two cases, have been well-recognised over time but unfortunately never really addressed. Finally, we discuss how alternatives such as the precautionary principle and alternative assessment may help to ensure a more timely and transparent foundation for policymaking. First, however, we provide a short introduction to the principles of environmental risk assessment in the EU.

2. Environmental risk assessment in Europe

2.1. Laying down the principles of risk assessment in the EU

Directive 93/67/EEC describes how a risk assessment entails hazard identification, dose (concentration)–response (effect) assessment, exposure assessment for environmental compartments (i.e. aquatic environment, terrestrial environment and air) and risk characterisation (EC, 1993b). The objective of the dose (concentration)–response (effect) assessment is to 'predict the concentration of the substance below which adverse effects in the environmental compartment of concern are not expected to occur'. This concentration is known as the "predicted no-effect concentration" (PNEC) and has to be determined on the basis of information in the notification dossier, e.g. a 21-day study on daphnia magna, testing of higher plant orders and earthworms. A PNEC has to be derived by applying an assessment factor to the values resulting from tests on organisms, e.g. LC_{50} (median lethal concentration), EC_{50} (median effective concentration) and NOEL(C) (no-observed-effect level (concentration)) (Table 1). These assessment factors (AFs) are seen as '[…] an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment', and an AF of the order of 1000 is typically applied to an L(E)C50 value derived from the results of testing for acute toxicity, though it may be reduced in the light of other relevant information. A lower AF is typically applied to a NOEC derived from the results of testing for chronic toxicity, and the AF can be lowered further in cases where more comprehensive data, such as species sensitivity distributions, are available.

The final step in the risk assessment methodology entails comparing the predicted exposure concentration (PEC) with the PNEC for any given compartment, so that a PEC/PNEC ratio may be derived. If the PEC/PNEC ratio is ≤ 1, it implies that there is no immediate concern according to the available information. If the ratio is ≥ 1, the competent

Table 1
Assessment factors for deriving a $PNEC_{aquatic}$[a], recommended in Table 16 of the 2003 Technical Guidance document (EC, 2003).

Available data	Assessment factor
At least one short-term $L(E)C_{50}$[b] from each of the three trophic levels of the base set (fish, daphnia and algae)	1000
One long-term NOEC[c] (either fish or daphnia)	100
Two long-term NOECs from species representing two trophic levels (fish and/or daphnia and/or algae)	50
Long-term NOECs from at least three species (normally fish, daphnia and algae) representing three trophic levels	10
Species sensitivity distribution (SSD) method	5–1 (To be fully justified case by case)
Field data or model ecosystem	Reviewed on a case by case basis

[a] $PNEC_{aquatic}$: predicted no effect concentration for the aquatic environment.
[b] $L(E)C_{50}$: lethal(effect) concentration for 50% of the test specimens.
[c] NOEC: no observed effect concentration.