

## PERSPECTIVE ARTICLE

# Risk Assessment of Activities Involving Nanomaterials: Quantitative or Qualitative-That Is the Problem

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## ABSTRACT

Health risk assessment of activities involving nanomaterials is a basic and necessary step toward reducing exposure to nanomaterials and, consequently, minimizing the effects resulting from such exposure. Health risk assessment methodologies in the presence of chemical substances, including nanomaterials, can be divided into three major groups: quantitative, semi-quantitative, and qualitative methods. The quantitative assessment of risks associated with activities involving nanomaterials faces a series of inherent limitations, which have led to its limited acceptance. The absence of well-established and universally agreed-upon occupational exposure limits, and the uncertainties surrounding the effects of nanomaterials on humans, are some of these limitations. Qualitative approaches, based on precautionary principles and expert judgment, offer flexible, context-sensitive evaluation, whereas semi-quantitative approaches have a more ordered framework that nonetheless allows for adaptability in the balancing of numerical analysis with qualitative insight. Yet, parallel efforts toward the development and refinement of quantitative methods must not be forsaken, as such methods are considered indispensable for the future to realize more accurate and reliable risk assessments. This will give a more holistic and realistic assessment of nanomaterial risks due to this dual approach.

**KEYWORDS:** *Nanoparticles, Risk assessment, Nanotechnology, Health and safety*

## INTRODUCTION

In the last decades, nanotechnology developments have promised an enormous number of new nanomaterials with unparalleled properties. The advances made in technology have also made it possible to apply nanomaterials in almost all fields of science and industry, starting from structural engineering up to electronics and optics, consumer products, energy production and storage, soil and water conservation, and even medical therapy and diagnostics [1].

On the other hand, the advent of nanotechnology and nanoparticles resulting from industrial or laboratory production is exposing workers, consumers, and the environment to a new generation of risks because of the particulate matter in the air [2]. Concerns about nanomaterials increased when in vitro and in vivo studies showed that nanomaterials also possess novel biological properties. These include translocation to secondary target organs, poor clearance by macrophages, the ability to travel through the axons of sensory neurons, and the ability to reach intracellular structures such as mitochondria and the nucleus, among other features [3].

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It is expected that more than eight million workers will be exposed to nanomaterials at their workplace all over the world by 2029. A number of reports have identified that nanomaterials are harmful to human beings, the environment, and other organisms. Many occupational studies have also identified that nanomaterials exert an adverse effect on exposed workers as compared to unexposed ones [4]. Therefore, health risk assessment of activities involving nanomaterials is a basic and necessary step toward reducing exposure to nanomaterials and, consequently, minimizing the effects resulting from such exposure.

#### *Different Approaches in Health Risk Assessment*

Health risk assessment methodologies in the presence of chemical substances, including nanomaterials, can be divided into two major groups: quantitative and qualitative methods. It is noteworthy that there also exist some intermediate approaches, called semi-quantitative methods [5].

#### *Quantitative Approach*

This approach uses numerical data and mathematical models to estimate the probability and magnitude of health risks. It involves precise measurements of exposure, dose-response relationships, and risk characterization. It relies on measurable data, such as the concentration of a chemical, duration of exposure, and toxicity values. It uses statistical and probabilistic models to predict risks and provides a clear, numerical estimate of the risk—for example, a 1 in 10,000 chance of developing cancer [6].

Some of the advantages of a quantitative approach are that it has high precision and objectivity, enables the comparison of risks among different risk scenarios, and is useful for regulatory decisions and exposure limit setting. On the other hand, its limitations include the need for extensive and high-quality data, its complexity and time-consuming nature, and the presence of data and model uncertainties that may lead to inaccuracies [7].

#### *Qualitative Approach*

The qualitative risk assessment approach is based on descriptive analysis and the judgment of experts. It does not apply numerical data but categorizes risks based on their nature, severity, and likelihood. It makes use of descriptive terms such as *low*, *moderate*, and *high*, or narrative descriptions, and is heavily dependent on expert opinion and experience. It focuses on the identification and characterization of risks, not their quantification [8].

The advantages of the qualitative approach are its simplicity and quickness in implementation; it is useful when data is scarce or uncertain. In addition, it may be effective in the initial screening and prioritization of risks. The limitations of the qualitative approach include a lack of precision and objectivity, difficulty in comparing risks quantitatively, and potential inadequacy in satisfying regulatory requirements when detailed risk assessment is necessary [9].

#### *Semi-Quantitative Approach*

The semi-quantitative approach embodies both qualitative and quantitative elements. Numerical scales or scoring systems rank or categorize risks without providing precise numerical estimates. Such scoring systems are often in the form of low-medium-high risk matrices. The approach incorporates both measurable data and expert judgment, balancing simplicity with precision [10].

Its advantages are that it offers more flexibility compared to purely quantitative methods, ease of implementation with limited data, and a structured way to prioritize risks. Its limitations are that it is less precise than a fully quantitative approach, scoring may involve subjective judgment thus introducing bias and it might not be the best fit in highly complex risk scenarios [11].

Table 1 summarizes and compares these approaches.

#### *Quantitative Chemical Risk Assessment: Under Criticism*

The critique of quantitative risk assessment (QRA) of chemical health hazards points out several challenges and limitations, the most important of which are complexities in the prediction of health effects arising from chemical exposure, variable data and methodologies, and difficulty in effectively integrating qualitative and quantitative assessments [12].

One of the important criticisms related to QRA is the complexity of predicting health outcomes from exposure to chemicals. The response of the human body to chemical exposure can be highly variable, depending on many factors such as the type of chemical, its concentration at the time of exposure, duration of exposure, individual health status, and others. This variability makes it challenging to establish specific threshold limits or accurately predict the health effects of chemical exposure [13]. Consequently, the question has been raised as to whether it is even possible to properly quantify these factors.

**Table 1.** Comparing Quantitative, Semi-Quantitative, and Qualitative Approaches

Approach	Quantitative	Semi-Quantitative	Qualitative
Definition	Uses numerical data and models for precise risk estimation.	Combines numerical scales with expert judgment.	Relies on descriptive analysis and expert opinion.
Data Requirements	High-quality, extensive numerical data.	Moderate data; can work with limited data.	Minimal data; relies on expert judgment.
Precision	High precision; provides numerical risk estimates.	Moderate precision; uses scoring systems.	Low precision; descriptive categorization.
Complexity	High complexity; requires advanced modeling.	Moderate complexity; simpler than quantitative.	Low complexity; easy to implement.
Time and Resources	Time-consuming and resource-intensive.	Less time-consuming than quantitative.	Quick and cost-effective.
Use Cases	Regulatory decision-making, setting exposure limits.	Risk prioritization, screening assessments.	Initial risk screening, qualitative analysis.
Strengths	Objective, precise, and comparable results.	Balances precision and simplicity.	Simple, quick, and flexible.
Limitations	Requires extensive data; complex and costly.	Subjectivity in scoring; less precise.	Lacks precision; difficult to compare risks.

These differences in data and methodologies within QRA make it difficult to obtain consistent and reliable results from risk evaluations. Variations in data related to the type of data, the diversity of analytical methods, and the assumptions considered during the assessment process contribute significantly to discrepancies in risk estimates. In particular, the issue of assumptions, as virtually no method exists without at least one, can strongly affect the outcome of a quantitative risk assessment and further distance the results from reality. Additionally, this diversity can complicate the comparison of results across different studies or hinder the integration of QRA results with qualitative assessments [14].

Furthermore, critiques suggest that further research in QRA should be undertaken to enhance its accuracy and reliability. This can be achieved by developing more sophisticated models to evaluate health consequences from chemical exposure, generating consistent and higher-quality data for QRA, and proposing innovative approaches for integrating quantitative and qualitative assessments. QRA should also be extended to encompass a broader range of chemicals and exposure scenarios, including those that are non-carcinogenic, non-mutagenic, and non-developmental toxicants. While non-CMR chemicals may be less harmful, they should not be excluded from risk assessments [15].

What has been discussed above represents several, though not all, criticisms directed at quantitative risk assessment (QRA) of chemicals in general. On the other hand, when addressing the QRA of specific chemicals, we may encounter additional challenges unique to

those substances. Indeed, such challenges arise in the quantitative risk assessment of nanomaterials. The quantitative assessment of risks associated with activities involving nanomaterials faces a series of inherent limitations, which have led to its limited acceptance. One of the most significant challenges in the context of nanomaterials is the absence of well-established and universally agreed-upon occupational exposure limits for these materials. This limitation has restricted—and in some cases rendered impossible the application of quantitative health risk assessment methods for nanomaterials (even though certain organizations and researchers have proposed such limits for some engineered nanomaterials) [16, 17].

The uncertainties surrounding the effects of nanomaterials on humans—particularly regarding long-term exposure, toxicological mechanisms, bio-nano interactions, exposure scenarios, and the behavior of nanomaterials in various media [18] along with the high costs and lack of access to necessary equipment for risk assessment, are among other limitations. Despite these challenges, some organizations have proposed methods for sampling and conducting quantitative research on engineered nanomaterials [19], though these have not been widely adopted.

Consequently, while QRA provides valuable insights into the risks associated with chemical exposures, it is not without limitations and challenges. Addressing these criticisms requires a multidisciplinary approach that integrates rigorous scientific research with practical considerations for workplace risk management.

### *Inclination toward semi-quantitative and qualitative methods*

The critique surrounding quantitative methods has led to increased attention toward semi-quantitative and qualitative methods for assessing the risks associated with nanomaterials. Qualitative methods, which embrace uncertainty and prioritize the avoidance of harm, apply the precautionary principle even in the presence of information gaps. These methodologies permit the use of expert views, while taking into account the values of interested parties and contextual information that may not be considered in quantitative approaches. Qualitative methods prioritize the identification of potential hazards and the implementation of preventive controls even in the absence of specific requirements for quantification [20].

Semi-quantitative methods attempt to combine the strengths of both approaches. They use numerical ranking and scoring systems to introduce added structure and transparency beyond purely qualitative assessments, while still relying on expert judgment to incorporate qualitative factors and address uncertainty. Semi-quantitative methods do not require the extensive data and computational demands of fully quantitative approaches, yet they are not solely dependent on qualitative information. As a result, they offer a feasible alternative in cases where data for a full quantitative analysis is lacking. These methods are less complex than fully quantitative models and are generally easier to apply and interpret [21].

That accessibility makes them valuable for non-specialists in quantitative modeling who aim to achieve a reasonable degree of accuracy. Semi-quantitative approaches are also adaptable—they can be customized for specific conditions and chemical substances under analysis. By integrating a range of techniques, they can yield a comprehensive risk evaluation. This shift in approach has contributed to the popularization of tools such as Monte Carlo simulations, Bayesian techniques, layered approaches, multi-criteria decision-making methods, decision tree analysis, and Control Banding (CB) in the risk assessment of activities involving nanomaterials [22].

### **CONCLUSION**

Considering the challenges and limitations of QRA methods, and taking into account the general risks associated with nanomaterials, it is more scientifically reasonable to apply qualitative and semi-quantitative approaches. Qualitative methods are particularly

suited to addressing the uncertainties and complexities involved with nanomaterials, such as the lack of established exposure limits, variability in toxicological data, and the unpredictability of long-term health effects. In particular, qualitative approaches based on precautionary principles and expert judgment offer flexible, context-sensitive evaluations. Semi-quantitative approaches, meanwhile, provide a more structured framework that still allows for adaptability in balancing numerical analysis with qualitative insight. Nevertheless, parallel efforts toward the development and refinement of quantitative methods should not be neglected, as such methods are considered indispensable for achieving more accurate and reliable risk assessments in the future. Adopting this dual approach can yield a more holistic and realistic evaluation of nanomaterial-related risks.

### **CONFLICT OF INTEREST**

The authors declare that they have no conflict of interest.

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