STUDY OF INCONSISTENCIES IN HEALTH RISK ASSESSMENT: THE ROLE OF ASSESSMENT CONTEXT IN DECISION ANALYSIS AIMED AT THEIR REDUCTION

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Doctoral Dissertation
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Doctoral Dissertation

ŠTUDIJA NEDOSLEDNOSTI PRI OCENJEVANJU ZDRAVSTVENIH TVEGANJ: VLOGA OCENJEVALNEGA KONTEKSTA ZA POTREBE ODLOČITVENE ANALIZE PRI NJIHOVEM ZMANJŠEVANJU

Doktorska disertacija

Supervisor: Dr. Branko Kontić

Ljubljana, Slovenia, May 2022

"The knowledge of anything, since all things have causes, is not acquired or complete unless it is known by its causes."
Ibn Sina

To my Emil Olav, Erik Aksel and Tamara.

Acknowledgments

I want to express my deepest gratitude to my mentor Branko for invaluable guidance, which helped me steer towards the completion of my doctorate. I will keep on asking *“Why?”*.

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Last but not least, I thank my Tamara, Emil Olav and Erik Aksel. Thank you for sharing this journey, my dreams and seeing my future in your eyes. Love you all to the moon and back...

Abstract

The area of risk assessment continues to be challenged by foundational issues that limit its potential to inform public health decisions. This doctoral work improves our understanding of the interaction between science and public and environmental health policy by addressing specific challenges in risk assessment within and for decision-making. The focus is on analyzing current health risk assessment practices and understanding health risk assessment (HRA) and health impact assessment (HIA) in a decision-making context to identify specific opportunities for clarifying and improving the value and impact of HRA on public health decisions.

The research followed two general approaches: policy to science (P2S) and science to policy (S2P). The P2S approach was based on the principle of auditing, which was adapted for the public health domain. In contrast, the S2P approach included decision analysis methods, case studies focusing on risk-informed decision-making processes, reviewing the use of human biomonitoring (HBM) data for HRA and related policy decisions, and a survey focusing on understanding HRA in the context of decision-making.

An audit of the selected Slovenian public health strategy on the health of children and adolescents regarding the environment highlighted the issue of inconsistent or indirect associations between available environmental quality information and assumed exposures contributing to specific health outcomes, which impedes the evaluation of public health policy's success. In addition, a review of HBM for HRA and within the environmental health paradigm supported the need for consolidating the understanding of the usefulness and limitations of HBM, which is crucial for targeted risk management interventions. From this analysis, several ways of improving the risk-informing potential of HRAs that use HBM data are suggested, including specific and related epidemiological evidence, stakeholder involvement, clarification of the assessment context, and transparent reporting of underlying assumptions and limitations.

A survey of the understanding of HRA revealed widespread inconsistencies in how the issues relating to the evaluation process and the core terms and principles of risk analysis are understood. It was found that opportunities for improving HRA's impact on decisions occur at the beginning of the HRA process, where the assessment and decision contexts should be clarified for all relevant and participating stakeholders. Such clarifications can be facilitated by using decision analysis tools or methods. The thesis also highlights the necessity of having a decision follow-up step at the end of the process for evaluating decision implementation and identifying the real success and benefits of HRA. As a decision follow-up step, this thesis shows how auditing can help evaluate the implementation, compliance, and adherence to selected public health policy and the accountability and honesty of those involved in policy development and implementation. It can also provide evidence of stakeholder satisfaction in terms of their effective participation and contribution to decisions, which can, in turn, add to the overall credibility of the assessment process, decision making and policy implementation.

Povzetek

Področje ocenjevanja tveganj se sooča s ponavljajočimi temeljnimi izzivi, ki omejujejo potencial ocen tveganja za informiranje javnozdravstvenih odločitev. Doktorat prispeva k izboljšanju interakcije znanosti in politike na področjih javnega zdravja in okolja, tako da obravnava različne izzive ocenjevanja tveganja v kontekstu odločanja. Delo se osredotoča na analizo trenutne prakse ocenjevanja zdravstvenih tveganj in na razumevanje ter uporabo rezultatov ocene zdravstvenih tveganj (HRA) in ocene zdravstvenih vplivov (HIA) pri javnozdravstvenih odločitvah.

Raziskovanje je sledilo dvema splošnima pristopoma: od politik do znanosti in od znanosti do politike. Pristop od politik do znanosti je temeljil na načelih pregledovanja, presojanja in revidiranja (angleško *auditing*), prilagojenih za področje javnega zdravja. Pristop od znanosti do politike je vključeval metode odločitvene analize, študije primerov, ki se osredotočajo na različne postopke odločanja na podlagi informacij o tveganju, pregled uporabe rezultatov človeškega biomonitoringa (HBM) za HRA ter raziskavo, ki se osredotoča na razumevanje HRA v kontekstu odločanja in sprejemanja odločitev.

Pregled javnozdravstvene politike Strategije Republike Slovenije za zdravje otrok in mladostnikov v povezavi z okoljem 2012–2020 je izpostavil problematiko nedoslednih in/ali posrednih povezav med razpoložljivimi podatki o kakovosti okolja in domnevnimi izpostavljenostmi, ki naj bi prispevale k specifičnim zdravstvenim posledicam, kar slabi, ovira in celo onemogoča pregledno in učinkovito ocenjevanje uspeha izbrane javnozdravstvene politike. Pregled HBM za HRA v okviru paradigme zdravja in okolja je podprl potrebo po utrditvi razumevanja uporabnosti in omejitev HBM za ta namen. Predlagani načini izboljšanja HRA, ki uporabljajo HBM podatke, vključujejo uporabo specifičnih in povezanih epidemioloških dokazov, vključevanja deležnikov, razjasnitev konteksta ocenjevanja in pregledno poročanje o osnovnih predpostavkah in omejitvah.

Raziskava o razumevanju HRA je pokazala veliko razpršenost nedoslednosti pri razumevanju procesa ocenjevanja ter temeljev na področju analize tveganja. Nejasnosti in nerazumevanje so bili potrjeni tudi pri povezavah med HRA in odločanjem. Doktorat je pokazal na možnosti za utrditev razumevanja HRA ter povečano preglednost vpliva HRA na odločitve. Slednje so na začetku HRA procesa, kjer je potrebna razjasnitev konteksta odločitve in ocenjevanja med vsemi pomembnimi in sodelujočimi deležniki. V pomoč takšnim razjasnitvam so lahko orodja in metode odločitvene analize. Na koncu procesa ocenjevanja je ključen korak, ki je namenjen nadaljnjemu spremljanju in vrednotenju izvajanja odločitev ter ugotavljanju dejanskega uspeha odločitve ter koristi HRA. To je lahko narejeno kot organiziran proces pregleda (*audita*), ki omogoča oceniti izvajanje javnozdravstvene politike, kot tudi ravnanje tistih, ki so vključeni v razvoj in izvajanje politike. Zagotovi lahko tudi povratne informacije o zadovoljstvu vključenih deležnikov z vidika uspešnosti njihovega sodelovanja in prispevka k odločitvam, kar lahko posledično prispeva k splošni verodostojnosti postopka ocenjevanja, sprejemanja odločitev in izvajanja politike.

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Abbreviations

ARRS	...	Slovenian Research Agency (in Slovene: Javna agencija za raziskovalno dejavnost Republike Slovenije)
CDC	...	Centers for Disease Control and Prevention
COVID-19	...	Coronavirus disease 2019
DEXi	...	Decision expert
EIA	...	Environmental Impact Assessment
ENHIS	...	Environmental and Health Information System
ESRs	...	Early stage researchers
GiSdT	...	Guided Interactive Statistical Decision Tools
HBM	...	Human biomonitoring
HIA	...	Health Impact Assessment
HRA	...	Health Risk Assessment
IAEA	...	International Atomic Energy Agency
IPS	...	International Postgraduate School
ISAM	...	Improvement of Safety Assessment Methodologies
JSI	...	Jožef Stefan Institute
MODARIA II	...	2^{nd} Modelling and Data for Radiological Impact Assessments programme of the IAEA
NIJZ	...	Slovenian National Institute of Public Health (in Slovene: Nacionalni inštitut za javno zdravje)
NORM	...	Naturally occurring radioactive material
NRC	...	National Research Council
P2S	...	Policy to science
RA	...	Risk Analysis
RŽV	...	Uranium mine Žirovski vrh (in Slovene: Rudnik Žirovski Vrh)
SDM	...	Structured decision-making
SRA	...	Society for risk analysis
S2P	...	Science to policy
URSK	...	Chemicals Office of the Republic of Slovenia (in Slovene: Urad Republike Slovenije za kemikalije)
US EPA	...	United States Environmental Protection Agency
US FDA	...	United States Food and Drug Administration
WHO	...	World Health Organization

Chapter 1

Introduction

Having a sufficient amount of knowledge is a prerequisite for meaningful decision-making in public health, where poor, non-transparent, unjustified and not followed-up decisions can have devastating impacts on the health of a population. However, the sheer amount of available knowledge does not yet guarantee its effective consideration in public health decision-making. Moreover, the increasing amount of knowledge that can be used when assessing health risks or impacts makes it increasingly challenging to integrate as much relevant information as possible in the assessments such as health risk assessment (HRA) or health impact assessment (HIA), which can inform the development of science-based risk-informed policies.

The Coronavirus disease 2019 (COVID-19) pandemic revealed the relevance and challenges of effectively assessing health risks for informing decisions about policies or measures meant to reduce disease transmission or limit other COVID-19 related impacts. The pandemic also highlighted the importance of risk analysis in general, from a basic understanding of its core principles to risk assessment, risk management and risk communication relating to public health protection (Aven & Bouder, 2020). However, the pandemic also exposed a lack of a broader recognition of the risk analysis discipline, which continues to be riddled with recurring foundational challenges, such as an inconsistent or diverse understanding of its core terms and principles (Aven & Flage, 2020; Aven & Zio, 2014). Risk assessment and risk management frameworks, developed and improved over forty years of use, are drifting towards less complicated scientific assessments, leading to misunderstandings and obstructions in risk-informed decision-making (Anderson et al., 2020).

1.1 Scientific Knowledge and Public Health Decision-Making and Decisions

Addressing the possible health impacts related to development planning and decision-making processes is an effective way to prevent adverse health effects and improve the health status of affected populations. The World Health Organization (WHO) has long emphasized creating and promoting policies supporting health through various strategic documents (WHO, 1978, 1981; WHO Regional Office for Europe, 1984, 2013; WHO Regional Office for Europe & European Centre for Health Policy, 1999). Understanding of health and the determinants of health (Dahlgren & Whitehead, 1991, 2021; den Broeder et al., 2003; WHO, 2011) can have significant implications for health promotion, practice, policies and services (Leonardi, 2018; Sartorius, 2006). One of the most common definitions of health is from the constitution of the WHO, where health is defined in broad terms as "*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*"(WHO, 1946, p. 1315). However, regardless of how broadly or narrowly health is understood in a specific context, it only makes sense to consider and include health aspects in policy development if the possible health effects of a policy can be predicted (Kemm, 2013; Vohra et al., 2010).

Tools like HIA aim to facilitate the transfer of knowledge into decision-making and may contribute to bridging the policy-knowledge gap (Douglas & Wildavsky, 1982; O'Mullane, 2013). There is a need for clear differentiation between the scientific and other bases (e.g., differentiation between facts and values; scientific and other factors, such as economic, societal, etc.) in HIA and HRA and their integration within the policy-making process, i.e. HIA is yet to be implemented widely and effectively (Vohra et al., 2016; WHO, 2019). Assessment of health impacts or health risks can be pointless when reasonably assuming that the findings of an assessment will not impact decision-making (O'Mullane, 2013). Since the development, implementation and evaluation of public policies should be a shared responsibility, it is essential to enhance collaboration between researchers in relevant fields, policymakers and other stakeholders to improve population health. Despite many differences among those involved in the assessment process, stakeholders must find common ground (i.e., reach consent about what and why is the assessment performed) and scientists creating new knowledge should ensure that the most recent and most relevant scientific knowledge is applied (Brownson et al., 2006). Clarification of the current state of the available scientific and other types of knowledge, generally and in specific areas, and the clarification of the effectiveness of knowledge transfer in public health policy and practice, e.g., policy impact of research (Alla et al., 2017) can form a solid foundation for further efforts aiming at health improvements.

1.2 Health Risk Assessment and Health Impact Assessment

1.2.1 Health Risk Assessment

The HRA process evolved in the 1960s by applying approaches and methods to quantitatively estimate risks associated with low-level exposure to carcinogens (National Research Council (NRC), 1994). Their focus is on estimating "the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media, now or in the future" (United States Environmental Protection Agency (US EPA), 2021, first paragraph). However, there should be a clear differentiation between the process and purpose of an HRA on one side and specific scientific and analytical methods applied in assessing the probability and magnitude of health outcomes due to exposure on the other. Only if both are sufficiently adequately integrated and interpreted in a participatory decision context will HRA provide the desired results. The most common understanding of HRA focuses primarily on the four steps defined in the risk assessment Red book (NRC, 1983) (Figure 1). The knowledge gathered through the first three steps (hazard identification, dose-response evaluation, and exposure assessment) should be critically integrated and summarized in the risk characterization step, which should aim at providing synthesized conclusions about the risks to inform the risk managers and should follow four general principles: transparency, clarity, consistency and reasonableness (US EPA, 2014). Ideally, the description of the risk management or other decisions taken should include information on how and where were HRA or other factors considered in decision-making (US EPA, 2014). However, such transparency regarding the impacts of HRA on decisions is not commonly observed (United States Food and Drug Administration (US FDA), 2016; Wu et al., 2016).

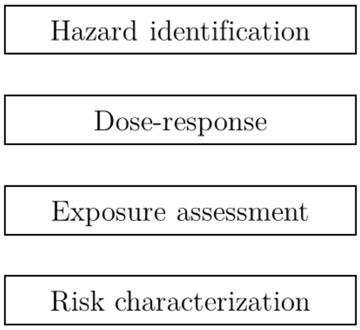

Figure 1: Typical four steps of HRA.

The risk management purpose of HRA has been recognized repeatedly since its development (Aven, 2003; Aven & Renn, 2010; NRC, 1983, 1996, 2009; US EPA, 2014). HRA can be used as a public-policy tool and can support decisions, prioritize research needs, and help develop approaches to evaluating the costs and benefits of regulatory policies (NRC, 1996, 2009). If the risk management purpose of HRA is acknowledged, then HRA needs to be understood within a broader risk analysis context, including also risk communication, risk management, and policies relating to risk (Society for Risk Analysis (SRA), 2018c). Furthermore, establishing risk analysis as a separate field or discipline (Aven, 2020a, 2020b) requires a solid conceptual foundation and firm risk science knowledge base, which would ensure that the risk assessors, decision-makers, and other stakeholders, including those affected by such risks, understand the basic principles and terminology of risk analysis consistently, regardless of the various areas of application. All the same, the discipline of risk analysis and its practice continues to be challenged by recurring issues, especially during times when useful information about health risks is most needed, such as during the COVID-19 pandemic (Aven & Bouder, 2020; Derbyshire, 2022; Iavicoli et al., 2021; Pluchino et al., 2021). There is also a persistent lack of clarity concerning the key scientific pillars of risk analysis, no consensus on basic terminology and principles of risk analysis, insufficient targeted scientific support, and little justification for many recent definitions that are supported by simple methods and tools, such as checklists, maps, and matrices provided by various consultants.

HRAs are also too often reduced to simple "box-checking" exercises designed to fulfil regulatory requirements or simplistic rating or scoring analyses that do not consider actual physical, biological or chemical processes of exposure pathways in exposed individuals or populations (Greenberg et al., 2015). The lack of understanding of the HRA process and its application inevitably causes HRA and risk management frameworks to oversimplify complex scientific assessments, resulting in misunderstandings that hinder decision-making and reduce confidence in their conclusions (Anderson et al., 2020; Greenberg et al., 2015). Another problem is that HRA and risk-informed decision-making often become bogged down. For example, major risk assessments for trichloroethylene, formaldehyde, and dioxin can take more than 10 years (NRC, 2009). At the same time, according to the NRC (2009, p. 4), "*uncertainty, an inherent property of scientific data, continues to lead to multiple interpretations and contributes to decision-making gridlock*".

A search of the current literature reveals a lack of studies addressing the impacts of HRA in informing decisions. Factors that contribute to the effective integration of HRA results in public health decision-making are either understudied or insufficiently understood (US FDA, 2016; Wu et al., 2016). In addition, advances in specific disciplines useful for HRA, e.g., human biomonitoring, modeling, and in vitro studies (Krewski et al., 2014) alone cannot ensure any improvement of HRA's effectiveness in informing public health decisions without a broader recognition and consolidation of core HRA principles and concepts (Asante-Duah, 2017); additional efforts are needed to address this issue (Aven, 2012; Aven & Flage, 2020; Aven & Zio, 2014; Hansson & Aven, 2014).

1.2.2 Health Impact Assessment

As a formal procedure, the concept of an HIA began to develop in the 1990s with the acknowledgement that a proposal's health consequences could be predicted to protect human health, similar to how an Environmental Impact Assessment (EIA) predicts environmental impacts of a proposal to protect the environment. In this way, an HIA aims to improve public health by providing information for decision-makers about the anticipated health effects related to their decision (Kemm, 2013). The WHO's Gothenburg Consensus paper defines HIA as "*a combination of procedures, methods and tools by which a policy, program or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population*" (WHO Regional Office for Europe & European Centre for Health Policy, 1999, p. 4). The four guiding principles of HIA are democracy, equity, sustainability and ethical use of evidence (World Health Organization Regional Office for Europe & European Centre for Health Policy, 1999), while additional values, such as impartiality, openness, a broad view of health, utilitarianism and value for money, are also deserving of attention (Kemm, 2013).

Comprehensive HIA should consider the full range of potential impacts of a development proposal and related decisions on health, along with all other factors affecting human health directly or indirectly. There is no single right way to perform an HIA (Kemm, 2013), but only general guidance on the basic steps to follow when undertaking an HIA (NRC, 2011) (Figure 2). During the screening step, a plan, project, or policy reasons and background for which an HIA would be useful is identified, while the scoping step serves to appropriately plan the analytical part of the HIA and identify the health measures requiring consideration. The assessment step identifies analytical methods, tools, and potentially affected populations and presents the potential health impacts of a proposed development. The recommendation step is there to suggest reasonable changes and practical actions to promote positive health impacts and minimize adverse health impacts. The reporting step informs the decision-makers, affected communities and other stakeholders. Finally, monitoring and post-evaluation are performed to determine HIA's impact on the decision and the health status of the population affected by the implemented plan, project or policy (Centers for Disease Control and Prevention (CDC), 2016; NRC, 2011).

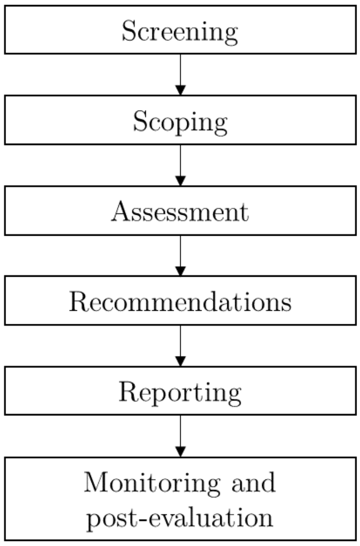

Figure 2: Basic steps of HIA.

HIAs, in general, have not yet been implemented widely nor effectively (Vohra et al., 2016) and most HIAs performed have been related to projects. Development planners and competent authorities as policy makers have only recently started to explore its use for policy making (Kemm, 2013). Nevertheless, HIA has established itself as one of the primary means of facilitating the challenging intersectoral action to improve health (Gulis et al., 2012). Many experts also believe that HIA should be integrated into the policy planning process and should aim at the best possible way of informing it about the relevant health impacts. Integration of HIA with EIA, which already has a legal basis in the EU (Directive 2014/52/EU), can encourage assessing the impacts of policies and simplify the decision-making process while ensuring consistent assumptions and methods for all types of assessments used. Such integrated impact assessments can also help to avoid competition between separate assessments and facilitate a fast decision-making process and decisions without major health concerns. However, health is typically not covered adequately in integrated assessments, if at all, although it is an endpoint within an EIA. Two possible responses to generally poor consideration of health in EIA are (1) the development of separate HIA for complementing EIA or (2) reforming the practice of EIA to improve health coverage (Kemm, 2013). The latter is currently being pursued by the WHO (Nowacki, 2018; Vohra et al., 2016; WHO, 2019).

From the literature, it is clear that health systems focus too much on providing medical services and core public health functions, while the lack of intersectoral collaboration means that health systems are not routinely and actively involved in the planning and activities of other sectors that can have health implications, e.g. economic, education and infrastructure development (Harris-Roxas et al., 2012). The usefulness of HIA in informing proposals determines the success and the acceptance of HIAs (O'Mullane, 2013). If an HIA (or HRA) is misunderstood, it can only serve as an administrative burden, which means that it will likely be abandoned by decision-makers (Krieger et al., 2003; Parry & Stevens, 2001). However, suppose an HIA is really to become a valuable tool in policy making, it follows that health needs to be valued higher on policy makers' agendas across all sectors (WHO Regional Office for Europe, 1999), while health impact assessors need to improve their understanding of policy-making (Kemm, 2013). In addition, proactive research on the understanding of the policy process is urgently needed to improve the integration of HIA practice in decision-making (O'Mullane, 2013).

Chapter 2

Aims and Hypotheses

In my dissertation, I focus on the science to policy (S2P) interaction in public and environmental health and address the recurring challenges of risk assessment within and for decision-making. I also attempt to clarify the many foundational challenges in risk analysis and identify practical ways to improve the impact of HRA in policy development and decision-making for the benefit of individual and population health. Specifically, I examine factors influencing knowledge transfer into policy development and decision-making in the environmental and public health domain to help bridge the ‘‘know-do’’ gap (van den Driessen Mareeuw et al., 2015) and improve evidence-based health policy development and implementation. I also perform an analysis of the current practice of HRA and investigate the role of HRA and HIA in the decision-making context in order to identify specific opportunities for clarifying and improving the impact of HRA. My dissertation aims to answer the following questions:

- How can the translation of scientific knowledge into decision-making and decisions be improved – more specifically, how to improve the usefulness of HRA (or HIA) in informing decision-making?

- What elements of HRA are perceived as important for effective consideration of HRA in informing risk management decisions, e.g., type of HRA results, stakeholder inclusion, clear purpose, and identification of alternatives?

The main goals of this dissertation were:

1. To improve S2P interaction: generally, in the development policy areas, specifically, in the environmental health and public health area;

2. To contribute to the clarifications of the scientific foundations of risk analysis, namely risk assessment and risk management;

3. To improve the understanding of HIA, HRA and their key concepts, focusing on their differentiation and application in policy development and decision-making context;

4. To assess the current risk assessment practice when applying human biomonitoring data through the context of core risk analysis principles;

5. To improve the understanding and contribution of the assessment context and stakeholder participation in informing decision-making to improve public health policies.

The doctoral research, which provides the basis for this dissertation, was guided by the following five research hypotheses:

1. Potential health effects of development proposals are not adequately considered in management/policy decisions.

2. Inconsistencies exist between available and related environmental and health data applied for policy development and decision-making purposes.

3. There is a lack of experience with currently available tools such as HIA and HRA to inform public health or other developmental decisions.

4. There are inconsistencies in the understanding and differentiation of HRA and HIA, especially regarding their potential use in informing decision-making.

5. Understanding key risk analysis concepts, e.g. hazard, risk, exposure, dose, and uncertainty, is not coherent among the broader scientific community.

Chapter 3

Methodology

The doctoral research follows two general approaches: policy to science (P2S) and science S2P. The P2S approach is based on the principles of auditing, while the S2P approach includes decision analysis methods, reviewing existing scientific literature, and performing a targeted survey.

3.1 Auditing

The P2S approach was used to assess the extent and clarity of the consideration of scientific knowledge in policy decision-making and to assess the implementation of policy decisions after the selected policy entered into force and began to be implemented. This approach follows the key principles of auditing (Cahill et al., 1987; Center for Chemical Process Safety, 2011; European Court of Auditors, 2017; International Organization of Supreme Audit Institutions, 2004) adapted for public health policy making (Bizjak et al., 2020). The idea is to determine how decision-making can be improved by assessing the status of the audited subject (i.e., public health policy) and the actions and measures aimed at achieving or increasing its quality (Bizjak & Kontić, 2019). The critical elements of an audit process are shown in Figure 3. To demonstrate the benefits of auditing in the public health domain, I focused on the evaluation of the performance of the Slovenian National Strategy on Children and Adolescents related to environmental quality for the period 2012-2020 (referred to as the Strategy; Government of the Republic of Slovenia, 2011, 2015). I also compared the health status of children and adolescents and other environmental and health indicators before and after implementing the strategy. The evaluation aimed to assign (positive) changes to the strategy or related activities as specified in the Strategy's action plan. It was based on predetermined evaluation categories, which were assigned to the specific health and environmental endpoints based on the indicators that were determined for monitoring purposes by the Strategy and the Strategy's action plan (Bizjak et al., 2020).

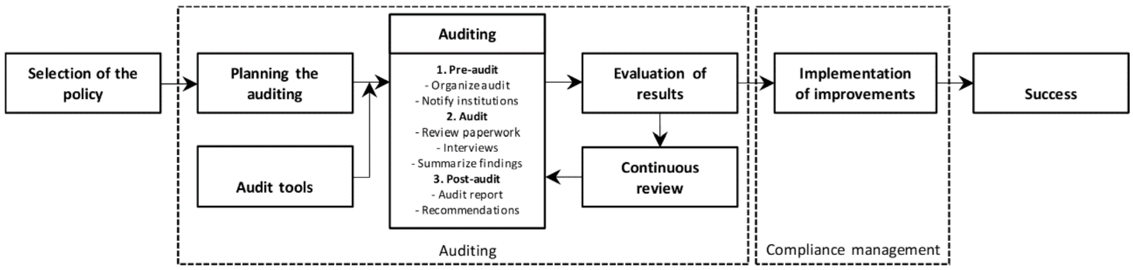

Figure 3: Key elements of an audit process.

3.2 Decision Analysis

The decision analysis approach adopted in a case study concerning the management of the former uranium mine at Žirovski Vrh (RŽV) is generally known as Bayesian (French et al., 2009; Goodwin & Wright, 2014; Gregory et al., 2012; Howard & Abbas, 2015). The Bayesian approach builds on the deterministic cost-benefit analysis through multi-attribute utility functions. These functions facilitate the valuation of non-tangibles, e.g., preferences for different possible outcomes of a decision and enable the formal consideration of attitudes towards uncertain risks, and support focused discussions among decision-makers and stakeholders (Dyer, 2005; French & Argyris, 2018; Hsu & Sandford, 2007; Ishizaka & Nemery, 2013; Slovic, 2000). The RŽV case study includes the application of two decision analysis tools: decision expert—DEXi, which is a hierarchical and qualitative multi-criteria decision-making method that applies DEX methodology (Bohanec et al., 2013; Dyer, 2005), and Guided Interactive Statistical Decision Tools, GiSdT (Neptune and Company Inc, 2017), which applies structured decision-making (SDM) evaluation (Kontić et al., 2022).

3.3 Review

The review of scientific publications dealing with the application of HBM in the assessment of health risk (Bizjak, Capodiferro, et al., 2022) followed PRISMA guidelines for systematic reviews (Page et al., 2021) that ensure good quality of reviews. The review included 36 scientific publications that had both "human biomonitoring" and "risk assessment" in their titles, keywords, or abstracts and were published in the last five years (2016-2021). The review of the presence and clarity of selected fundamental HRA elements in these publications was performed with the help of an appraisal tool (Table 1) and ten of the 14 NEUROSOME early stage researchers (ESRs). The appraisal tool included ten questions about selected HRA elements that are important for judging the overall quality of HRAs (Fenner-Crisp & Dellarco, 2016; SRA, 2021). The appraisal questions facilitated a "Yes", i.e., if a specific HRA element was clear or "No" if it was unclear.

Table 1: Appraisal tool.

<table>
<tr><td colspan="6">Appraised publication: e.g. TITLE</td></tr>
<tr><td colspan="6">Appraisal tool</td></tr>
<tr><td colspan="2">HRA element</td><td>Appraisal question</td><td>Answer (Yes/No)*</td><td>HBM**</td><td>Comments</td></tr>
<tr><td colspan="2">Assessment context of HRA
(assessment context answers the following key questions: what is to be assessed, why is to be assessed, which assessment endpoint is relevant, assessment timeframe; it is more specific than the general context of the publication)</td><td>Does the assessment clearly identify what is assessed and why at the start? Has assessment context been followed/applied in the HRA process?</td><td></td><td></td><td></td></tr>
<tr><td colspan="2">Dose/exposure—response relationship</td><td>Is the applicability of the selected dose/exposure - response relationship for the assessment thoroughly discussed?</td><td></td><td></td><td></td></tr>
<tr><td rowspan="4">Exposure assessment
(specific activities during which a specified number of individuals are exposed knowingly or unknowingly to the hazardous substances, location and characteristics of the location where the activities takes place, duration of activities, reason for activities, sources causing the presence of hazardous material in the environment where the activities take place...)</td><td>Exposure setting</td><td>Are the characteristics of the place of exposure clearly described?</td><td></td><td></td><td></td></tr>
<tr><td>Exposure sources</td><td>Are the major sources of hazardous material and/or activities causing the release(s) of hazardous material(s) into the environment identified?</td><td></td><td></td><td></td></tr>
<tr><td>Exposure duration</td><td>Is the duration and frequency of the exposure identified?</td><td></td><td></td><td></td></tr>
<tr><td>Exposed population</td><td>Is it clear who is really exposed (population/individuals, their number), and why are they exposed (e.g. their activities leading to exposure)?</td><td></td><td></td><td></td></tr>
<tr><td colspan="2">Magnitude of risk
(is risk assessment explicitly determining the size of undesired effects)</td><td>Are the types of the expected adverse outcomes, their severity and the probability of their occurrence identified clearly?</td><td></td><td></td><td></td></tr>
<tr><td colspan="2">Uncertainty of HRA results</td><td>Are the major sources of uncertainty evaluated?</td><td></td><td></td><td></td></tr>
<tr><td colspan="2">Options for mitigating/avoiding exposure
(specific options for mitigating exposure that are consistent and explicitly connected with the assessment context)</td><td>Are there any specific actions for avoiding or mitigating the exposure to the selected hazardous materials identified and/or proposed?</td><td></td><td></td><td></td></tr>
<tr><td colspan="2">Transparency and clarity of the assessment process</td><td>Is it transparent and clear how was the assessment performed and its conclusions obtained?</td><td></td><td></td><td></td></tr>
<tr><td colspan="6">*answer with "Yes" if the publication demonstrates that the HRA element has been clearly shown ("No" if it does not)
**mark with "X" only if it is clearly demonstrated that HBM is used in specific element (otherwise leave the column blank)</td></tr>
</table>

3.4 Survey

In order to test my research hypotheses, a targeted survey was performed to analyze the understanding of selected risk assessment and decision analysis topics (Bizjak, Kontić, et al., 2022). The survey was guided by the three assumptions outlined in Table 2, which influenced the development of two questionnaires administered to four distinct groups of professionals. The first group was made up of participants from a workshop: "Attempt at an interpretation of biomonitoring results in connection with environmental pollution monitoring data, with the emphasis on air pollution and assessment of potential impacts of these pollutants on the health of inhabitants", funded by the Slovenian Research Agency (ARRS). The workshop participants consisted of professionals from various backgrounds and expertise from the Slovenian National Institute of Public Health Institute (NIJZ), Jožef Stefan Institute (JSI), Faculty of Health Sciences of the University of Ljubljana, Chemicals Office of Republic of Slovenia (URSK) and representatives from industry. The second group comprised ESRs and other researchers within the NEUROSOME project. The third target group comprised participants of "*Environmental Health Risk: Analysis and Applications educational activities*" organized by the Harvard T.H. Chan School of Public Health on 9-12 March 2020. The fourth group comprised established researchers in the risk analysis and decision-analysis domain.

Table 2: The three assumptions guiding the survey.

1.	The informing potential of HRA results is limited because some of the various types of results may not conform to or properly fit the area/policy of their application.
2.	HRA is not applied in a consistent and integrated manner; rather, only some elements of HRA are practiced because of a limited understanding of the overall process of HRA, particularly its purpose.
3.	There are diverse understandings of the importance of different elements of HRA for public health decision-making. This is evident from the interpretation of HRA results, especially in cases when consultation with the users of HRA results is poor or is missing, so the interpretation is biased by, for example, assessors, or in the opposite case, when the users of the results are consulted; however, a deeper exploration of their different understandings is missing.

Since the survey sample was non-probabilistic (i.e., judgmental type), I restricted the statistical analysis of responses to qualitative relative comparisons of responses between groups or regarding the respondents' background.

Chapter 4

Publications

The results of this work are published in five internationally recognized journals.

4.1 Auditing in Addition to Compliance Monitoring: A Way to Improve Public Health

The commentary "*Auditing in addition to compliance monitoring: a way to improve public health*", published in the International Journal of Public Health in August 2019 (doi: 10.1007/s00038-019-01291-4), was written by T. Bizjak and B. Kontić. I contributed to the conceptualization, writing of the original draft, reviewing and editing.

The commentary, which discusses specific issues behind the first two hypotheses guiding my doctoral research, was in response to an editorial in the International Journal of Public Health (Gulis, 2019) that emphasized the non-compliance to national public health policies and international agreements and called for contributions that reveal the reasons for this non-compliance. The commentary highlighted that the implementation and compliance with public health policies could not be improved with targeted interventions without follow-up evaluations that would provide useful information concerning the policies' effectiveness. In this context, my commentary aimed to stimulate responsible institutions and authorities to consider regular and systematic auditing of public health policies. Auditing, as a form of a follow-up, has proved effective in protecting the environment and economic or occupational health interests and could prove to be a success story in contributing to improved public health status in Europe by evaluating the implementation status of policy, checking policy compliance and adherence, and the accountability and honesty of those involved in the policy development and implementation.

International Journal of Public Health
https://doi.org/10.1007/s00038-019-01291-4

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COMMENTARY

Check for updates

Auditing in addition to compliance monitoring: a way to improve public health

Tine Bizjak[1,2] · Branko Kontić[1]

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The success of public health policies has recently been questioned in the editorial of the International Journal of Public Health (Gulis 2019), where the author discusses diverse levels of compliance to national health policies and related international agreements. He points out the enduring lack of compliance within countries and concludes with a call for contributions that reveal reasons for this situation. The issue certainly deserves wider attention. In this view, we contribute a deliberation aimed at stimulating national responsible and competent institutions and authorities to consider regular, systematic auditing of public health policies, with the aim of achieving increased policy effectiveness.

The actual effect a public health policy has on a society is determined by the degree of its implementation, which is often unknown or uncertain, due to the scarcity of evidence (Donkor et al. 2018; Kaur 2010). European Commission recently emphasized the importance of responsible application of the EU law (EC 2018). In this context, however, the question of compliance with existing international and national policies remains unanswered, although all EU member states have the same rules, the same access to knowledge, methods and tools (Gulis 2019). Despite differences in political systems, there is a universal condition for ensuring good implementation of health policies: it is the existence of a functional system of active, responsible and competent authorities, who have a clear view about priority areas in the actual public health policy and the power to effectively distribute the available budget. Such a system inevitably includes continuous evaluation of the success of the implementation, focuses on the degree of goals achieved and identifies barriers and drivers encountered in order to make policy improvements.

It is unrealistic to expect intrinsic, successful policy implementation just because it will benefit society. Monitoring the implementation is often limited to collecting general information on the performance and status of activities covered by the policy (Donkor et al. 2018; Usmanova and Mokdad 2013), without thorough evaluation and linkage of the findings to the primary purpose of the monitoring—early alert about needs for policy improvement. Consequently, monitoring can be deficient in terms of identifying barriers and drivers contributing to policy performance. Effective follow-up will continually be needed and should ideally be an integral part of the policy from its planning stages. This follow-up can be performed internally or externally in the form of an audit with appropriate depth and comprehensiveness. Audits generally aim at determining the ways and possibilities of improving a situation in a subject area, checking both the substantial status of the audited subject and the system of actions and measures aimed at achieving its quality. Audits are usually accompanied by contextual questions: "Do we (really) do what we say we do?" and "How good are we in what we are doing?" The answers are used as a non-exhaustive source of improvement measures.

During the past several decades, the inclusion of health into all policies has been repeatedly recognized and advocated (Ståhl et al. 2006; WHO 2017). EU level studies, which review the application and effectiveness of the strategic environmental assessment (SEA) and environmental impact assessment (EIA) directives (Directive 2001/42/EC; Directive 2014/52/EU), also collect information on how health impacts are evaluated in these frameworks. They show that health issues are dealt with unsystematically in the assessments (EC 2016). Regrettably, while recommendations for improving the effectiveness, relevance and coherence of SEA (EC 2016) are included, there are no recommendations for improvement

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in the area of health impact assessment (HIA). Most recent activities by the WHO Europe again strive to improve the situation in this complex and demanding area (WHO 2019). Additionally, on-going national and international research aims to develop better insight into these issues and their resolution, e.g. within the two EU projects: Integrating Environment and Health Research: a Vision for the EU-HERA (https://www.heraresearcheu.eu/), and Exploring the Neurological Exposome—NEUROSOME (http://www.neurosome.eu/). HERA's goal is to create a European Health and Environment Research Agenda for 2020–2030, based on the analysis of actual content and gaps in international and national strategies, policies, priorities and research. NEUROSOME focuses on issues related to exposure assessment and neurodevelopmental disorders. Results of these endeavours are expected to help bridge the "know-do" gap and to improve evidence-based health policy development and implementation (van den Driessen et al. 2015; Gulis 2019).

Audits in environmental and industrial safety have already proved effective in protecting the environment and safeguarding economic and occupational health interests. Why should it not be so with regular public health policy audits at the EU and national levels? Besides evaluating the implementation status of the policy, the audits may also effectively check the compliance and adherence on one side and the accountability and honesty of those involved in policy development and implementation on the other. Striving for overall system transparency should be an imperative. In this way, the audits may well prove a success story in contributing to the improved public health status in Europe.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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4.2 Evaluating the Success of Slovenia's Policy on the Health of Children and Adolescents: Results of an Audit

The original article "*Evaluating the success of Slovenia's policy on the health of children and adolescents: results of an audit",* published in the International Journal of Public Health in July 2020 (doi: 10.1007/s00038-020-01432-0), was written by T. Bizjak, R. Novak, M. Vudrag, A. Kukec, and B. Kontić. As the first author, I contributed to the conceptualization, methodology, investigation, data curation, analysis, writing of the original draft, reviewing, editing and visualization.

The article expands on my original commentary (Bizjak & Kontić, 2019). It addresses my first two research hypotheses. The article demonstrates the contribution of an auditing process for evaluating the success of the Slovenian national strategy on children and adolescent health concerning environmental quality for the period 2012–2020 and the benefits of auditing in improving public health policy by improving S2P interactions.

The auditing followed key aspects and principles according to the guidance offered by Cahill & Kane (2011), the Center for Chemical Process Safety (2011), the European Court of Auditors (2017), the International Organization of Supreme Audit Institutions (2004), and the acknowledged experiences of Bernet et al. (2018), Brownson et al. (2010), and Shankar et al. (2011) from the public health policy domain. The audit is based on publicly available information and focuses on the Action plan for implementing the Strategy and, annual environmental quality reports, and related health status from 2012 to 2019 provided by the NIJZ. In addition, several interviews were performed with the representatives from the Slovenian Ministry of Health, the NIJZ and the Slovenian Ministry of the Environment and Spatial Planning to verify the specific policy information in the reviewed documents in the context of intersectoral coordination. I performed the evaluation either quantitatively or quantitatively/qualitatively (depending on the indicators and metrics). It compares the available information about the health status of children and adolescents before and after the Strategy's implementation and attempts to assign positive changes to the Strategy and related activities.

There was no clear evidence that the Strategy contributed to positive changes in child and adolescent health, although specific activities to improve environmental quality can have positive long term health impacts. Only a few indicators demonstrate a correlation between the specific activities of the action plan with well-documented results, while most indicators show either weak correlation or could not be evaluated due to poor or absent data. The findings highlighted the issue of inconsistent or indirect associations between available environmental quality information and assumed exposures contributing to specific health outcomes, which impedes the process of evaluating the Strategy's success. Recommendations for the future include appropriately planned and systematically performed auditing and re-auditing as an integral part of the monitoring of policy implementation. Another recommendation is that monitoring should be based on metrics that have to be defined sufficiently by the policy (e.g., environmental health indicators should fit for purpose). Finally, effective intersectoral work as emphasized by the Ostrava declaration (WHO, 2017) is needed, and although it is not fully realized in practice (Kontić et al., 2019b, 2019a), it is critical for the success of public health interventions (Bjegovic-Mikanovic et al., 2018).

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ORIGINAL ARTICLE

Evaluating the success of Slovenia's policy on the health of children and adolescents: results of an audit

Tine Bizjak[1,2] · Rok Novak[1,2] · Marko Vudrag[3] · Andreja Kukec[4,5] · Branko Kontić[1]

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Abstract

Objectives The aims of this audit were twofold: (1) to demonstrate the contribution of the auditing process in evaluating the success of child and adolescent health policy in Slovenia between 2012 and 2019, and (2) to expand on the commentary published in the International Journal of Public Health in 2019 to demonstrate the benefits of auditing in improving public health policy in general.

Methods The audit followed health, safety and environmental approaches as per the standards of public health policy.

Results Due to poor intersectoral coordination and weak associations between environmental and health indicators, no clear evidence could be established that child and adolescent health policy contributed to positive changes in child and adolescent health from 2012 to 2019.

Conclusions Auditing should become an essential component of measuring the success of public health policies. Attention should also be paid to the following issues affecting youth health: sleeping and eating habits, economic migration, poverty, etc.

Keywords Public health · Adolescent health · Auditing · Environmental quality · Indicators

This article is part of the special issue "Adolescent Health in Central and Eastern Europe".

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Introduction

In a piece of 2019 commentary published in the International Journal of Public Health, 'Auditing in addition to compliance monitoring: a way to improve public health', authors stressed that the actual effects of public health policy on society is determined by the quality of its implementation (Bizjak and Kontić 2019). They further argued a key condition for ensuring health policies' successful implementation: an active system of responsible and competent authorities capable of prioritizing issues, assigning responsibilities and effectively distributing the available budget. Such a system invariably entails continuous monitoring to evaluate the success of implemented measures, assess the extent to which goals are achieved and identify barriers in attempted policy improvements. In terms of monitoring policy implementation, there are some caveats regarding limited information about its performance (Kaur 2010; Usmanova and Mokdad 2013; van den Driessen Mareeuw et al. 2015; Donkor et al. 2018; Gulis 2019). In this context, the European Commission recently stressed the importance of learning from assessments of existing air quality legislation in view of regularly updating public health policy (The Green Deal; European Commission 2019). However, despite general recognition that auditing is beneficial, few studies focus on the effectiveness of public health or health services (Kingdon 1995; Brownson et al. 2010; Shankar et al. 2011; Singh 2014; Bradley et al. 2016; Bernet et al. 2018).

To demonstrate that auditing is an effective tool in identifying possibilities to improve public health in Slovenia, an agreement was made in 2019 between national public health professionals and an auditing team to check the performance of the national strategy on children and adolescent health related to environmental quality for the period 2012–2020 (referred to as the Strategy, the Government of the Republic of Slovenia 2011; see summary below). This Strategy was selected for the following characteristics: (1) it is a national level policy; (2) it builds on international efforts and policies regarding health and environmental initiatives [World Health Organisation (WHO), United Nations Environment Programme, United Nations Development Programme, European Environment Agency, European Food and Safety Agency, etc.]; (3) it is accompanied by a specific action plan to implement the Strategy (referred to as the action plan (AP); Government of the Republic of Slovenia 2015), which details priority goals, related activities, monitoring indicators, etc.; and (4) there is an intergovernmental working group (IWG) that has been established to follow the implementation of the Strategy and regularly report its findings to the government. The audit lasted from September 2019 to April 2020 with an open end for a post-audit phase. This was occasioned by the changed priorities triggered by the COVID-19 pandemic. The scope and foci of the audit are depicted in Table 1.

Summary of the strategy

By signing the Parma Declaration in 2010 (WHO Regional Office for Europe 2010), the Republic of Slovenia has committed itself to protecting adolescent health against harmful environmental factors, acknowledging it as an integral part of the country's public health and environmental policies. Other important backgrounds of the Strategy are the European Environment and Health Strategy (EC 2003), European Environment and Health Action Plan 2004–2010 (EC 2004) and the 6th Environment Action Programme of the European Community 2002–2012 (EC 2011).

On 29 July 2010, the Slovenian government appointed the IWG to implement the commitments of the Strategy. The IWG's first task was preparing the Adolescent Environmental Health Action Programme and the Chemical Safety Action Programme, which were merged to form the Strategy.

The Strategy determined four general priority goals: (1) ensuring population health by improving access to safe drinking water and appropriate municipal wastewater management, (2) reducing injury and obesity through safe environments and healthy diet paired with physical activity, respectively, (3) preventing disease by improving indoor and outdoor air quality and (4) preventing diseases caused by chemical, biological and physical risk factors. The AP further specified the activities leading to the achievement of goals, the duration of said activities, monitoring indicators and the institutions responsible. Specific areas of focus were also determined, such as youth participation, climate change, inequality, new technology and excessively polluted areas.

The WHO/ENHIS indicators, combined with those developed by the National Institute of Public Health (NIJZ) and Slovenian Environment Agency, were applied in the context of monitoring the effects of Strategy implementation. The initial set included regulatory aspects of environmental protection, air pollution in cities, drinking water quality, infant mortality due to respiratory disease, asthma and allergic diseases in children, child exposure to polluted air—PM_{10} particles, waterborne disease outbreaks (epidemics), access to safe drinking water, etc. The indicators had to be updated regularly to properly capture new and additional views on the relationships between exposure to environmental risk factors and observed health outcomes. Some additional health indicators were obesity, diabetes, congenital irregularities, etc. Annual surveys and reporting of adolescent health status according to these indicators were to be provided by the NIJZ.

The Strategy defined that the IWG will report to the Government every 2 years on the Strategy's implementation progress, the findings of which would be used to plan future health and environmental policy.

Methods

The key aspects and principles of auditing were applied according to the definitions and guidance offered by Cahill et al. (1987), INTOSAI (2004), CCPS (2011) and ECA (2017). Adaptations to the area of public health policy followed the experience of Brownson et al. (2010), Shankar et al. (2011) and Bernet et al. (2018). Figure 1 shows the main elements of an established audit programme. Standard auditing tools, such as questionnaires, worksheets, guidelines, etc. were used to collect, sort, analyse and retrieve audit information.

The audit was based on reviewing the Strategy's AP and the annual reporting of environmental quality and related health status from 2012 to 2019, provided by the NIJZ. Interviewing the personnel engaged in Slovenian public

Table 1 Auditing topics and relations (applicable generally when auditing public health policies)

Auditing topics and relations	Rationale
1. Character of the Strategy: preventive/curative/both	Differences between the preventive and curative character of the Strategy can direct the auditing process towards either (1) examining whether the Strategy's success should be evaluated in terms of fixing pressing issues, leading to improved future circumstances (curative) or (2) examining the Strategy's success in preventing public health status from worsening compared to the outset of the Strategy's implementation (preventive)
2. Consistency between the Strategy and the AP: substance, timing, activities, responsible bodies and indicators	The audit checks whether the Strategy and its AP accord with one another and are complete. If so, the credibility and trustworthiness of both can be confirmed; otherwise, inconsistent or/and conflicting issues should be identified and fixed prior to any barriers to implementation
3. Functional strength of the indicators: clearness, measurability, meaning and associations and history of record	Indicators should be 'fit for purpose'. This means that they provide information as needed, allowing for tractable intermediate and final examinations of the Strategy's success
4. Links between environmental quality and health indicators	The Strategy deals with adolescent health in relation to environmental quality. This is the core of the overall evaluation of the measures applied through the Strategy and the AP. Indicators applied throughout the Strategy's implementation should be accordingly selected and synthesised
5. Evaluation of association, possibly causality, between environmental quality and health status changes as determined by the indicators' values	Similar to the one given in pt. 4; if causality is to be established, proper evidence-based information—e.g. measures commonly applied in epidemiology—should support interpretation of indicators' values pertaining to the evaluation period
6. Strategy compliance with legal and agreed-upon commitments	Compliance is a standard component of auditing
7. Expected versus actual work of the IWG: accountability, transparency, intervention (as needed), meeting frequency, coordination, management and recording and reporting	Management performance is a key auditing component. It contributes to the Strategy's overall credibility and trustworthiness. Responsible behaviour is one of the related topics
8. Evaluation of the Strategy's success: children and adolescent health status improvement during the period 2012–2020, proposals for future work	The audit checks whether this final step of the Strategy implementation has been conducted comprehensively and as per the prescribed quality standards
9. Overall transparency and participation of interested parties	The audit assesses the democratic aspects of the Strategy

AP action plan, *IWG* intergovernmental working group

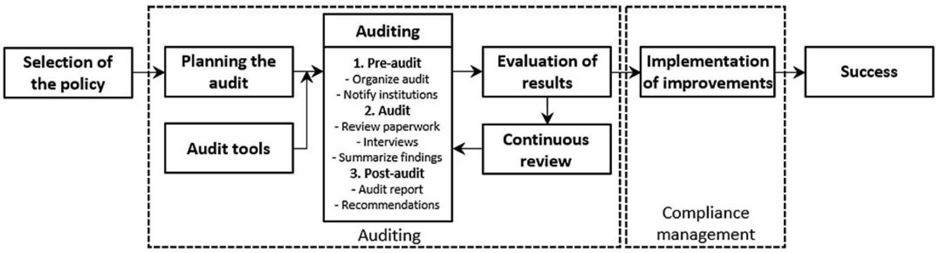


Fig. 1 Elements of the audit programme

health policy preparation, primarily from the Ministry of Health, the NIJZ and the Ministry of the Environment and Spatial Planning, was performed to verify specific policy information in the reviewed documents in the context of intersectoral coordination. The head of the IWG was also consulted regarding its work.

In the pre-audit phase, three meetings were held with experts from the three institutions engaged in preparing the

Strategy. At these meetings, which were also associated with work on the European Union-funded project on the Health and Environment Research Agenda (HERA: https://www.heraresearcheu.eu/) for Europe, the selection of documents for review were discussed and approved. Since the initially selected documentation covered practically all components of environmental and public health issues, the audit team decided to narrow the scope and perform the audit only for the Strategy documents. The key reasons for this relate to the characteristics of the Strategy as described in the introduction in items (1) through (4).

The evaluation was conducted to compare the health status of children and adolescents before and after the Strategy's implementation. The attempt was to assign (positive) changes to the Strategy and related AP activities. Key metrics were based on associations between selected health and environmental indicators, and trends in the observed period were to be analysed. The overall policy evaluation included the following topics: design and consistency between the Strategy and AP, implementation monitoring, outcome variables (i.e. the performance of the activities and their results: qualitative, qualitative or both), transparency and reporting and availability of data for evaluation. Some indicators were quantitative (e.g. share of monitored drinking water and measured air quality parameters), while others required combined quantitative and qualitative metrics (e.g. determining if and to what extent municipalities follow public health guidelines). The evaluation categories, applied in Tables 2 and 3, were:

G—Good performance of the activity (complete and quality), results documented and auditable
W—Weak performance of the activity, results unclear/non-transparent or poorly documented
O—Not observed or evaluated. Available information was not complete enough for thorough evaluation
X—Not applicable: evaluation based on selected indicators is not applicable (sensible)
Y—Consistent: full overall or specific consistency between the Strategy and AP
N—Not consistent: Strategy and AP are not consistent
P—Partial consistency between the Strategy and AP

Results

Results for priority Goals 1 and 3 are presented in Tables 2 and 3 (Legal Information System 2015; Okorn 2016; National Institute of Public Health 2019, 2020a, b). Similar findings are available for priority Goals 2 and 4; however, they are not shown here due to space limitations.

Discussion

Limited healthcare resources and related issues make evaluating the impact of public health interventions increasingly important (Mays and Smith 2011; Méndez and Osorio 2017; Bernet et al. 2018; Saeed et al. 2019). The need for more child and adolescent health research was emphasised in relation to the child and adolescent health strategy development (Dratva et al. 2018). The auditing of the Strategy and its AP provided a framework to encourage and facilitate continuous evaluation of the effectiveness of activities with a specific focus on the health of children and adolescents in relation to the environment. The activities of the AP were both preventive and curative and concerned environmental quality. Regarding adolescent health, however, they were strictly preventive, with no evidence for necessary interventions prior to the implementation of the Strategy. In this context, the AP activities aimed at improving environmental quality can yield a positive long-term health impact. The Strategy and AP are not fully consistent; the Strategy's time span is from 2012 to 2020, but the AP's activity plans cover 2015–2020. The AP includes some additional topics and activities, but it does not include some topics identified as important by the Strategy. It also fails to include some of the Strategy's specific areas of interest, e.g. youth participation, new technology, etc.

Policy effectiveness (e.g. measured by expenditures, investment costs or timing) does not necessarily lead to success in terms of the policy's original goals. However, the challenge when evaluating the effectiveness of public health efforts, especially in an environmental context, requires the development of appropriate metrics for evaluating health changes resulting from different policy approaches (Kingdon 1995; Brownson et al. 2010). This is one of the audit's key findings. Only a few indicators (Tables 2, 3) demonstrate the AP activities' good performance with well-documented results, while the majority show either weak performance or could not be evaluated due to poor or absent data. Several indicators defined by the AP are not fit for their intended purpose in terms of evaluating the effectiveness or success of actions (Table 2 indicators 2.2, 3, 4.1, 6, and 7; Table 3 indicators 4.3 and 4.4). Examples of such indicators are those related to drinking water quality and city air pollution associated with public transport. These indicators suffer from unclear goals and intended uses; as a result, it was not possible to evaluate their impact on health improvements. A number of indicators include 'raising awareness' and 'informing the public' without providing specifics about the events to be included in the evaluation, groups to be addressed, etc. Most of the activities and their indicators do not

Table 2 Audit findings for priority Goal 1 (Slovenia 2012–2019)

Priority Goal 1: Ensuring population health by improving access to safe drinking water and appropriate municipal wastewater management

Activities planned for achieving the expected results—AP
Implementation of the Protocol on Water and Health. Activity 1
Improved access to safe drinking water, municipal wastewater management. Activities 2–7
Quality control of swimming water. Activities 8 and 9

AP activities	Indicators[a] and performance evaluation of activities	Audit findings	
		Consistency	Additional comments (according to Table 1)
1. Protocol on Water and Health	Ratification of the Protocol Status/ Score: W	Y	Protocol prepared but not ratified
2. Water protection areas. Raising awareness about conservation of drinking water resources	2.1 Share of protected water resources Status/Score: O 2.2. Awareness-raising about the importance of good quality/safe drinking water through nature conservation Status/Score: X 2.3 Population with unknown drinking water quality (APR) Status/Score: W 2.4 Microbiologically non-compliant drinking water samples (APR) Status/Score: G 2.5 Exposure to nitrates and pesticides in drinking water (APR) Status/Score: O	P (e.g. GIS supported monitoring system)	2.1 Data not available; water protection areas remained unchanged during 2013–2016 2.2 Indicator not auditable 2.3 Share of the population whose drinking water resources were not monitored was reduced from 7.3% in 2012 to 5.8% in 2018 2.4 Share of microbiologically non-compliant drinking water dropped from 16% in 2012 to 12% in 2018 2.5 No trends observed. Number of exposed varies. Data on drinking water quality and infectious diseases cannot be clearly associated. Annual data on water quality is not comparable (different sampling)
3. Connectivity of relevant databases	Connectivity of databases Status/Score: X	N (activities introduced by the NIJZ in 2016)	Indicator not auditable: no data
4. Measures for safe and economical use of drinking water facilities	4.1 Number of actions Status/Score: X 4.2 Number of waterborne infection outbreaks Status/Score: W	Y	4.1 Indicator not auditable: no data 4.2 Only a few outbreaks were reported between 2012 and 2017, and the number of infected was below 100 except in 2016 (around 400). About 60% of gastroenterocolitis cases were of unknown etiology
5. Treatment of municipal wastewater	5.1 Proportion of treated wastewater Status/Score: G 5.2 Number of gastroenterocolitis cases in children and youth under 15 years of age (APR) Status/Score: W	P (e.g. no clear goals set)	5.1 Share of population with treated wastewater increased by about 20%, share of tertiary treatment by about 25% (2012–2018) 5.2 No trend observed. The 1–4 year and 5–14 year age groups have consistently had the highest infections rates (e.g. 7206 and 5891 out of 29,168 cases in 2015, respectively; 2632 and 3510 out of 10,493 cases in 2018, respectively). The majority of cases were of unknown etiology
6. Hygiene practices of vulnerable groups	Actions taken in this area Status/Score: X	N	Indicator not auditable Limited effect of the national programme on Roma is reported (Okorn 2016)
7. Raising awareness about the importance of good drinking water and hygiene	Scope and results of raising awareness Status/Score: X	Y	Indicator not auditable The Strategy targets all groups; the AP only targeted educators, teachers, children, and parents
8. Setting hygiene requirements for swimming pools	Adopted regulations Status/Score: G	Y	Rules on minimum hygiene requirements for bathing water in swimming pools were adopted in 2015

Table 2 (continued)

Priority Goal 1: Ensuring population health by improving access to safe drinking water and appropriate municipal wastewater management			
Activities planned for achieving the expected results—AP Implementation of the Protocol on Water and Health. Activity 1 Improved access to safe drinking water, municipal wastewater management. Activities 2–7 Quality control of swimming water. Activities 8 and 9			
AP activities	Indicators[a] and performance evaluation of activities	Audit findings	
		Consistency	Additional comments (according to Table 1)
9. Swimming areas, monitoring water quality and informing the public	Marked swimming areas and informative dashboards placed Status/Score: W	Y	Monitoring and public information was provided for municipal swimming pools and coastal water swimming areas

AP action plan, *APR* action plan rationale, *GIS* geographic information system, *NIJZ* National Institute of Public Health

[a]Indicators have been defined by the AP or are based on the APR

specifically target children or adolescents but rather focus on the entire population. This presents a barrier in the assessment of associations between environmental quality and specific child and adolescent health outcomes.

The auditing highlighted the issue of inconsistent and indirect associations between specific available environmental quality data and potential (assumed) exposure with specific health outcomes. This is illustrated by an example (Fig. 2), though several have been observed during the audit (National Institute of Public Health 2020a; SEA 2020). Figure 2 shows the issues in determining associations between air quality data and health outcomes (National Institute of Public Health 2020b, c; SEA 2019; Statistical Office of the Republic of Slovenia 2019). Levels of PM_{10} and $PM_{2.5}$ were largely constant in the entire observed period ($\pm$ 5 µg/m^3 seasonal variations) (SEA 2019). That said, the hospitalisation of children and adolescents due to respiratory diseases decreased (National Institute of Public Health 2020b). In the city of Ljubljana, asthma-related hospitalisations increased by almost 35% from 2016 to 2019, while PM_{10} and $PM_{2.5}$ concentrations stayed the same or even decreased (National Institute of Public Health 2020c). Changes in hospitalisation due to respiratory diseases could be explained by several reasons not directly associated with air quality, such as behavioural changes, the impact of influenza season, varying health data records in the health information system, different meteorological conditions, variations in sensitivity, etc. Another issue in analysing the data involves inconsistencies in their interpretation, as highlighted in Fig. 2c. The plot presents PM_{10} and $PM_{2.5}$ concentrations, while the formal interpretation as provided by the data source defines them as 'population exposure data' (Statistical Office of the Republic of Slovenia 2019). Such inconsistencies hinder the process of evaluating the success of the Strategy.

In terms of the IWG's expected versus actual work, we conclude that there could have been greater transparency, including in its reporting of the Strategy implementation and of goals achieved (based on publicly available information). Moreover, transparency regarding the participation of interested parties is not clear. Collaboration between sectors, NGOs or youth organisations is reported (Ministry of Health of the Republic of Slovenia 2015); however, no information on the effectiveness of such collaborations are available.

Limitations

The audit was performed based on publicly available information. Additional data could improve the overall review of the Strategy and its impacts.

Conclusions

There is no clear evidence that the Strategy has contributed to positive changes in child and adolescent health in Slovenia during the period 2012–2019. Therefore, proposals for future work are as follows:

- Monitoring policy implementation and its results is crucial, and metrics should be defined in detail along with policy.
- Environmental health indicators should be fit for their intended purposes.
- Effective intersectoral work is needed (e.g. a permanent body comprising involved sectors) and is crucial for successful public health interventions (Bjegovic-Mikanovic et al. 2018).
- Audits should be properly planned and systematically performed. They should be understood as an integral part of monitoring any policy implementation. In this

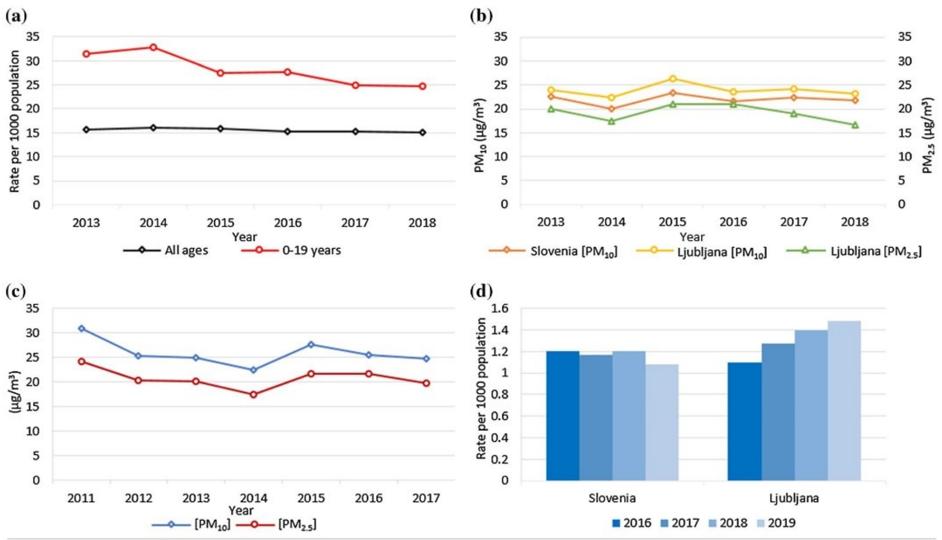
Table 3 Audit findings regarding priority Goal 3 (Slovenia 2012–2019)

Priority Goal 3: Disease prevention by improving indoor and outdoor air quality

Activities planned for achieving the expected results—AP
Reduction in exposure to particulate matter and other substances. Activity 1 (a–c)
AQ monitoring and forecasting. Activity 2
Intersectoral policies that reduce indoor air pollution, including radon. Activities 3 and 4

AP activities	Indicators and performance evaluation of the activities	Audit findings	
		Consistency	Additional comments (according to Table 1)
1. Encouraging municipalities to (a) Plan non-commercial infrastructure away from busy roads (b) Integrate sustainable mobility solutions into spatial policy, and (c) Introduce greater energy efficiency and RES Stricter control of individual household biomass combustion (and prevention of waste combustion)	1.1 Adopt and implement guidelines for considering human health in spatial planning Status/Score: W 1.2 Share of people living near busy roads Status/Score: O 1.3 Expand bicycle network Status/Score: O 1.4 Increased use of public transport Status/Score: G 1.5 Energy efficiency, household energy use and use of RES Status/Score: W 1.6 Control over household combustion systems Status/Score: W	P (e.g. unclear roles and obligations of municipalities)	1.1 The Spatial Planning Act of 2018 broadly defines health protection directions for municipal spatial planning (no direct rules) and encourages municipalities to provide the connectivity of green and built open spaces within and outside settlements 1.2, 1.3 No consistent and accessible data 1.4 Volume of public transport (rail and road) has increased from 39 to 41 million passengers; car use has also increased 1.5 Electric energy use has increased and so have the shares of RES and energy efficiency. Energy policy is set at the national level 1.6 No effective control over the quality of household wood combustion systems or the amount/type of waste burnt in households
2. Upgrading AQ monitoring and forecasting systems	2.1 Establish an air pollution forecasting system and a user-friendly web portal Status/Score: W 2.2 Number of measuring points and parameters Status/Score: W	Y	2.1 Implemented forecasting system and web portal. No data on the effectiveness regarding citizens' health improvement 2.2 National AQ monitoring network expanded from 18 to 22 measuring points. No change in number of measured parameters
3. Linking health and environmental inspections	An established inter-ministerial working group Status/Score: W	N	Not among activities of the Strategy. No public information on the group's establishment
4. Radon Monitoring: (a) Exposure at the national level (b) Recommendations on permissible concentrations in areas where children spend the most time (c) Remediation work on buildings, and (d) Measures to reduce radon concentrations	4.1 A radon atlas Status/Score: P 4.2 Annual measurements of radon concentrations at refurbished facilities Status/Score: O 4.3 Proportion of remediated buildings Status/Score: X 4.4 Use of materials and construction methods to prevent elevated radon concentrations Status/Score: X	N	4.1 Not consistent. Radon is discussed in another goal of the Strategy, not in AQ monitoring No radon atlas. A list of municipalities with higher potential of elevated radon levels is available 4.2 No data available 4.3 Indicator not auditable. No definition of 'buildings in need of remediation', no remediation specifications, etc 4.4 Indicator not auditable. No specifics on construction materials and methods, sectors for implementation, etc

AP action plan, *AQ* air quality, *RES* renewable energy sources



PM_{10} is particulate matter 10 µm or less in diameter; $PM_{2.5}$ is particulate matter 2.5 µm or less in diameter

Fig. 2 Air quality and adolescent health in Slovenia between 2013 and 2018. **a** Annual hospitalisations due to respiratory conditions by age group in Slovenia from 2013 to 2018; **b** concentrations of PM_{10} (Slovenia and Ljubljana) and $PM_{2.5}$ (Ljubljana) from 2013 to 2018; **c** potential exposure of urban population to PM_{10} and $PM_{2.5}$ air pollution in Slovenia from 2011 to 2017; **d** annual asthma-related hospitalisations in children and adolescents under 20 years of age in Slovenia and Ljubljana from 2016 to 2019

view, no public policy is to be excluded from performance auditing; as has been observed recently, not even those of the WHO (Nature 2020).

- Re-auditing is vital; without undertaking re-audits regularly, there is no way of knowing whether the midcourse corrections that have been made have improved the situation.
- Attention should be paid to the current and forthcoming issues affecting the health of young people: sleeping and eating habits, economic migration, changes in family structure, drop in fertility rates, poverty, etc.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors. Formal consent is not required for this type of study.

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4.3 Demonstrating the Use of a Framework for Risk-Informed Decisions with Stakeholder Engagement Through Case Studies for NORM and Nuclear Legacy Sites

The paper "*Demonstrating the use of a framework for risk-informed decisions with stakeholder engagement through case studies for NORM and nuclear legacy sites*", published in the Journal of Radiological Protection in March 2022 (doi: 10.1088/1361-6498/ac581), was written by B. Kontić, P. Black, S. French, A. Paulley, M. Zhu, T. Yankovich, M. Webster, S. Pepin, T. Bizjak, and M. Bohanec. My main contribution was to the second case study. I also contributed to writing the original draft, reviewing, editing, and visualization.

The paper addressed the first and the third hypothesis of this work. It was based on the work of Working Group 1, i.e., assessment and decision-making of existing exposure situations for naturally occurring radioactive material and nuclear legacy sites outlined in the second Modelling and Data for Radiological Impact Assessments (MODARIA II) programme established by the International Atomic Energy Agency (IAEA; IAEA, 2019; Zhu & Yankovich, 2018). Working Group 1's objective was to demonstrate and provide guidance for supporting decision-making through the example of case studies involving remediation of sites; it emphasizes an ongoing and iterative deliberation process between regulators, stakeholders, and experts.

The paper presents a framework for risk-informed decision analysis with the engagement of stakeholders. The three case studies include (1) remediation of uranium mining activities at Beaverlodge Lake in Northern Saskatchewan, Canada, (2) decision analysis support for waste disposal ore processing material site Boršt at RŽV, Slovenia, and (3) a radiological safety assessment of the Kepkensberg sludge basin in Tessenderlo area, Belgium. The Beaverlodge case study adopted Bayesian decision analysis methods, which combined scientific data with preferences for ranking possible actions according to expected utilities. The RŽV case study used two decision analysis tools: decision expert (DEXi) and Guided Interactive Statistical Decision Tools (GiSdT). The Kepkensberg case study followed IAEA's Improvement of Safety Assessment Methodologies (ISAM) (IAEA, 2004) and several risk assessment tools and models (AMBER, GoldSim, NORM And LegacY Site Assessment, Preliminary Remediation Goals (PRG)-dose compliance concentration calculator, and RESRAD-OFFSITE; Pepin et al., 2022).

The Beaverlodge and RŽV case studies demonstrated the main lessons in risk-informed decision-making, while Kepkensberg encompasses the overarching goal of ecological restoration, where radiological protection represents only a minor part. Beaverlodge also demonstrates the involvement of stakeholders, as discussed in the IAEA's MODARIA I and II programmes, while RŽV discusses the selection of decision analysis tools (DEXi and GiSdT) for supporting pending final decisions. Both case studies highlight the importance of stakeholder involvement and input, which requires a commitment to engagement and collaboration, transparency, and trust-building.

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PAPER

Demonstrating the use of a framework for risk-informed decisions with stakeholder engagement through case studies for NORM and nuclear legacy sites

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Keywords: decision analysis, risk assessment, stakeholder engagement, naturally occurring radioactive materials and nuclear legacy sites, remediation

Abstract

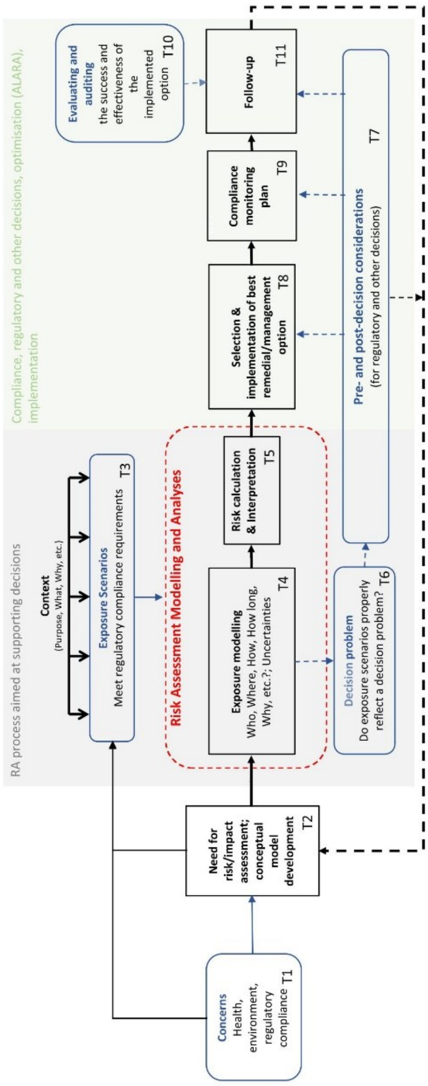
The international community has come a long way in developing a consensus that the remediation and management of naturally occurring radioactive materials and nuclear legacy sites will benefit from the use of the framework for risk-informed decision-making. Such a framework should ideally integrate risk assessment and decision-making. The framework presented in this paper specifically addresses the needs and expectations in the wider socio-economic and environmental context, as well as a narrower human health context. The framework was demonstrated as part of the International Atomic Energy Agency's second Modelling and Data for Radiological Impact Assessments Programme. Three case studies, which have used or could use this integrative approach, are used for illustration. The first concerns remediation from uranium mining activities at Beaverlodge Lake in northern Saskatchewan, Canada, engaging stakeholders (also called 'interested parties') in the decision-making process on further options. The second case study suggests how decision analysis could support the selection of the best option for waste disposal for uranium ore processing at Žirovski vrh, Slovenia, taking into account a potential landslide and migration of waste throughout the adjacent valley in the event of flooding. The third case study presents the process and results of radiological safety assessment of the Kepkensberg sludge basin in Tessenderlo area, Belgium both before and after the disposal of material from remediation of the nearby Winterbeek River. It illustrates how such assessments could interface with decision analysis for the purpose of supporting the regulatory decisions related to future approval of a waste disposal option. Results show that formal stakeholder engagement in decision analysis provides a strong contribution to objective, robust, and transparent decision-making not only for radiation protection area but also in others where health and environmental impacts are of concern. A number of recommendations for future work have also been made.

1. Introduction

Assessment of radiation doses and corresponding risks to humans and the environment requires the consideration of many features, events, and processes (van Dorp 1994, OECD 2000). For a particular environmental system, a variety of radionuclide transport and transfer processes take place leading to specific exposure conditions. Moreover, in accordance with the radiation protection principle of optimization of protection and safety, the risk assessment (RA) and management need to take into account a much wider range of socio-economic, land use, environmental policy and other issues in addition to those related to human health (IAEA 2014, 2022, Yankovich *et al* 2022 in this special issue). There is also a general need in many societies to engage stakeholders in the decision-making and remediation process and consult with them throughout the process. To address this overall need for risk-informed decisions with stakeholder engagement, with specific focus on the remediation of naturally occurring radioactive materials (NORMs) and nuclear legacy sites, the International Atomic Energy Agency (IAEA) established working group 1 on assessment and decision-making of existing exposure situations for NORM and nuclear legacy sites as part of the second Modelling and Data for Radiological Impact Assessments (MODARIA II) Programme. This integrated the related efforts in two working groups under MODARIA I regarding remediation strategies and decision aiding techniques and NORM and nuclear legacy sites (note: in terms of the term 'nuclear legacy' we understand that it pertains to residues—material and non-material—for which due care need to be taken as to avoid/minimise future detrimental consequences. This is in accordance with the NEA's description of the term and the caveats regarding its strict definition (NEA 2019)).

In both the MODARIA I and MODARIA II Programmes, decision-making on remediation was specifically discussed. MODARIA I focused on decision-aiding tools and processes for planning and implementation of remediation, with some emphasis on potential means to engage with stakeholders. That work also provided a high-level overview of decision analysis and surveyed many evaluation tools from several schools of decision analysis. The MODARIA II Working Group 1 had a subtly different objective of providing demonstration and guidance to support the decision-making through case studies involving remediation of sites (IAEA 2016). In particular, it emphasized an ongoing and iterative deliberation process between regulators, stakeholders, and experts. Several comparison studies were, therefore, undertaken to provide information on the applicability of the different RA tools considered, their different strengths, the consistency that might be expected between their results, and their appropriateness for different management decisions and contexts. These efforts are among the various other efforts of the IAEA and other international programmes that have common interests in this area, such as: the update of IAEA WS-G-3.1, which will be superseded by IAEA General Safety Guide, GSG-15, on remediation strategy and process for areas affected by past activities or events (IAEA 2022, Yankovich *et al* 2022 in this special issue); network on environmental management and remediation—determination of environmental remediation end states (ENVIRONET—DERES), intended to produce guidance on the determination of site end-state in remediation of different sites (IAEA 2020); risk perception, communication and ethics of exposures to ionising radiation (RICOMET); NEA EGLM—Nuclear Energy Agency Expert Group on Legacy Management (NEA EGLM) (NEA 2019); EU projects aimed 'to enhance uncertainties reduction and stakeholders involvement towards integrated and graded risk management of humans and wildlife In long-lasting radiological exposure situations' (TERRITORIES); and coping with uncertainties for improved modelling and decision making in nuclear emergencies (CONFIDENCE), established to perform radiation protection research focused on uncertainties in the area of emergency management and long-term rehabilitation. Among similarities of all these efforts we emphasize similarities of EGLM conclusions and recommendations with MODARIA work. One of these is uncertainty due to lack of data and records about nuclear legacy sites and their remediation which makes life difficult to regulators and also to managers and other stakeholders in terms of optimising decisions. A way out in such situations is wide stakeholder engagement and consultation with alocation of responsibilities, a holistic approach with sharing experience in planning and considering different types and aspects of hazards/impacts (e.g. competing safety interests, as between radionuclides, other contaminants and other hazards, and that this should be done on a balanced and proportionate basis in terms of assessment methods and criteria), options for their solution, different exposure situations, and prescriptive and performance-related regulations. The latter need to apply follow-up evaluations of the effectiveness and success of implemented protection option together with the concerned parties (stakeholders). All these issues have been considered in MODARIA II WG1 work and are captured in figure 1(b) with related recommendations.

Our aim in this paper is to present a framework for risk-informed decision analysis with engagement of stakeholders in deliberations on remediation and post-remediation management, recognising the wider context of the problem. We advocate the participation of stakeholders in a formalized, structured, decision analysis process and demonstrate this approach through three case studies for existing exposure situations needing remediation in which the proposed framework has either been used or could have been used. The first case study concerns remediation from uranium mining activities at Beaverlodge Lake in northern Saskatchewan, Canada. The study sought further remediation options by engaging stakeholders to obtain informed, clear, and documented feedback about the predicted benefits and costs of a range of remediation



(a)

Figure 1. (a) The traditional approach to modelling in remediation and regulation. (b) The use of decision analysis within remediation and regulation to articulate discussions between all stakeholders.

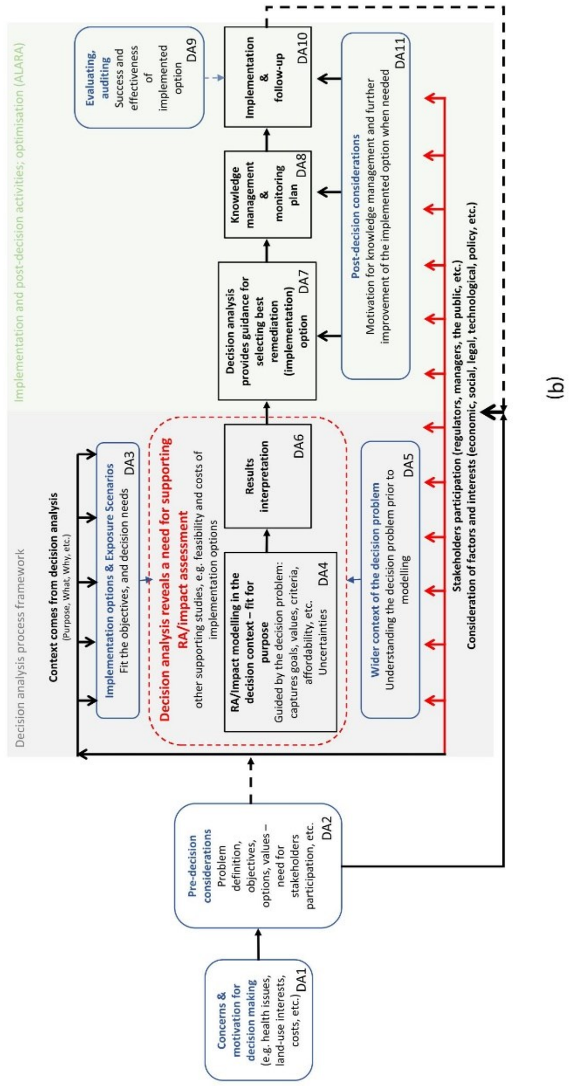


Figure 1. (Continued.)

options. The second case study illustrates how decision analysis could support the selection of the best option for waste disposal for uranium ore processing material at Žirovski vrh, Slovenia (RŽV), taking into account the potential for a landslide and migration of waste throughout the adjacent valley in the event of flooding (Križman and Zabric Bilić 2016). The third case study presents the process and results of radiological safety assessment of the Kepkensberg sludge basin in Belgium both before and after the disposal of material from remediation of the nearby Winterbeek River (see Pepin *et al* 2022 in this special issue). This study suggests how such assessments could interface with decision analysis for the purpose of supporting the regulatory decision-making process related to future approval of a waste disposal option.

Remediation and post-remediation management of radioactive contamination[10] normally involve four main activities (see also IAEA GSG-15; IAEA 2022):

(a) initial gathering of available site-specific information, including the possibility of implementing a site characterization study and identifying the potential need for remediation (i.e. to determine whether or not remediation is justified), identifying stakeholders and their interests, and selecting appropriate remediation criteria, including those related to regulatory compliance;
(b) identification of remediation options and their optimization in the broadest of senses balancing all objectives, followed by subsequent development and approval of the remediation plan;
(c) implementation of the remediation plan; and
(d) post-remediation management with possible release from regulatory control of all or part of a site from regulatory control.

Following the completion of each of these main activities, a decision should be made about whether to release the site (or part of it) for either restricted or unrestricted use or to proceed to the next activity (IAEA 2020). To support these decisions, assessment of radionuclide environmental transport and transfer and the potential risks to human health and the environment is needed to demonstrate compliance with regulatory requirements and the rationale for the safe use of remediated areas in the future. In recent years, decision-making regarding radioactivity on NORM and nuclear legacy sites has been moving towards using a risk-informed, performance-based approach (e.g. National Research Council 2014, IAEA 2019, 2022). The term, 'risk-informed decision-making', pertains to the assessment of human health and the ecological risk to support a decision-making process, as appropriate. However, there are many other contributing factors or objectives that inform a more complete decision analysis, such as worker safety, economic (cost) constraints, financing and insurance, economic health and employment of local communities, stakeholder expectations and preferences, environmental justice, and others (IAEA 2002, 2022, NUREG 1757 2006). Considerations such as these are increasingly being considered when addressing decommissioning, remediation, and waste management issues in a holistic manner that accommodates other relevant objectives in addition to regulatory compliance (IAEA 2002). The intent is to find the most appropriate solution that meets the objectives of the decision makers and stakeholders. This risk-informed decision-making process places traditional human health and ecological RAs within a more complete decision analysis structure. In this way, RA and decision analysis are interconnected activities; while RA provides the toolsets and risk information that are a valuable input to decision-making, decision analysis can identify the specific needs and guide the selection of exposure scenarios for conducting the RA, or can be used as part of justification and optimization in selecting feasible remediation options (IAEA 2020). This comprehensive approach to decision-making also articulates the deliberations that are necessary between regulators and other decision makers, while also drawing in and engaging additional stakeholders in the discussions (IAEA 2002).

Figures 1(a) and (b) illustrate the broad differences between the traditional approach to the use of RA modelling in the process of remediation within the legal and regulatory framework and the more participative, deliberative approaches that use decision analysis to organize the whole process, specify all the objectives, uncertainties, and concerns driving the process, and, in particular, involve stakeholders throughout, articulating discussion and building a shared understanding of the issues. The latter is emphasized by red arrows at the bottom of figure 1(b). The transparency, explicit reasoning, and auditability brought through formal decision analysis feeds naturally into the planning, knowledge, and process management needed during the implementation stages, which can take several years. The structured, explicit, auditable reasoning brought by decision analysis is also promoted in other literature, such as policy analysis, life cycle costing, and risk management (Miettinen and Hämäläinen 1997, Aven 2003, Daniell *et al* 2016).

[10] That is, those that are affected by contaminated residues from, for example, the mining industry (uranium, metals, etc), the phosphate industry, or past nuclear research or production activities. We note that the modelling tools and processes that are recommended herein have a much wider applicability to managing the risks from radioactivity arising, for example, from decommissioning and radioactive waste management.

In comparison with the traditional approach in figure 1(a), the participative, deliberative decision analysis with stakeholder engagement in figure 1(b) offers the advantages of addressing the following questions:

- does the scale of health, environmental, economic, and other risks justify a full analysis of possible remedial measures?
  Activities DA1 and DA2 in the pre-decision phase in figure 1(b) include more detailed consideration of the wider concerns and motivations for decision-making, problem definition, clarification of objectives than those activities in T1 and T2 of figure 1(a).
- How can an optimum decision be made for managing a particular contaminated area, considering all relevant contributing factors, for example, environmental and ecological impacts, worker safety, land use, environmental justice, and remediation costs?
  Activities DA1 and DA2 in figure 1(b) are more comprehensive than those in T1 and T2 in figure 1(a), ensuring that interests of stakeholders are appropriately identified and represented. Activities DA5 and DA11, then, encourage active and effective participation of these stakeholders in the evaluation and deliberation stages.
- What are the preferred, optimal remediation options?
  The decision analysis modelling and other supporting studies in activities DA4 and DA6 in figure 1(b) consider a broader range of objectives and contextual issues from DA3 than the radiation risk modelling of T4 and T5 in figure 1(a), driven by the focus on regulatory requirements in T3. It should be noted that there may be iterations between DA3, DA4, and DA6 as the analysis identifies further issues.
- Can it be demonstrated that the preferred remediation options can be undertaken safely, i.e. such that the implementation risks address competing safety interests, for example worker health and environmental protection, as between radionuclides, other contaminants and other hazards, and that this should be done on a balanced and proportionate basis in terms of assessment methods and criteria, and that are kept as low as reasonably achievable (ALARA)?
  This is a long-lasting task consisting of targeted risk and impact assessment, followed by knowledge management and further improvement of the implemented option when needed, regular auditing of the success and effectiveness of implemented option, and looping the results back to stakeholder participation in support of confidence building (activities DA7, DA8, DA9, DA10, and DA11 in figure 1(b)). Activities T7, T8, T9, T10, and T11 in figure 1(a) have a much narrower focus on regulatory issues.
- In addition to regulatory requirements, can long term safety be demonstrated in a manner that achieves public confidence?
  The continuous stakeholder participation with transparent iteration and feedback of key information throughout the decision-making process and implementation are designed specifically to foster and ensure public confidence (activity DA11 in figure 1(b)). Stakeholders are not explicitly involved in the activities in figure 1(a), though they may be informally involved.

In summary, operational differences between traditional and participative, deliberative approach could be described as follows:

- if one needs (wants) to demonstrate meeting requirements based on IAEA Basic Safety Standards or other quantitative standards and regulatory conditions which are scientifically adducible the usage of the process as described in figure 1(a) is adequate, while
- if such demonstration is to include stakeholder support then usage of the process as described in figure 1(b) is needed. Such approach is supported and further argumented by OECD NEA Forum on Stakeholder Confidence, naming it 'added value' in the very recent document explaining key terms on stakeholder confidence related to radioactive waste management (IAEA 2003, Lindborg *et al* 2022, NEA 2022 in this special issue).

Although the working group focused its attention on the objectives of remediation of NORM and nuclear legacy sites, we note again that the methodologies that we discuss here are also applicable to decision-making related to decommissioning, nuclear waste management, and, indeed, all decision-making related to managing the risks arising from radioactivity or other types of hazards. This is demonstrated in the IAEA's document on integrated approach to planning the remediation (IAEA 2009) which highlights the importance of linking decommissioning to remediation. Among other similarities between messages in this document and MODARIA II WG1 work, such as the role of non-technical (including value based) factors in decision making, it is important to note common ideas behind figures 1 and 2 in the IAEA document and figures 1(a) and (b) in this paper, especially the assessment and decision contexts as they are emphasized there.

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2. Risk assessment, decision analysis, and the process of decision-making

Before presenting the details of case studies in relation to figures 1(a) and (b), it will be helpful to first discuss, more generally, the concept of decision analysis and its relationship to RA. The approach adopted here is generally known as Bayesian (French and Rios Insua 2000, French *et al* 2009, Goodwin and Wright 2009, Gregory *et al* 2013, Keeney 2013, Abbas and Howard 2015), which includes the following features:

(a) it provides a comprehensive approach to dealing with uncertainty and value judgements in very sophisticated models;
(b) it is based on a well-established and explicit set of principles of rationality;
(c) it can draw evidence from both hard data and expert judgement;
(d) simpler, compatible sub-models can be used to focus on specific issues; and
(e) there is considerable experience in its wide application.

Figure 2 provides a broad overview of the Bayesian approach, which typically separates the issues into two distinct perspectives:

- Science: What might happen? This is where the scientific knowledge of the situation enters the analysis. What remedial actions might be taken? What will be the consequences of these actions? How uncertain are the consequences?
- Values: How much do the different potential consequences matter? This is where the decision makers and stakeholders have to deliberate on the impact that the consequences will have on each party.

The science side of the figure corresponds broadly to conventional RA, including modelling of uncertainties with probabilities. If, as is often the case, there is a need to acquire more data to reduce the uncertainties, prior assessments are combined with the data to update the probabilities (Zapounidis and Pardalos 2010, Parnell *et al* 2013). Also tiered or graded approaches to assessments, e.g. ERICA, are useful in such situations where later stages of assessments may apply information from most recent studies (Beresford *et al* 2007, IAEA 2009; Brown *et al* 2016).

The values side corresponds to what may have been conducted, in the past, by deterministic cost-benefit analysis. The Bayesian approach extends this by using multi-attribute utility functions, which enable easier valuations of non-tangibles (e.g. preferences for different possible outcomes of a decision), a formal introduction of attitudes to risk in the face of uncertainties, and more intuitive support for deliberations between decision makers, regulators, and other stakeholders (Sjöberg 1999, Slovic 2000, Andersson 2001, IAEA 2002, 2009, Dyer 2005, Hsu and Sandford 2007, Ishizaka and Nemery 2013, French and Argyris 2018). The methods described in these references have been used in many environmental areas including nuclear safety and radiation protection. But the uptake is not as full as we would wish (Modaria I and II working groups 1 would not have happened if they were!). French and Argyris (2018) discuss some of the problems in making them more commonly used. Given the length of the current paper we feel that to explore case studies and the reasons that we are still promoting them after a couple of decades from their first use would be to extend the paper beyond our main aims. The science and values perspectives are drawn together by exploring expected utility rankings through a variety of sensitivity and robustness analyses. If discussions suggest that important elements may have been omitted from the modelling and analysis, the process may iterate until the decision makers feel that they have gained enough understanding that the analysis is adequate, i.e. it is sufficiently detailed for them to make a confident decision. On the right, the figure shows the three decision-making steps:

- Pre-decision—general discussions and investigations in which the issues are formulated and modelled.
- Decision-making—a range of quantitative explorations of the model(s) to build an understanding of the issues, their balance, and ultimately, to recommend a decision.
- Post-decision—interpreting the model recommendation into real-world actions and risk managing their implementation.

2.1. Brief description of the case studies

2.1.1. Case study 1: Beaverlodge

During the period of 1952–1982, uranium mining activities, on a site with three mineshafts and significant underground workings, took place north-east of Beaverlodge Lake in northern Saskatchewan, Canada. There

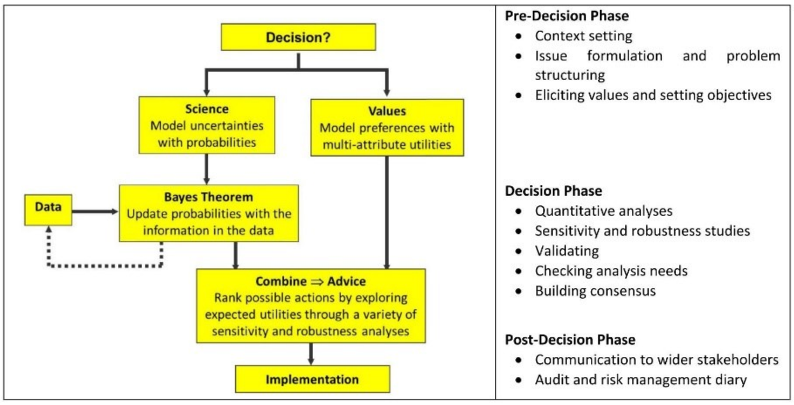

Figure 2. Bayesian RA and decision analysis.

are many lakes and other aquatic features in the area. From 1982 to 1985, the Beaverlodge mine was decommissioned and reclaimed following a plan approved by the federal and provincial regulators. This was the first Canadian uranium mining operation to be subjected to regulatory approval of a formal decommissioning and remediation strategy. Since 1988, the Cameco Corporation, henceforth Cameco, has conducted environmental monitoring and investigations, as well as necessary maintenance on the decommissioned Beaverlodge properties, on behalf of the Canadian Government (Cameco Corporation 2012, Webster and Hockley 2013). This monitoring and maintenance phase had been expected to last some 10 years from the end of decommissioning in 1985, but had to be extended, as there was no acceptable regulatory framework to accept the decommissioned properties back to Provincial Government (Province of Saskatchewan) control. In addition, during the post-remediation period, there were increased regulatory expectations and requirements; for example, for both uranium and selenium in aquatic environments. In 2007, the Saskatchewan Institutional Control Program was introduced with legislation establishing further regulatory requirements for decommissioned sites. The programme also established a process through which sites, once acceptably remediated and released from regulatory control, could be returned to the Province. This catalysed a process of investigating potential remediation options that could be reasonably implemented on the Beaverlodge properties to address residual risks, and in 2009, a process of engagement with stakeholders was initiated, recognising a wide range of criteria.

The decision-making process had the overall objective of obtaining informed, clear, and documented feedback about the predicted benefits and estimated costs of a range of remediation options from a range of stakeholders. It involved three broad stages. Firstly, an options identification workshop was held in 2009 with key interested parties to build a common understanding of all issues and concerns, possible remediation techniques, and investigations that would need to be completed before any detailed remediation strategy could be specified and initiated. The second stage involved many investigations and quantitative analyses to predict the effectiveness of different remediation options. The third stage again brought together the interested parties in an options evaluation workshop to undertake a more detailed evaluation of possible remediation strategies and provide feedback for Cameco to consider while developing the path forward. After the 2009 workshop, Cameco identified over 20 studies that needed to be performed, which they undertook in the three years that followed. These were used to facilitate the development of a quantitative site model (QSM), which modelled the environmental transport and pathways. The QSM enabled the prediction of concentrations of constituents of potential concern (e.g. uranium, radium, and selenium) and predicted changes in the residual risk profile as a result of the implementation of various remedial actions being considered. In addition, Cameco estimated the order of magnitude costs for each of these potential remediation options.

In April 2012, a further workshop was held to discuss and evaluate remediation strategies. Cameco used the results of the options evaluation workshop in developing a path forward plan (Cameco Corporation 2012).

2.1.2. Case study 2: Uranium mine at Žirovski vrh (RŽV), Slovenia

The uranium mine at Žirovski vrh consists of three main facilities (the Mill Site, the Waste Pile Jazbec, and the Mill Tailings Boršt). The mine is in the last phase of closing. Two facilities have already been remediated and closed: the Mill Site was remediated and turned into an economic zone in 2000 and the Waste Pile Jazbec was closed in 2012. The third facility—the Mill Tailings Boršt—is still under remediation. The site is on a hill above the inversion altitude to allow for radon dispersion and to minimize its impact on the population in the adjacent valley. Altogether, around 610 000 tons of the tailings are deposited in this facility, total activity is 48.8 TBq (Resolution 2016). The waste at Boršt started sliding down after a heavy rainfall event in November 1990. The sliding velocity was in the range of several cm/year. To control or stop the sliding, a drainage tunnel was constructed in 1995, but it was not effective. After subsequent heavy rainfall events—the last in 2016—the regulatory authority the Slovenian nuclear safety administration (SNSA) required improvement of the drainage efficiency with consideration of additional monitoring. There was concern about waste slipping down to the adjacent valley and widely dispersion throughout the valley in case of flooding. A preliminary dose assessment for individuals living in the valley showed values exceeding the annual dose limit of 1 mSv yr^{-1} (Križman and Zabric Bilić 2016). The final closing activities have been deferred until the remediation provides dropp of the sliding velocity to the required 1.5 cm yr^{-1} (Safety report on remediation of Mill Tailings Boršt 2007, Geotechnical report 2010, Resolution 2016). This requirement has still not been achieved (Klemenčič 2019), next evaluation is planned in 2021 (Klemenčič 2020).

The overall situation and approach to identifying and comparing remediation options have been regularly discussed since 1990. In 1994 and 1995 the first comparative evaluation of the three possible remediation options (options A, B, C—see brief description below) has been made (IJS 1995). Option A with a drainage tunnel as the key measure against sliding of the waste was selected in 1995. The tunnel did not stop sliding, only reduced its velocity to 2–7 cm yr^{-1} (Klemenčič 2019). The most recent discussions in 2018 with the regulators—the SNSA, the Ministry of the Environment and Spatial Planning (MESP), the Mining Inspectorate at the Ministry of Infrastructure (MI), and the Agency for Radioactive Waste Management (ARWM) led to the identification of two possible approaches to final remediation: SNSA and the ARWM proposed further work to improve the performance of the drainage tunnel, while MESP suggested developing a more comprehensive RA as a basis for final decision-making, although MESP did not articulate how the results of this assessment will be used in decision-making (Kontić 2018, MODARIA II WG1 Interim Meeting 2018). MI has not expressed an opinion on the issue yet. Moreover, the participation of stakeholders in the decision process was not defined; therefore, further discussion and agreement are needed. One of the basis for this discussion is the decision analysis and its results as presented in this paper.

The remediation options identified and discussed since the early 1990s include the following:

- Option A: maintaining the status quo, involving additional work to improve the efficiency of the drainage tunnel with the aim of preventing further sliding of the waste;
- Option B: removing the tailings and disposing of them in the mine pits for long-term (permanent) isolation of the waste;
- Option C: removing the tailings and disposing of them at the Jazbec site to avoid the sliding and incidental dispersion of the waste throughout the adjacent valley in case of heavy rains.

After selecting option A in 1995 the other two were not actual any longer.

2.1.3. Case study 3: Tessenderlo area, Belgium

This case study deals with remediation of the area contaminated by past activities by the company, Tessenderlo Chemie (TCH), which processed phosphate ore for the production of dicalciumphosphate. Details of the situation and the need for remediation can be found in the article by Pepin *et al* (2022) in this Special Issue of Journal of Radiological Protection.

The decision context for the remediation concept of the Tessenderlo area is complex; radiation protection considerations are not the driving factor in the decision-making process. The significant chloride and contamination by heavy metals also form the basis of the risk analysis and the remediation plan for the Winterbeek River. Remediation needs to comply with the overarching goals of achieving ecological restoration of the marshland area adjacent to the site, and of integrated water management—including the control of flooding in the area.

2.2. Decision analysis methods and tools

The decision-making process for the Beaverlodge site followed the method described in the literature (French *et al* 2009, Goodwin and Wright 2009, Gregory *et al* 2013, Parnell *et al* 2013), similar to that depicted in figure 1(b). It is the Bayesian decision analysis method that combines scientific data with preferences (i.e. values someone places on something, e.g. objectives, concerns) towards ranking the possible actions according to expected utilities.

For the RŽV case study, two decision analysis tools were used: decision expert—DEXi (Bohanec 2020); and Guided Interactive Statistical Decision Tools—GiSdT (Neptune and Company Inc 2017). DEXi applies DEX methodology; it is a hierarchical and qualitative multi-criteria decision-making method (Dyer 2005, Saaty 2008, Bohanec *et al* 2013, Moshkovich and Mechitov 2013, Trdin and Bohanec 2014). GiSdT applies structured decision-making (SDM) evaluation.

For the RA of the Kepkensberg/Tessenderlo case study, the IAEA's Improvement of Safety Assessment Methodologies (ISAM) approach (IAEA 2004) was followed. Several RA tools were applied, including, for example, Amber, the NORMALYSA (NORM and Legacy Site Assessment) software tool, and RESRAD-OFFSITE (Pepin *et al* 2022 in this special issue).

3. Results

3.1. Results of applied decision analysis and RA

3.1.1. Case study 1: Beaverlodge

As mentioned earlier, there were three phases of the decision analysis process for Beaverlodge site remediation: The Options Identification Workshop; the investigations; and the options evaluation workshop (Webster and Hockley 2013). Due to space limitations of this paper, we have only summarized the results of the third phase. The options evaluation workshop began with a presentation of remediation options to the participants. Each option was fully described, including its remedial effects as predicted by the QSM and its estimated cost. The modelling assumptions that had been made were also clearly explained. Once each option had been presented, participants were asked to identify the most pertinent 'pros and cons'. This stimulated a discussion of the option itself, as well as an exploration of the assumptions underpinning the QSM modelling and cost estimates. Each group of interested parties then evaluated each option. The evaluations were captured in a consistent manner using agreed terminology with each group stating whether it 'strongly agreed', 'agreed', 'disagreed', or 'strongly disagreed' with each statement (see table 1 for an example). When there was significant disagreement between the various interested parties, the reasons for the disagreement were discussed and captured. However, despite the varied perspectives of the participants, there were many points of agreement and consistent evaluation of options. The 'do-nothing' option was found to be unacceptable by all participants. In general, however, participants did not think that large-scale remediation options would improve environmental conditions or reduce ecological or human health risks, at least not in relation to their high cost. There were a few options identified that had relatively low cost and measurable local benefit, and all groups agreed that those should be the focus of further actions. Cameco used the results of the options evaluation workshop in developing a path forward plan for remediation of the Beaverlodge properties (Cameco Corporation 2012).

3.1.2. Case study 2: RŽV

In DEXi, option suitability is the top attribute of the decision problem. Attribute scales determine the qualitatively expressed categories that each attribute can attain (e.g. high, medium, low; not suitable, less suitable, suitable, excellent; and each of these have appropriate and transparent quantification behind them). Utility functions determine how different combinations of lower attribute values aggregate into the values of the attributes above them. Based on the utility functions, the decision model aggregates each of the option values from the bottom up (Bohanec *et al* 2013).

The result of the decision analysis, as presented below, has been produced without participation of regulators or stakeholders. Besides a review of the decision analysis and decision-making up to 2019, especially with regard to the consideration of remediation options A, B, and C in 1990s, its aim was to investigate what additional remediation work could be appropriate in the current situation to prevent the sliding at Boršt.

The evaluation using GiSdT was based on the objectives to be achieved by each of the remediation options. The hierarchy of objectives was determined based on assumed preferences of stakeholders (figure 3). Categorical or continuous measures were determined to enable the evaluation of success of each objective in the structured decision.

Table 1. Evaluation example from the options evaluation workshop (Hovdebo *et al* 2012).

	Stakeholder						
Objective	Uranium city	Northern Saskatchewan environmental quality Committee	Saskatchewan Ministry of Environment	Canadian Nuclear Safety Commission	Other federal	Cameco A	Cameco B
This option will protect the safety and health of local people	Agree	Disagree	Disagree	Disagree	Neutral	Neutral	Neutral
This option will protect fish and animals within the Beaverlodge mine area	Disagree	Disagree	Disagree	Neutral	Disagree	Disagree	—
This option will improve water quality near the mine area	Agree	Agree	Neutral	Agree	Agree	Agree	—
This option will improve recovery times of Beaverlodge Lake and downstream water bodies	—	Disagree	Disagree	Disagree	Disagree	Strongly disagree	—
This option will allow traditional use of land and water in the area	Disagree	Disagree	Disagree	—	—	—	—
This option will present good opportunities for local businesses and workers	Agree	Disagree	Agree	—	—	Disagree	—
This option will fit into the local landsacpe	Neutral	Disagree	Neutral	—	—	Agree	—
This option's implementation risks and short-term impacts will be acceptable	—	Neutral	Agree	—	Agree	Agree	Neutral
This option will be technically feasible	—	Agree	Agree	Agree	Agree	Agree	Agree
This option will be reliable over the long term	—	Neutral	Agree	Agree	Agree	Agree	Agree
This option meets the standard of good mine closure practice elsewhere	—	Disagree	Agree	Agree	Agree	Agree	Agree
This option will meet applicable provincial and federal regulations	—	Disagree	Neutral	Neutral	Neutral	—	—
This option will allow the site to be handed over to institutional control	—	Disagree	Agree	Neutral	—	—	Agree
This option will be a good use of public funds	Neutral	Disagree	Disagree	Agree	Agree	Neutral	Neutral

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Figure 3. Objectives hierarchy.

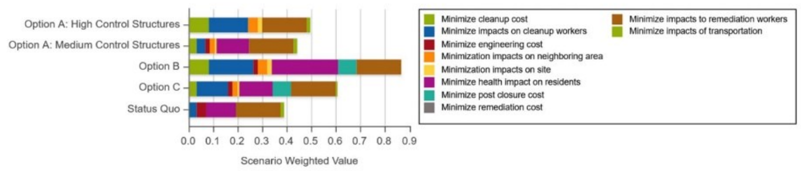

Figure 4. Consequence chart.

The decision analysis options in GiSdT were as follows:

- 'Option A'[11]:
  - 'Status Quo' (existing state of the drainage tunnel; no additional structures or measures).
  - 'Medium control structures' (clean-up of the clogged perforated drainage collection tubes in the drainage tunnel—performed in 2018 and 2019).
  - 'High control structures' (additional structures around the site for preventing background water infiltration into the mill tailings and beneath shales, marls, sandstones and conglomerates, which also slide together with the mill tailings; regular clean-up of the clogged drainage collection tubes will be needed).
- 'Option B' includes the removal of mill tailings from the Borst site and disposal in the mine pits.
- 'Option C' includes the total removal of mill tailings from the Borst and disposal on the Jazbec site.

Evaluation of the performance of the options was made using a consequence table and Bayesian network (Neptune and Company Inc 2017). The consequence table approach (figure 4) indicated that additional control structures improve the performance of option A—status Quo. The high control structures option is better than the medium control structures option. Option B as the best one.

The Bayesian network approach involved building a conceptual model to define causal links of the decision analysis model as shown in figure 5.

The Bayesian network evaluation indicated similar results as the consequence table approach. However, the introduction of the probabilities of the processes and the objectives indicators which measure objectives' success connected with each option reduces the differences between them. The status Quo and other two sub-options of A are valued relatively better compared to the consequence table approach (see figure 4) and may not be disregarded when making decisions.

[11] It should be noted that Option A is extended compared to what was considered using the DEXi decision analysis model. Options B and C, despite they are not actual any longer, were used in this decision analysis for the purpose of comparing DEXi and GiSdT.

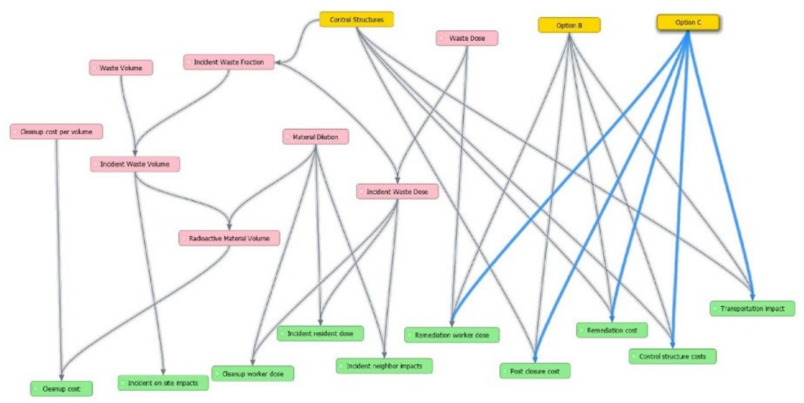

Figure 5. Bayesian network; yellow = options; pink = processes; and green = objectives indicators.

3.1.3. Case study 3: Kepkensberg/Tessenderlo

Different models and tools have been tested (AMBER, GoldSim, NORMALYSA, PC-CREAM08, PRG-DCC calculator, and RESRAD-OFFSITE). While the models showed some differences in their quantitative results for the end-points of the calculations—e.g. due to different assumptions regarding default values of parameters—they provided a fairly good qualitative agreement, as these differences were inside one order of magnitude. The radiological dose assessments as input for in the decision-making process was, thus, rather consistent regardless of the model applied. Details could be found in (Pepin *et al* 2022) in this special issue.

In the context of regulatory decision-making, the results of the radiological RA show that the annual dose limit of 1 mSv yr^{-1} in a planned exposure situation as the permitted dose is unlikely to be exceeded. It can, therefore, be concluded that these results support the hypothesis that it is acceptable from the regulatory point of view to dispose of the Winterbeek remediated sediment in the Kepkensberg sludge basin. However, the imperative of remediation should always be to implement best available, reasonable option, i.e. to strive for the least damageable one from all different aspects, not only radiological (ALARA).

Radiation is generally subjectively perceived as a higher risk compared to other hazards; however, this is often not the case. Objectively assessing the magnitude of the dose impact provides public reassurance regarding the radiological aspects of the contamination and allows for a proper and objective balance evaluation of radiological risk with relative to all other factors affecting decision-making in a remediation process. For the remediation of the Tessenderlo site, the relatively moderate dose impact confirms the appropriateness of the approach taken, where the chemical components of the contamination and the ecological restoration of the river formed the basis for the decision-making process.

3.2. Findings of the overview of the elements of figure 1(b) in selected case studies

The Beaverlodge case study is closest to the desired level of integrating decision analysis and RA with active and effective participation of stakeholders. It covers all the elements of a participative, deliberative approach, as presented in figure 1(b). This case study could serve as a reference for other situations where remediation of NORM or other types of nuclear legacy sites is needed.

The Slovenian case study (RŽV) reveals a situation that is closer to figure 1(a) than figure 1(b). The final decision is pending and it could be beneficial to take into account the decision analysis results described in this paper. According to the RŽV plan for 2021 (Klemenčič 2020), it is possible that the medium control structures option will be selected as final remediation option. Consideration of monitoring results for sliding velocities in 2020 and 2021, which need to be below 1.5 cm yr^{-1}, could add weight to the final decision. If, based on an evaluation of the monitoring data, the medium control structures option is found to be impractical (i.e. if it does not meet the 1.5 cm yr^{-1} criterion for sliding velocity), the high control structures option could be considered as a potentially feasible final remedial option. In such a situation, it seems reasonable to also reconsider options B and C, since both DEXi and GiSdT indicate that these options perform better than option A (see figures 4 and 6). As highlighted in the Beaverlodge case, in considering the possible remedial options for RŽV, a possible next step could be to communicate these decision analysis

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Attribute	A - Existing state	B - Mine pits	C - Jazbec site
OPTION_SUITABILITY	not_suitable	suitable	less_suitable
ENVIRONMENTAL PROTECTION	less-suitable	excellent	suitable
RADIOACTIVITY	not-suitable	suitable	less-suitable
WASTE PILE STABILITY	not-suitable	suitable	less-suitable
DEGRADATION	high	medium	high
EVENTS	low	low	low
EROSION	high	low	medium
TRANSPORT OF RADIONUCLIDES	high	medium	medium
WATER	high	medium	medium
INTRUSION	medium	low	medium
LAND-USE	suitable	suitable	suitable
SETTLEMENTS	suitable	suitable	suitable
RECREATION	less-suitable	suitable	less-suitable
RATIONALITY	not-suitable	less-suitable	not-suitable
THRIFTINESS	high	medium	high
MONITORING-MAINTENANCE	high	low	high
INTERVENTIONS	high	medium	high
EXPOSURES	not-suitable	less-suitable	less-suitable
OPTION STABILISATION	low	high	high
DIGGING	low	high	high
TRANSPORT	low	high	high
SOLIDIFICATION	low	high	high
CLEAN-UP	high	low	medium
WASTE SITE	medium	low	medium
NEIGHBORING AREA	high	low	medium

Figure 6. Evaluation results of the RŽV.

results in an open and participative manner to the decision makers (SNSA, MESP, MI, ARWM) and stakeholders (e.g. the municipality administration and farmers in the surroundings of the site) aiming to reach consensus on which remedial option is to be implemented, possibly following the approach in figure 1(b).

In the Belgian case study, radiation protection aspects formed only a minor part of the overall decision-making context (see Pepin *et al* 2022 in this special issue). The remediation process for the Winterbeek River was instead driven, on the one hand, by considerations related to the non-radioactive contamination (chloride and heavy metals) and, on the other, by considerations related to integrated water management and restoration of the ecological quality of the marshland area. Protection of the specific biota living in that area prevented, for instance, the application of intrusive remediation techniques (such as ground excavation) in the ecologically sensitive parts of the contaminated area. All these factors were discussed and weighed within a multi-agency committee with participation of different national and local authorities or institutes in charge of, for example, environmental protection, water management, nature conservation, and radiation protection.

An overview evaluating how well each of the three case studies aligned with the elements of more participative, deliberative approaches to decision analysis (depicted in figure 1(b)) is summarized in table 2.

4. Discussion

The key lessons in the area of risk-informed decision-making come from the Beaverlodge and the RŽV case studies, while the Kepkensberg case study demonstrates overarching goal of achieving ecological restoration of the marshland area and of integrated water management, where radiation protection aspects formed only a minor part of the overall considerations. The first of these cases demonstrates the approach, methods, and specificities regarding effective stakeholder engagement, as discussed in the IAEA's MODARIA I and II programmes, and the second case shows the transparent application of computer-aided decision analysis tools as support to pending final decision. Both case studies show that methods that genuinely seek stakeholder inputs need a firm commitment to engagement, transparency, and building trust among the stakeholders. The specific elements include:

- a clear and documented understanding of the decision-aiding process, including the participants, roles, and responsibilities. This has been done in case study 1 (Beaverlodge), but not in case study 2 (RŽV). Therefore, it is reasonable to conclude that omitting to make the decision process for RŽV open and participatory makes final decision uncertain and delayed;
- extensive consultation on the options to be evaluated. Again, the Beaverlodge case study shows success also with regard to identifying and evaluating remediation options in a wide participation and consultation with stakeholders, while such consultation in the case of RŽV was missing so far. It remains to be seen whether this will change in the future;
- sufficient time and financial resources for the supporting studies. Differences between case study 1 and case study 2 are conceptually same as above; and

Table 2. Overview of the elements of figure 1(b) in selected case studies.

Elements of figure 1(b) / Case Studies	Communication	Pre-decision phase		Decision-making phase		Post-decision phase	
	Stakeholder participation, inclusive consideration of factors and interests	Concerns and motivation for decision-making	Framework of considerations	Wider context of the decision problem, options for solving a problem	Decision analysis provides the need for supporting RA/impact assessment and other supporting studies. RA should follow the decision context—fit for purpose	Post-decision considerations	Implementation of selected option and follow-up
Beaverlodge, Canada	Yes (continuous stakeholder participation with transparent iteration and looping of key information throughout the decision-making process)	Yes (consideration of concerns and motivation for decision-making, problem definition, clarification of objectives)	Yes (an iterative process which starts with pre-decision considerations, continues with decision analysis, and ends with the decision on implementation option)	Yes (aiming to provide guidance for selecting best implementation option)	Yes (according to the results of stakeholder participation and decision analysis, which reveals the need for other supporting studies in addition to risk/impact assessment)	Yes (knowledge management, regular auditing of the effectiveness of implemented option, and looping back to stakeholder participation with confidence building)	Yes (follow-up and transparent and inclusive auditing of the success of implemented option are important contributors to public confidence)
Uranium mill tailings RŽV, Slovenia	Partly (continuous stakeholder participation is not established)	Partly (regulatory compliance is the key motivation)	Limited (regulatory requirements form the basis and framework of considerations)	Limited (regulatory requirements form the basis and framework of considerations)	On-going (decision analysis is to be further extended; participation of other stakeholders is envisaged)	Not applicable (final decision has not been made yet)	Not applicable (final decision has not been made yet)
Kepkensberg (Tessenderlo area), Belgium	Remediation was required to comply with the overarching goal of achieving ecological restoration of the marshland area and of integrated water management, including the control of flooding in the area. In this context, radiation protection aspects formed only a minor part of the overall considerations. The factors were discussed and weighed within a multi-agency committee with participation of different national and local authorities in charge of, for example, environmental protection, water management, nature conservation, and radiation protection.						

- participation by regulatory and other expert groups in the design and review of the supporting studies. This participation in the RŽV case study was formal and limited to regulatory requirements (i.e. according to legislation).

In dealing with multiple stakeholder groups, one must be prepared to 'speak their language' literally and metaphorically. That necessarily means that there can be no one decision-aiding method that is universally applicable. For example, the evaluation questions used in this case are likely to need extensive re-working for any other project. However, the basic philosophy of fully engaging stakeholders in 'plain English' dialogue, built on a foundation of rigorous decision analysis, has been successfully applied to other cases.

Lessons learnt regarding two decision analysis tools that were used in the RŽV case study are described here. Both DEXi and GiSdT are based on breaking and organizing the main goal or an objective of a decision problem into sub-problems, and consequently, creating a hierarchically organized tree of objectives (in GiSdT) or attributes (in DEXi). The DEXi evaluation is based on the tree of attributes that are aggregated into the main decision attribute for each option. Each attribute describes specific characteristic or performance of the options; nodes in the tree synthesise these specific characteristics/performances towards the main decision attribute (Bohanec 2020). GiSdT evaluation focuses on how the preference-weighed objectives of the decision problem are met by each option. Importantly, for GiSdT, the values and preferences of the interested parties need to be structured before the options become defined. Both DEXi and GiSdT use categorical scales and continuous measures. Additionally, the GiSdT Bayesian network evaluation enables the introduction of uncertainty of processes through the determination of discrete probabilities. The final step in GiSdT is the adaptive management step. DEXi does not directly include such a follow-up step after the decision is made and implemented. Instead, an iterative re-evaluation of the implemented option can be done using DEXi by introducing additional options and modifying the decision model accordingly.

More general discussion of how these methods improve the quality of decision-making may be found in Gregory *et al* (2013) and Spetzler *et al* (2016).

Regarding the application of different RA models and tools for the Belgian case study, the findings are presented and widely discussed in Pepin *et al* (2022) in this special issue.

Proposals for modelling improvements to better fit decision needs and contexts are given below in the form of statements and questions that should be considered on a case-by-case basis Griffault *et al* 2022, Thorne *et al* 2022). The proposals also come from the experience gained within the case study 3:

- Modellers should have possibilities to facilitate open communication with the decision makers and other stakeholders on issues that need to be known and identified through decision analysis and prior to risk modelling. Regarding radiological modelling in case study 3 (Tessenderlo site) this communication was limited and was concentrated on communication with Federal Agency for Nuclear Control.
- Conceptual modelling should be open to questions, proposals, views, and standpoints of the parties involved in problem-solving within the decision context. The experience from case study 3 is similar as above: assessors/analysts communicated among themselves and with Federal Agency for Nuclear Control.
- Scenarios should meet the needs and expectations of the decision makers. To achieve this, the decision makers and other stakeholders should be involved in the development of the assessment context, as well as other key components of risk modelling, such as conceptual model development, modelling scenarios to fit specific concerns and needs, and other components, as relevant. Since it was about a regulatory decision the needs and expectations considered were those from Federal Agency for Nuclear Control.
- Scenarios should clearly consider management options to be considered, compared, and finalized (e.g. engineered features and arrangements) and should facilitate optimization in support of decisions. Case study 3 considered one option only.
- Calculation timeframes should reflect decision needs. Scenarios should clearly present related epistemological modelling uncertainties, for example, pertaining to expected or assumed long-term societal and environmental changes, possible exposure situations, human behaviour, food availability and nutrition habits, non-work-related and work-related activities for time frames beyond several hundreds of years, and others, as relevant. The level of uncertainty around such factors would contribute to the overall confidence in the RAs. Modelling timeframes were not thoroughly examined and consulted in case study 3 so it remains to pay more attention to this issue in the future.
- Does modelling adequately represent the decision contexts for the final arrangement of the sites (end state) pertaining to implemented the remediation and management option? How is the end state determined?
- How to evaluate success of the modelling? Who are evaluators when the modelling and RA process follows the framework of figure 1(b)? Which indicators and measures are best in such evaluation and how much do they support credibility of modelling results—are they in any relation with objectives set in the assessment context and in a decision analysis framework? Should decision context and decision needs provide specific

measures of success? Should the measures include trust and respect among stakeholders throughout the process?

5. Conclusion

The international community has come a long way in developing a consensus that the remediation and management of NORM and other types of nuclear legacy sites will benefit from the use of the framework for risk-informed decision-making. Such a framework has been developed primarily in MODARIA I and II Programmes. In addition, several other programmes, networks, and projects have also contributed to this consensus; for example, ENVIRONET—DERES, RICOMET, NEA EGLM, TERRITORIES, and CONFIDENCE. New knowledge and lessons learnt through all these research and collaboration efforts have led to a number of recommendations for future work. It is proposed that these recommendations are considered for implementation in the follow up to the MODARIA II programme (Harmonized MEthods for Radiological Environmental Impact Assessment (MEREIA)), perhaps by means of specific case studies covering, for instance, decision concepts as captured in figure 1(b), integration of decisions, RA, improvements to model-data comparisons and their role to support the decision analysis, and related topics. If such integrated and targeted approach to MEREIA were also to include formal stakeholder engagement in decision analysis, it would be a strong contribution to objective, robust, and transparent decision-making not only for radiation protection (e.g. in support of optimization of protection and safety) but also for other areas where human and environmental impacts are of concern.

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Conflicts of interest

Authors and co-authors have no conflict(s) of interest with regard to submitting this article.

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RICOMET (available at: www.ssh-share.eu/ricomet2021/ricomet2020webinars)
TERRITORIES (available at: https://territories.eu)

4.4 Human Biomonitoring Data in Health Risk Assessments Published in Peer-Reviewed Journals Between 2016 and 2021: Confronting Reality After a Preliminary Review

The review "*Human Biomonitoring Data in Health Risk Assessments Published in Peer-Reviewed Journals between 2016 and 2021: Confronting Reality after a Preliminary Review*", written by T. Bizjak, M. Capodiferro, D. Deepika, Ö. Dinçkol, V. Dzhedzheia, L. Lopez-Suarez, I. Petridis, A. A. Runkel, D. R. Schultz, and B. Kontić, was published in the International Journal of Environmental Research and Public Health in March 2022 (doi: 10.3390/ijerph19063362). As the first author, I contributed to the conceptualization, methodology, investigation, data analysis, data curation and visualization, writing the original draft, and reviewing and editing.

The review includes papers identified through systematic searches in April 2021 using PubMed and Scopus search engines using pre-defined criteria. The acceptance criteria included papers published in the last 5 years, including HBM and HRA in the title, keywords, abstract, and focus on a specific population. Reviews or method development publications were excluded. In total, 36 publications were selected for the review. The review was performed with the help of the appraisal tool, which helps assess the clarity of the HRA elements and if HBM has been used in them. Appraised HRA elements are crucial for judging the overall quality of HRA (Fenner-Crisp & Dellarco, 2016).

Human biomonitoring (HBM) has the potential to improve the estimates of exposure and dose (Sexton et al., 1995) and has been emphasized by many as a way of improving HRA (Albertini et al., 2006; Louro et al., 2019; WHO & International Programme on Chemical Safety, 2001). However, the actual value of HBM in HRA practice remains to be clarified, despite a continuously increasing number of scientific publications per year about HBM and HRA since 2006. As a first of its kind, the review focuses on two questions: First, are fundamental elements of HRA considered in the publications about the practical integration of HBM data and HRA? Second, in which HRA elements is the use of HBM data clearly demonstrated and reported? The paper addressed the second, third, and fifth hypotheses guiding my doctoral research.

The paper's findings support the need for more significant work to improve the use of HBM in HRA and risk-informed decision-making. It also highlights the need to consolidate the understanding of the usefulness and limitations of HBM for HRA and within the environmental health paradigm, which is crucial for targeted risk management interventions. While the reviewed publications report some type of an assessment of risk, none evaluated or reported all the appraised HRA elements. In fact, most of them do not demonstrate the use of HBM in any of the appraised HRA elements, which limits any clear conclusions regarding the actual usefulness of HBM data within HRA or a broader risk analysis context. The suggested ways of improving the risk-informing potential of HRAs that use HBM data include the involvement of stakeholders, clarification of assessment and decision contexts in the early HRA stages, and transparent reporting of underlying assumptions of the HRA process.

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Review

Human Biomonitoring Data in Health Risk Assessments Published in Peer-Reviewed Journals between 2016 and 2021: Confronting Reality after a Preliminary Review

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Abstract: Human biomonitoring (HBM) is a rapidly developing field that is emphasized as an important approach for the assessment of health risks. However, its value for health risk assessment (HRA) remains to be clarified. We performed a review of publications concerned with applications of HBM in the assessment of health risks. The selection of publications for this review was limited by the search engines used (only PubMed and Scopus) and a timeframe of the last five years. The review focused on the clarity of 10 HRA elements, which influence the quality of HRA. We show that the usage of HBM data in HRA is limited and unclear. Primarily, the key HRA elements are not consistently applied or followed when using HBM in such assessments, and secondly, there are inconsistencies regarding the understanding of fundamental risk analysis principles and good practices in risk analysis. Our recommendations are as follows: (i) potential usage of HBM data in HRA should not be non-critically overestimated but rather limited and aligned to a specific value for exposure assessment or for the interpretation of health damage; (ii) improvements to HRA approaches, using HBM information or not, are needed and should strictly follow theoretical foundations of risk analysis.

Keywords: review; human biomonitoring; health risk assessment; exposure assessment

1. Introduction

Human biomonitoring (HBM) refers to measuring the presence and levels of substances in different human tissues (hair, blood, urine, etc.). Measured biomarkers are either markers of exposure or of an effect and provide aggregated information about different exposures through different pathways [1]. Despite confirming that an exposure occurred, the exposure biomarkers are actually direct measurements of a dose and not exposure. The differences between the two terms need to be acknowledged for appropriate HBM data interpretation within the environmental health paradigm [2] and especially in terms of exposure assessment for risk-assessment purposes (more on this issue is in the discussion section). Health risk assessment (HRA) is a method that uses "factual base to define the health effects of exposure of individuals or population to hazardous materials and situations" [3]. General principles and fundamental elements of HRA were established by the risk assessment "Red book" [3] and continue to form the basis of developing HRA, despite being the subject of extensive discussion in various notable publications since then [4–7]. HRA should not be viewed as an end in itself, but as a method for evaluating the relative merits of various risk-management options [6] and has been used to inform various decision makers in protecting human health and the environment from a range of threats [5]. HBM and HRA present potential for addressing environmental health and public health concerns. HBM unequivocally confirms whether individuals or populations have been exposed and can, when used with available epidemiologic [8], toxicological [9], and pharmacokinetic (modeling) data [10], help in the estimation of the amount of substance absorbed into the body, which could indicate potential health risks [11]. HBM can improve estimates of exposure and dose [12] and has been continuously emphasized to potentially improve HRA for both workers and the general population [13–16].

A 2006 publication by the National Research Council (NRC) identified only a few HRA cases based on biomarker-response relationships established in epidemiologic studies and noted that, despite the potential presented in HBM information, it only rarely reduced uncertainty in the practice of HRA [11]. More recent publications, checked randomly [17–19], do not report a change in this NRC observation. The analysis of the number of documents by year shows that the number of publications in the HBM area has been rising substantially since around 2006 (Figure 1). A similar trend can be observed in the number of documents per year published about both HBM and HRA.

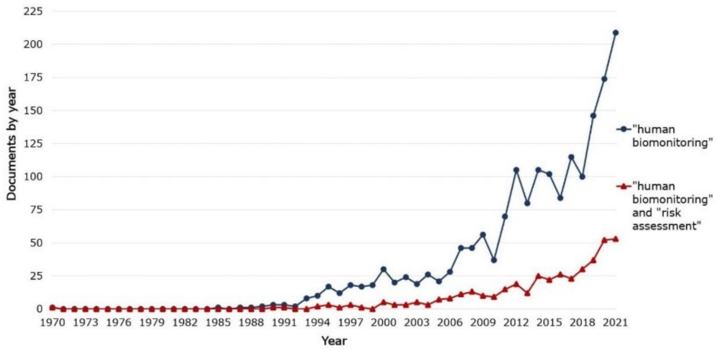

Figure 1. Documents by year for two types of searches using keywords on Scopus: "human biomonitoring" and "human biomonitoring" and "risk assessment" [20,21].

The interest in systematically checking the recent situation regarding the practice and usefulness of HBM data in HRA led us to design a review study of selected peer-reviewed publications published in the last five years (between January 2016 and April 2021). This review aimed to address two main questions:

1. Are fundamental elements of HRA [5] considered in the publications on the practical integration of HBM data and HRA?
2. In which HRA elements is the use of HBM data clearly demonstrated and reported?

This study also aimed to re-assess the validity of the observation by the NRC from 2006 that "the ability to generate new biomonitoring data often exceeds the ability to evaluate whether and how a chemical measured in an individual or population may cause a health risk or to evaluate its sources and pathways for exposure" [11] (p. 2).

2. Materials and Methods

2.1. Publication Search

The identification of peer-reviewed publications for the subject review matched the following criteria: publications had to involve both "human biomonitoring" and "risk assessment" in their title, keywords, or abstract and had to be published in the last five years. The PubMed (https://pubmed.ncbi.nlm.nih.gov/) and Scopus (https://www.scopus.com/) search engines were used. The publication search was performed on 30 April 2021. The following search queries were applied:

- PubMed: ((("risk assessment" [Title/Abstract] OR "HRA" [All Fields]) AND ("HBM" [Title/Abstract] OR "human biomonitoring" [Title/Abstract])) AND (y_5[Filter])) NOT (review [Title/Abstract]) Filters: in the last 5 years
- Scopus: (TITLE-ABS-KEY ("risk assessment" OR hra) AND TITLE-ABS-KEY ("Human biomonitoring" OR hbm) AND NOT TITLE-ABS-KEY (review)) AND (LIMIT-TO (PUBYEAR, 2021) OR LIMIT-TO (PUBYEAR, 2020) OR LIMIT-TO (PUBYEAR, 2019) OR LIMIT-TO (PUBYEAR, 2018) OR LIMIT-TO (PUBYEAR, 2017) OR LIMIT-TO (PUBYEAR, 2016)) AND (LIMIT-TO (DOCTYPE, "ar")) AND (LIMIT-TO (EXACTKEYWORD, "Risk Assessment")).

The search queries returned 83 records on PubMed and 140 on Scopus (Figure 2). Records of both databases were collated in Mendeley reference manager (https://www.mendeley.com, accessed on 11 March 2022). After the removal of the duplicates (n = 56), the remaining 167 records underwent eligibility screening. Eligibility assessments were performed by reviewing their titles, keywords, and abstracts based on the pre-defined eligibility criteria: articles had to focus on specific populations and the estimation/assessment/calculation/characterization of health risks in the selected population; however, review publications or method development publications were excluded. In total, 36 publications were selected, successfully retrieved, and included in the appraisal.

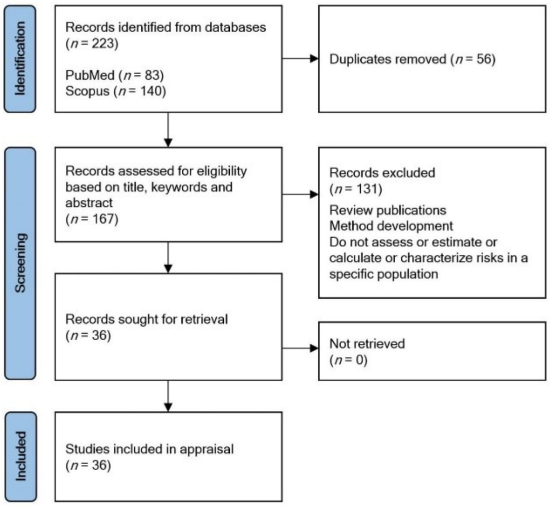

Figure 2. PRISMA flow diagram.

2.2. Appraisal Tool

A review of the presence and clarity of different fundamental HRA elements in publications about HBM and the assessments of health risks was performed with the help of a straightforward and transparent appraisal tool (see Supplementary file). It was designed for this particular review purpose and covers the evaluation of 10 selected HRA elements, namely the assessment context of HRA, dose/exposure-response relationship, exposure setting, exposure sources, exposure duration, exposed population, magnitude of risk, uncertainty of HRA results, options for mitigating/avoiding exposure, and transparency and clarity of the assessment process. These HRA elements are consistent with the core principles of HRA and risk analysis [3,6,12] and are among the proposed key elements for judging the quality of HRA [22]. The evaluation was performed by using a straightforward questionnaire and was, overall, both limited and preliminary. We intend to repeat the evaluation in the following years by involving a larger number of experienced experts and specialists in both fields of HBM and HRA.

The appraisal tool consisted of 10 appraisal questions about selected HRA elements (Table 1). Each of the selected HRA elements has various important aspects discussed in detail elsewhere [3,5,23,24]. To improve objectivity, the appraisal questions narrowed the focus regarding each HRA element and facilitated a clear "Yes" answer if the publication demonstrated that the HRA element had been clearly applied/reported (or "No" if it did not) and an "X" mark if it was clearly demonstrated that HBM data were used in a specific HRA element (if not, the column was left blank). Comments provided additional clarifications when appropriate. There were multiple discussions regarding the clarity of the appraisal tool among all persons involved in the review before and during the evaluation to improve the consistency of the review findings. The evaluation was performed by 10 of 14 NEUROSOME early stage researchers (ESRs) from different backgrounds and areas of interest between May and August 2021. NEUROSOME is a Horizon 2020 funded integrated training network that investigates causal associations among genetic predispositions, exposures to multiple environmental chemicals and neurodevelopmental disorders according to the exposome paradigm [25]. Within NEUROSOME [26] the ESRs conducted research in the leading research institutions in France, Greece, Italy, Slovenia, and Spain, and participated in different training activities and courses, which among other matters covered various aspects of HBM measurements and HBM data interpretation as well as selected topics related to different elements of HRA (e.g., hazard evaluation, dose–response evaluation, exposure assessment). Therefore, they were considered competent enough for reviewing selected publications. Every ESR appraised at least two publications that were related to their area of research and expertise as much as possible. Despite multiple discussions during the appraisal, there was no appraisal of a single publication by two or more ESRs in order to avoid the demanding step of harmonizing potential differences in their findings. Such an organization of the evaluation also contributed to its preliminary nature, which intentionally had a limited scope; the aim was to illustrate only the most general understanding of the covered topics among professionals with different backgrounds. A more comprehensive review with a wider scope and including more relevant professionals will follow this preliminary review.

Table 1. Selected health risk assessment (HRA) elements for the appraisal and related appraisal questions.

Appraised HRA Element *	Appraisal Question
Assessment context of HRA	Does the assessment clearly identify what is assessed and why at the start? Has assessment context been followed/applied in the HRA process?
Dose/exposure—response relationship	Is the applicability of the selected dose/exposure-response relationship for the assessment thoroughly discussed?
Exposure setting	Are the characteristics of the place of exposure clearly described?
Exposure sources	Are the major sources of hazardous material and/or activities causing the release(s) of hazardous material(s) into the environment identified?
Exposure duration	Is the duration and frequency of the exposure identified?
Exposed population	Is it clear who is really exposed (population/individuals, their number), and why are they exposed (e.g., their activities leading to exposure)?
Magnitude of risk	Are the types of the expected adverse outcomes, their severity and the probability of their occurrence identified clearly?
Uncertainty of HRA results	Are the major sources of uncertainty evaluated?
Options for mitigating/avoiding exposure	Are there any specific actions for avoiding or mitigating the exposure to the selected hazardous materials identified and/or proposed?
Transparency and clarity of the assessment process	Is it transparent and clear how was the assessment performed and its conclusions obtained?

* A more complete list and description of HRA process and all of its elements can be found elsewhere [3,5,6].

3. Results

The results and discussion are presented as a summary of the general findings. Subsections discuss conclusions regarding the dose/exposure-response and exposure assessment, the overall HRA process, its results and risk management, the value of HBM data for HRA and risk management, and the strengths and weaknesses of the study.

The limited review found that although the appraised papers reported some type of assessment of risks, with some claiming to perform an HRA, none of them evaluated all of the HRA elements included in the appraisal or provided an argument for why these elements were not addressed. Furthermore, the review of the publications did not provide any clear conclusions regarding the actual usefulness of HBM information within the risk analysis context—for the HRA, risk communication, and especially for risk management purposes. None of the HRA elements were included and assessed as clear for any of the appraised publications (Table 2). Most of the appraised publications did not clearly demonstrate the use of HBM for any of the HRA elements. The majority of the appraised publications were, despite stating otherwise in their abstracts, titles, or keywords, not actual examples of (comprehensive) HRAs, but were rather HBM-based exposure assessment studies, which, while undeniably confirming that the exposure to a detected substance or its metabolite occurred, lacked clear information regarding the other important exposure assessment estimates stressed by Sexton et al. [12]: for instance, activities causing the exposure, exposure sources, pathways, population exposed, etc. The limited assessment of risks in the studies was mostly performed through various types of threshold value approaches, such as comparisons with guidance values, acceptable daily intake values, reference doses, etc. The observation of the NRC that the ability to generate new HBM data exceeds the ability to assess whether and how a substance measured in an individual or population can cause health risks, or to evaluate exposure sources and pathways seems to be as strong and relevant as it was 15 years ago [11]. The Supplementary file includes a collection of comments accompanying the responses collected in Table 2.

Table 2. Clarity of HRA elements (Yes or No) and the use of human biomonitoring in specific HRA elements (marked with X).

Publication Title	Assessment context of HRA *	Dose/exposure—Response	Exposure Setting	Exposure Sources	Exposure Duration	Exposed Population	Magnitude of Risk	Uncertainty of HRA Results	Options for Mitigating Exposure	Transparency and Clarity
1. Biomonitoring and health risks assessment of trace elements in various age- and gender-groups exposed to road dust in habitable urban-industrial areas of Hefei, China [27]	No X	No	Yes	No	No	Yes	No	No	Yes	Yes
2. Health Risk Assessment of Trace Metals Through Breast Milk Consumption in Saudi Arabia [28]	Yes X	No	No	Yes	No	Yes	Yes X	Yes	No	Yes
3. Exposure levels, determinants and risk assessment of organophosphate flame retardants and plasticizers in adolescents (14–15 years) from the Flemish Environment and Health Study [29]	No X	No	Yes	Yes	No	No	No	Yes	No	Yes
4. Organophosphate pesticide exposure in children in Israel: Dietary associations and implications for risk assessment [30]	No	No	No	No	No	No X	No	Yes	Yes X	Yes
5. Exposure of Portuguese children to the novel non-phthalate plasticizer di-(iso-nonyl)-cyclohexane-1,2-dicarboxylate (DINCH) [31]	No	No	No	No	No	No	No	No	No	No
6. Exposure and Risk Assessment of Hg, Cd, As, Tl, Se, and Mo in Women of Reproductive Age Using Urinary Biomonitoring [32]	No	No	No	No	No	No	No	No	No	No
7. Exposure and risk assessment of the Czech population to chlorinated pesticides and polychlorinated biphenyls using archived serum samples from the period 1970 to 1990 [33]	Yes X	Yes X	Yes X	Yes X	No X	No X	No	Yes	No	Yes X
8. Risk assessment of deoxynivalenol in high-risk area of China by human biomonitoring using an improved high throughput UPLC-MS/MS method [34]	No	No	No	No	No	No X	No	No	No	Yes
9. Risk assessment of exposure to phthalates in breastfeeding women using human biomonitoring [35]	Yes X	Yes X	No	Yes X	No	Yes X	No	Yes	No	Yes
10. Evaluation of human biomonitoring data in a health risk based context: An updated analysis of population level data from the Canadian Health Measures Survey [36]	No	No X	No	No	No	No X	No	Yes X	No	Yes
11. Biomonitoring of non-persistent pesticides in urine from lactating mothers: Exposure and risk assessment [37]	No	No	No	No	No	No	No	No	No	No
12. Children's exposure to polycyclic aromatic hydrocarbons in the Valencian Region (Spain): Urinary levels, predictors of exposure and risk assessment [38]	Yes	No	Yes X	Yes X	Yes X	Yes X	Yes X	No	No	Yes
13. Evaluation of exposure to phthalate esters and DINCH in urine and nails from a Norwegian study population [39]	Yes X	Yes X	No	Yes	No	Yes X	No	No	No	Yes
14. Wastewater-based epidemiology for tracking human exposure to mycotoxins [40]	No	No	No	Yes	No	No X	No	Yes	No	Yes

Table 2. *Cont.*

Publication Title	Assessment context of HRA *	Dose/exposure—Response	Exposure Setting	Exposure Sources	Exposure Duration	Exposed Population	Magnitude of Risk	Uncertainty of HRA Results	Options for Mitigating Exposure	Transparency and Clarity
15. Biomonitoring of polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (dl-PCBs) in human milk: Exposure and risk assessment for lactating mothers and breastfed children from Spain [41]	No	Yes X	No	No	No	No	No	Yes	No	No
16. Predicted Mercury Soil Concentrations from a Kriging Approach for Improved Human Health Risk Assessment [42]	Yes X	No	Yes	Yes X	No	Yes	No	No	No	Yes
17. Lead and mercury levels in repeatedly collected urine samples of young children: A longitudinal biomonitoring study [43]	No	No	No	No	No	No	No	Yes X	No	No
18. Exposure to the plasticizer di(2-ethylhexyl) terephthalate (DEHTP) in Portuguese children–Urinary metabolite levels and estimated daily intakes [44]	Yes X	Yes X	Yes	No	No	Yes	No	No	No	Yes X
19. Exposure and health risk assessment of secondary contaminants closely related to brominated flame retardants (BFRs): Polybrominated dibenzo-p-dioxins and dibenzofurans (PBDD/Fs) in human milk in Shanghai [45]	No	No	No	No	No	No	No	No	No	No
20. Integration of biomonitoring data and reverse dosimetry modeling to assess population risks of arsenic-induced chronic kidney disease and urinary cancer [46]	Yes X	Yes X	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
21. Exposure assessment of Portuguese population to multiple mycotoxins: The human biomonitoring approach [47]	No	No	No	No	No	No	No	Yes X	No	Yes X
22. Glyphosate in Portuguese Adults- A Pilot Study [48]	No	No	No	No	No	No	No	Yes	No	No
23. Exposure of nursing mothers to polycyclic aromatic hydrocarbons: Levels of un-metabolized and metabolized compounds in breast milk, major sources of exposure and infants' health risks [49]	Yes X	No	Yes	No	Yes	Yes	No	No	No	Yes
24. Biomonitoring of mercury in hair of children living in the Valencian Region (Spain). Exposure and risk assessment [50]	No	No	No	No	No	No	No	No	Yes X	No
25. Estimating human exposure to pyrethroids' mixtures from biomonitoring data using physiologically based pharmacokinetic modeling [51]	Yes X	Yes X	Yes	No	No	Yes	No	Yes	No	Yes
26. Cadmium exposure in First Nations communities of the Northwest Territories, Canada: smoking is a greater contributor than consumption of cadmium-accumulating organ meats [52]	Yes	Yes X	Yes	Yes	No	Yes	No	Yes	No	Yes
27. Implementation of human biomonitoring in the Dehcho region of the Northwest Territories, Canada (2016–2017) [53]	Yes X	Yes	Yes X	Yes X	No X	No X	No	Yes	No	Yes X
28. Assessment of human exposure to selected pesticides in Norway by wastewater analysis [54]	No	No	No	Yes	No	No X	No	Yes	No	Yes

Table 2. *Cont.*

Publication Title	Assessment context of HRA *	Dose/exposure—Response	Exposure Setting	Exposure Sources	Exposure Duration	Exposed Population	Magnitude of Risk	Uncertainty of HRA Results	Options for Mitigating Exposure	Transparency and Clarity
29. Biomonitoring of bisphenols A, F, S and parabens in urine of breastfeeding mothers: Exposure and risk assessment [55]	Yes	No	No	Yes	No	Yes X	No	No	No	Yes
30. Integrated exposure and risk characterization of bisphenol-A in Europe [56]	No	No	No X	No	No X	No	No	No	No	No
31. Risk characterization of bisphenol-A in the Slovenian population starting from human biomonitoring data [57]	Yes X	Yes	Yes	No	Yes	No	No	Yes	No	Yes
32. Human biomonitoring in urine samples from the Environmental Specimen Bank reveals a decreasing trend over time in the exposure to the fragrance chemical lysmeral from 2000 to 2018 [58]	Yes	Yes X	No	Yes	No	Yes X	No	Yes	No	Yes X
33. Bisphenol A and six other environmental phenols in urine of children and adolescents in Germany-human biomonitoring results of the German Environmental Survey 2014–2017 (GerES V) [59]	Yes X	No	Yes	Yes	No	Yes	No	No	No	Yes
34. Multicenter biomonitoring of polybrominated diphenyl ethers (PBDEs) in colostrum from China: Body burden profile and risk assessment [60]	No	No	No	No	No	No	No	Yes	No	No
35. Biomonitoring and Subsequent Risk Assessment of Combined Exposure to Phthalates in Iranian Children and Adolescents [61]	No	Yes X	No	No	No	No	No	No	No	No
36. Antibiotic body burden of elderly Chinese population and health risk assessment: A human biomonitoring-based study [62]	No X	No	No	No	No	No	Yes X	Yes	Yes	No
Number of "Yes" (Yes proportion)	16 (44%)	12 (33%)	13 (36%)	15 (42%)	3 (8%)	14 (39%)	4 (11%)	20 (56%)	5 (14%)	24 (67%)
Number of "X" (X proportion)	15 (42%)	11 (31%)	4 (11%)	5 (14%)	4 (11%)	12 (33%)	3 (8%)	3 (8%)	2 (6%)	5 (14%)

* Assessment context answers the following key questions: what is to be assessed, why is to be assessed, which assessment endpoint is relevant, assessment timeframe; it is more specific than the general context of the publication.

4. Discussion

4.1. Dose/Exposure-Resopnse and Exposure Assessment

The dose/exposure-response relationship was evaluated as clear in 33% of the appraised publications (Table 2). Similarly, 31% of the appraised publications clearly demonstrated the use of HBM for the dose/exposure-response element of HRA. This finding is not surprising, since the HBM studies mostly assessed risks using one of the threshold value-based approaches, which only compare the estimated HBM-derived exposure estimates with various guidance values (regulatory limits, tolerable daily intakes, acceptable daily intakes, etc.). Authoritative bodies place too much focus on human health reference values [63] and continue to promote threshold-value based types of HRA results [23,64], which are—as observed in the reviewed studies—often reported as the only measures of risk without clear reporting and a discussion of the strength of knowledge and assumptions behind the specific guidance value and without the applicability of the selected HRA approach in each specific case. Despite being based on actual exposure/dose–response information, the threshold-value based approaches lead to under-acknowledgment of the "dose makes the poison" principle [65] across the entire range of possible exposures/doses and are limited in their ability to account for potentially important individual susceptibilities in the population of interest.

An exposure assessment involves the evaluation of the exposure of an organism or group of organisms [66] along with the characteristics of those exposed. It should ideally describe the exposure sources, pathways, routes, and uncertainties in the assessment [67]. An exposure assessment is the most critical step in the process of HRA since, without exposure, there is no risk or related adverse health effects. In the HRA process, the exposure assessment is usually the key area of uncertainty [24]. Our review included only four of the many important features of an in-depth, comprehensive exposure assessment. Additional exposure assessment elements that have not been included are, for example, exposure route, exposure point, exposure concentration, relevant environmental characteristics, etc. The exposure setting was evaluated as clear in 36% of the appraised publications, exposure sources were evaluated as clear in 42% of the appraised publications, and exposed populations were evaluated as clear in 31% of the appraised publications (Table 2). Exposure duration (8%) was one of the HRA elements that were evaluated as the least clear or not included in the appraised publications.

The use of HBM for evaluating exposure setting and exposure duration was clearly demonstrated in only four publications, the use of HBM for assessing exposure sources was clear in five publications, and 11 publications demonstrated a use of HBM for the assessment of the exposed population (Table 2). HBM demonstrates that exposure and uptake have occurred, but only provides direct information about internal presence and concentration (and rarely about dose) that is integrated across all types of exposure routes; it usually does not provide information about the relative importance of inhalation, ingestion, and dermal absorption. Serious limitations when reconstructing exposure based on HBM data include a lack of physiologically based pharmacokinetic models, an underlying lack of good understanding of pharmacokinetics, a lack of data for exposure situations, unvalidated default assumptions, etc. The papers reviewed did not provide clear answers to the majority of questions that should be considered when designing, conducting, or interpreting exposure studies in the context of biomonitoring, such as "have the primary sources of exposure been identified?", "are the pathways/routes of exposure understood?", "can human exposure be related to animal toxicology studies?", "is there some understanding of the exposure-dose relationship?", and "what is understood about temporality and duration of exposure?" [14] (p. 1758).

The risk analysis area is riddled with foundational issues that include an inconsistent understanding and acknowledgment of its main concepts and principles [68,69]. We can confirm that the confusion about terminology that seems to persist as one of the major problems of HRA [70,71] is also found in the area of HBM, as indicated by the studies included in our review. One such instance of confusion is related to the use of "internal exposure". HBM information is often reported as a measure of internal exposure [13,55,72,73]. While internal exposure is distinguished from external exposure in the case of radiation exposure [74], the difference between the two is in whether the source that emits radiation lies inside or outside the body, which is not applicable for nonradioactive substances. Without a clear meaning for the term, the use of "internal exposure" creates confusion, especially if established definitions of "exposure" and "dose" are considered (see Table 3). We argue that exposure biomarkers are, in general, direct or indirect measurements of a dose and that there is no need for the introduction and use of the term "internal exposure." The use of "internal exposure" does not contribute to clarity regarding the value of HBM for exposure assessment and HRA, and it is confusing when placing the HBM information within the environmental public health paradigm, which covers multiple areas, starting from the release of a substance (i.e., sources) to the adverse health outcomes in individuals or populations [2,75]. A recognized need for a better assessment of the link between external exposure sources and internal exposure [13] additionally illustrates the unnecessary use of "internal exposure" instead of "dose."

Table 3. Definitions for "exposure" and "dose".

Term	Definitions
Exposure	"Concentration or amount of a particular agent that reaches a target organism, system, or (sub)population in a specific frequency for a defined duration" [66] (p. 12). "Contact between an agent and a target. Contact takes place at an exposure surface over an exposure period" [67] (p. 3). 1. "Concentration, amount, or intensity of a particular physical or chemical agent or environmental agent that reaches the target population, organism, organ, tissue or cell, usually expressed in numerical terms of substance concentration, duration, and frequency (for chemical agents and micro-organisms) or intensity (for physical agents such as radiation). 2. Process by which a substance becomes available for absorption by the target population, organism, organ, tissue or cell, by any route" [76] (p. 2047). "Exposure is defined as contact of a biologic, chemical, or physical agent with the outer part of the human body, such as the skin, mouth, or nostrils" [12] (p. 17).
Dose	"Total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population" [66] (p. 11). "The amount of agent that enters a target after crossing an exposure surface. If the exposure surface is an absorption barrier, the dose is an absorbed dose/uptake dose; otherwise it is an intake dose" [67] (p. 3). "Total amount of a substance administered to, taken or absorbed by an organism" [76] (p. 2039). "Once the agent enters the body by either intake or uptake, it is described as a 'dose'" [12] (p. 19). "Potential, or administered dose, is the amount of the agent that is actually ingested, inhaled, or applied to the skin" [12] (p. 19). "Applied dose is the amount of the agent directly in contact with the body's absorption barriers, such as the skin, respiratory tract, and gastrointestinal tract, and therefore available for absorption" [12] (p. 19.). "The amount of the agent absorbed, and therefore available to undergo metabolism, transport, storage, or elimination, is referred to as the 'internal' or 'absorbed dose'" [12] (p. 19). The portion of the internal (absorbed) dose that reaches a tissue of interest is called the 'delivered dose'" [12] (p. 19). "The portion of the delivered dose that reaches the site or sites of toxic action is called the 'biologically effective dose'" [12] (p. 19).

4.2. Process and Results of Health Risk Assessment, and Risk Management

HRA needs to strive for transparency and clarity, in the same way as any form of scientific research [77]. Although none of the reviewed publications reported a comprehensive HRA, the assessment process was evaluated as transparent and clear in two-thirds of them, while only five publications clearly demonstrated the importance of HBM in the overall transparency and clarity of the publication (Table 2).

All persons involved in the HRA process and the users of HRA results, such as policy makers, public, etc., can come from various backgrounds, and can have different needs and expectations regarding the HRA. To ensure the utility of HRA results for specific risk-informing purposes, a consensus regarding the terminology, concepts and methods used in specific HRA needs to be reached. The HRA context must be clarified among all relevant stakeholders involved in the HRA process in its early stages. Clarification of the HRA context should provide clear answers to the questions "What is to be assessed?" and "Why is it to be assessed?"; such answers should be in accordance with future risk management decisions. During the assessment context step, all involved parties need to contribute to the clarity of the decision and assessment problem, scope of the assessment, methods to be applied, and available resources, including time constraints, etc. [5,78]. However, this preliminary review revealed that the assessment context was perceived as clear in only 44% of the publications (Table 2). The value of HBM for the assessment context was demonstrated clearly in 42% of the appraised publications (Table 2). Since none of the papers reported a comprehensive example of HRA, our review could not clearly distinguish between the context of the respective study and the context of the actual HRA, which may not be the same.

In general, the HRA process aims to assess the magnitude of risk (i.e., the severity of consequences), its probability, and the strength of knowledge supporting the assessment findings, which includes the uncertainty assessment [7]. Considering all of the above, the assessment of risk performed only with a comparison with guidance values is limited. This may explain why the magnitude of risk was understood among the HRA elements that were the least clear or not included in the appraised publications (Table 2). Only three publications clearly demonstrated the use of HBM for the assessment of the magnitude of risk. The uncertainty of the HRA results was clear in 56% of reviewed publications (Table 2). However, several publications (see Supplementary file) only provided a general uncertainty assessment or limitations assessment of the entire study. The use of HBM for assessing the uncertainty of HRA results was clear in only three publications.

From the risk-informed decision-making point of view, alternative decisions and/or options for mitigating or avoiding exposure are among the most important HRA elements. In specific cases, e.g., in the case of flame retardants [79], risk management must weigh the costs and benefits of various options. Our review showed that the options for mitigating exposure were among the HRA elements that were the least clear or not included in the appraised publications (Table 2). Only two publications demonstrated the use of HBM for assessing or identifying options for mitigating exposure.

4.3. Value of Human Biomonitoring Data for Health Risk Assessment and Risk Management

The observations of our review are in line with the conclusions of a review of the state-of-the-art use of HBM in HRA in Europe. It suggests that significant work is still needed to improve the implementation of HBM in regulatory HRA [13]. Figure 3 illustrates potential uses of HBM in the health risk assessment and risk-analysis contexts. The exposure assessment is a crucial element of HRA, especially in terms of identifying potential risk-management options. HBM can provide robust proof that an exposure to a certain substance or stressors has occurred (exposure biomarkers), can inform the assessor about specific health effects (effect biomarkers), or can be suitable for the development of a mechanistic understanding of environmental health processes (Figure 3 points 4 and 5). From a risk management perspective, it is essential to link biomarkers to exposure-related events, whereby public or private actions and changes in lifestyle can reduce the probability of adverse health outcomes. The value of biomarkers for exposure assessment "depends on whether they can be used to reconstruct internal dose and related exposures, and on whether they aid in identifying and quantifying the relative contributions of various sources and pathways to exposure/dose" [12] (p. 25). HBM often does not reveal exposure sources and routes [80] and even when the distribution of biomarkers of exposure or effect is well characterized in a defined population, and when there is a solid understanding of exposure routes and contributing sources, it remains challenging to predict the influence of changes in emissions from a small number of identified sources on the distribution of biomarkers [6]. Technological advances (e.g., high throughput mass spectrometry) have facilitated measurements of a large number of environmental agents. However, the challenge of including biomarkers of exposure and response in the development and validation of specific and sensitive measures of pathway perturbations and environmental exposures still exists [4]. HBM can also be useful for the identification of exposed (susceptible) populations, and can, together with "matching" environmental monitoring, be used for monitoring purposes (e.g., following an implementation of specific decisions, changes in specific activities/interventions, etc.; Figure 3 point 7). The clarification of the fitness and usefulness of HBM for specific HRA purposes requires a clear understanding of HBM information within the environmental health paradigm context. Without it, the knowledge acquired via the HRA process is not complete and cannot provide the best possible information for risk-informed decision making. Direct exposure measurements and measurements of dose (i.e., biomarkers) are not interchangeable but are complementary rather than competing methods for conducting realistic exposure assessments. It is critical to couple the HBM data with the collection of relevant environmental exposure, source, and health data to allow for the best possible interpretation of the implications of exposures to facilitate prevention and intervention [81]. In addition, the exposure information obtained must be accessible and its meaning and limitations made clear to community members if it is to inform decisions involving exposure prevention or intervention (Figure 3 points 2, 3 and 6) [81].

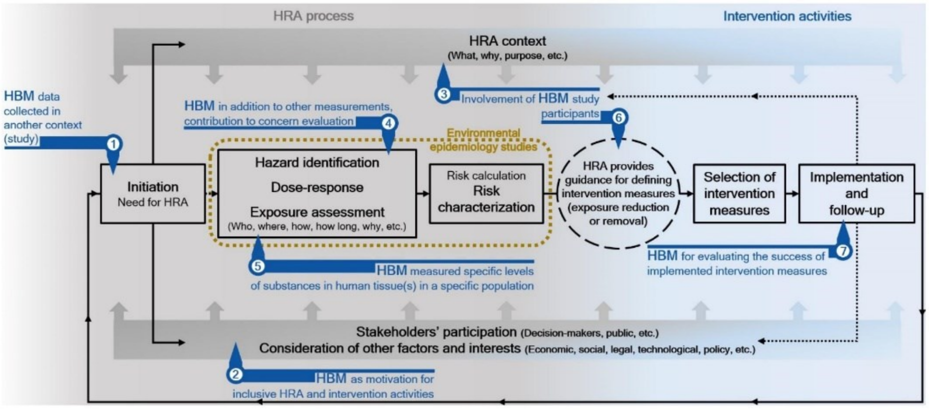

Figure 3. Potential uses of human biomonitoring in the health risk assessment context.

The usefulness of HBM information for specific HRA cannot be expected a priori if the assessment context [78] (a clear definition of what is to be assessed, assessment endpoints, assessment purpose—e.g., decisions about changing a causal relationship, or prevention of exposure, etc.) is not clarified among all relevant stakeholders, and if it is not considered during the planning of HBM and HRA (Figure 3 points 2 and 3). Expectations of obtaining useful HBM information for effective decision making in terms of policy development for the areas and populations of concern are reasonable only if a clear HRA purpose drives the HBM programs. If this is not the case, HBM information may only have limited value in terms of risk management. Furthermore, HBM information may implicate potential relationships between causes and effects, which warrants further investigation and assessment or may be used to document trends and status (e.g., population reference values). Documentation of trends and status is the simplest and least informative way of using HBM information, even if the levels measured can be compared to certain standards for evaluating the level of concern (i.e., hazard index, hazard quotient; Figure 3 point 1) [82]. Such comparisons must not be construed as more comprehensive HRAs with better risk-informed decision-making potential. In the absence of other information, assumptions are inevitable for the statistical associations between the measured concentrations and potential exposure sources identified by questionnaire responses, or for the estimation of exposure routes that can directly determine biologically effective dose, as illustrated by the example of chloroform exposure from showering [83]. The rationale behind the assumptions, which are necessary when the knowledge required for specific HRA is not complete, must be reported clearly. If HBM information is not reasonably fit for the specific HRA purpose, its utility for HRA cannot be improved by questionable assumptions that allocate it an additional desired value. If this is done, caveats stronger than formal uncertainty discussion regarding usage of these data and related HRA results in policy contexts by decision makers must be made. Advances in the HRA and risk analysis areas should acknowledge the need for greater stakeholder participation in both HRA and risk management [84], which makes the "decision process more democratic, improve the relevance and technical quality of the assessment and increases the legitimacy and public acceptance of the resulting decisions" [85] (p. 689). These issues can be addressed by procedural improvements, as emphasized and addressed by the various existing assessment frameworks [5,78]. A consideration of such a framework when performing HRAs can identify and clarify the need for HBM and its value for the assessment.

4.4. Strengths and Weaknesses

This review included 36 scientific publications that do not represent the entire body of research and related practice in the areas of HRA and HBM. Since the review only evaluated the presence, transparency, and clarity of the selected HRA elements in the selected publications, it cannot represent the actual understanding of the topics covered among the authors of the publications. There are many other important HRA or risk analysis elements that were not included in the appraisal tool, which does not mean they are without importance in specific studies/assessments; for example, stakeholders' participation, judgment of the strength of knowledge, peer review, etc., [22,86]. While the appraisal tool and the review did not focus on such elements, some of them may be clearly included in the appraised publications but were not considered in the evaluation.

HRAs are inherently subjective, as "the definition of risk controls the rational solution to the problem at hand" [85] (p. 699). By acknowledging the inherent subjectivity of all involved in the appraisal and the multidisciplinarity of the HRA and risk analysis areas, the appraisal aimed to mimic/represent a "real-world" situation of risk analysis cases involving multiple stakeholders (decision-makers, researchers, the public, etc.). Despite careful preparation of the appraisal tool, we cannot overlook the preliminary and limited character of the appraisal findings; this is also due to the limited experience of the ESRs who performed the review. It is important to note, however, that the limited review was not performed in a way that would force a specific understanding of the HRA elements upon all involved, but instead acknowledged the differences in their understanding. It was based on the assumed capability that those involved could develop a comparable set of criteria to obtain comparable answers to the appraisal questions, despite their different backgrounds, education, interests, and, last but not least, professional beliefs and values [84]. This assumption was confirmed several times during the development of the appraisal tool and during the review through multiple discussions. In this view, simple sums and percentages of specific answers as presented in Table 2 curb the different opinions and findings among the ESRs, if they were all reviewing all articles. Such an approach to the appraisal also avoided the inevitable step of consultation and harmonization among the ESRs about each of the reviewed articles (by applying, e.g., the Delphi method), which would otherwise be necessary. The discussions and the comments, which provided additional argumentation about appraisal findings, indicated that the inherent and inevitable differences in the understanding of HRA elements and especially in the understanding of papers reviewed potentially lead to only minor differences in the appraisal findings, which did not affect the general findings of the study. Nevertheless, our findings can inform future developments of the interconnected areas of HRA and HBM.

5. Conclusions

The application of HRA theory (e.g., its terminology and concepts) and practice in the human biomonitoring area is not consistent. While HBM has advantages, primarily as an undeniable proof of exposure, it has limited value in providing other types of crucial exposure-assessment information when assessing risks (i.e., exposure sources, exposure pathways, why are individuals/population exposed, etc.) and for targeted risk management interventions. Many of the HBM studies did not thoroughly specify the underlying uses and usefulness of HBM data for HRA purposes before sample collection. This leads to increasing amounts of HBM information that remain archived but unexploited in terms of their expected, even promised, yet unrealized usefulness for HRA and related risk-informed decision making.

The following points need to be considered to improve the risk-informing potential of HRAs that use HBM data:

1. Stakeholder involvement in the early stages of HRA is crucial for the clarification of an assessment context. Clear assessment context assures that HRA can address the needs or concerns of decision makers or other stakeholders. HBM, if performed for the purpose of HRA, must acknowledge the assessment context in its planning stages.
2. The lack of stakeholder involvement (e.g., when using existing databases) needs to be reported along with the discussion about the usefulness of obtained HRA results for specific purposes.
3. The use of the term "risk assessment" creates confusion/false expectations among decision makers or other stakeholders if only parts of the HRA process are practiced.
4. Underlying assumptions of HRA (e.g., related to HBM based exposure assessment, lacking pharmacokinetic knowledge, etc.) must be reported and thoroughly discussed, since they can be an important source of uncertainty or study limitations.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/ijerph19063362/s1, Supplementary file, which includes the appraisal tool and comments during the publication review.

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4.5 Practical Opportunities to Improve the Impact of Health Risk Assessment on Environmental and Public Health Decisions

The article "*Practical opportunities to improve the impact of health risk assessment on environmental and public health decisions*", written by T. Bizjak, D. Kontić and B. Kontić, was published in the International Journal of Environmental Research and Public Health in April 2022 (doi: 10.3390/ijerph19074200). As the first author, I contributed to its conceptualization, methodology, investigation, data analysis, curation and visualization, writing of the original draft, and reviewing and editing.

HRAs are meant to support public policy decisions or identify research priorities (NRC, 1983, 2009; US EPA, 2014). Fundamental challenges in the risk analysis area (Anderson et al., 2020; Aven & Flage, 2020) limit HRA's potential for improving risk management decision-making, while a multitude of HRA approaches makes it difficult to understand the relation of HRA to environmental protection, environmental health policies, occupational health, and regulation (Shaffer, 2021). The article specifically discusses the fundamental challenges of HRA practice, focusing on the pressing erosion of confidence in the risk informing value of HRA in public health decision-making. It specifically addresses the third, fourth, and fifth hypotheses guiding my doctoral research.

I performed a survey on understanding selected fundamental HRA concepts and principles in the decision-making context. Two questionnaires were administered to four carefully selected groups of professionals from various backgrounds involved in risk analysis between November 2019 and December 2020. The responses show inconsistencies regarding the influence of HRA and its results on risk management and decision-making and a lack, or at least inconsistent understanding, of core risk analysis principles (SRA, 2018a). However, the survey did not identify any apparent patterns or causes for the inconsistent, dispersed, and diverse understanding of HRA. The observed confusion between HIA and HRA further indicates a lack of understanding of why and when to conduct an assessment of health risks or impacts and its contribution to solving specific public health issues.

To address the observed inconsistencies and foundational challenges, I highlighted specific procedural improvements of the HRA praxis in order to improve and clarify the risk-informing potential of HRA. These include taking advantage of the opportunities for procedural improvements found at the beginning of the HRA process, where the initiation phase deserves more attention and needs to effectively involve all stakeholders to clarify the context of the decision problem and the context of the assessment, which should be considered in all subsequent steps of the HRA process to ensure the entire process is fit for purpose. Continuous stakeholder participation can be facilitated by using decision analysis tools and methods. Finally, there is a need for a decision follow-up step to evaluate the implementation of any risk management decisions and clarify the true success and benefits of the HRA in contributing to better public health.

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Practical Opportunities to Improve the Impact of Health Risk Assessment on Environmental and Public Health Decisions

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Abstract: Following alerts about the diminishing role of health risk assessment (HRA) in informing public health decisions, this study examines specific HRA topics with the aim of identifying possible solutions for addressing this compelling situation. The study administered a survey among different groups of stakeholders involved in HRA or decision-making, or both. The responses show various understandings of HRA in the decision-making context—including confusion with the health impact assessment (HIA)—and confirm recurring foundational issues within the risk analysis field that contribute to the growth of inconsistency in the HRA praxis. This inconsistency lowers the effectiveness of HRA to perform its primary purpose of informing public health decisions. Opportunities for improving this situation come at the beginning of the assessment process, where greater attention should be given to defining the assessment and decision-making contexts. Both must reflect the concerns and expectations of the stakeholders regarding the needs and purpose of an HRA on one side, and the methodological and procedural topics relevant for the decision case at hand on the other. The HRA process should end with a decision follow-up step with targeted auditing and the participation of stakeholders to measure its success.

Keywords: risk analysis; health risk assessment; health impact assessment; risk management; decision analysis; public health

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1. Introduction

Recent research has recognized a continuous spread of fundamental issues in health risk assessment (HRA), as well as a poor, or at least unclear, link between HRA results and (risk management) decision-making [1–5]. Some studies expressed concern about inconsistent practices that are drifting away from the definition and generally approved process of HRA [6–9], while others pointed out the possible detrimental effects of a narrow understanding of HRA founded on the deleterious interchange of HRA with hazard assessment, which results from an unclear understanding of the differences between hazard and risk [10,11]. In general, the term "risk" is used too loosely too often. Considering the basic meaning of "risk" [12] and how the term is understood in the risk analysis (RA) discipline [13], the term is regularly interchanged with terms such as "hazard", "possibility", "potential", "threat", and "safety".

The inconsistent or improper use of "risk" in everyday talk, by media, semi-scientific literature, etc., can contribute to the uncritical spread of a superficial understanding of the risk concepts, which might lead to a loss of the effectiveness of HRA for informing environmental and public health policy decisions and could negatively affect their implementation and public compliance [14]. This is what we observed during the COVID-19 pandemic on a daily basis [1,3]. For instance, phrases such as "risk of exposure", "risk of going out", and "risk of partying" [15–17] were being popularly used with the effect of pushing off the risk scientific more consistent ones [13], such as "risk of mortality in patients infected with SARS-CoV-2" [18], and without paying attention to the differences in their meanings. Notwithstanding their description as science based [19], the measures adopted throughout the world during the current pandemic often lacked clear and systematic support and justification by the results of targeted HRA or other public health impact evaluations but seemed unclear, more intuitive, non-transparent, and political, and in many cases imposed [20–22]. A better level of underlying understanding of RA terms and principles [19] during the COVID-19 pandemic could contribute to easier implementation and better compliance with even the more drastic measures, such as public life closures and travel restrictions [23].

1.1. Effectiveness of HRA for Decision-Making

A prerequisite for a good public health policy is building upon the experiences of past or existing policies, which requires well-planned and systematic follow-up activities that monitor policy implementation and its impacts [24,25]. Policy decision-making challenges arise when knowledge about health risks or impacts related to specific activities and exposures is uncertain or incomplete. The field of HRA was developed to address knowledge gaps and mitigate them [26]. In general, HRAs intend to support public policy decisions, set priorities among research needs, and help develop ways to evaluate the costs and benefits of regulatory decisions [7,9,27,28]. Challenges for policy decision-making, e.g., related to knowledge gaps about different health risks associated to hazardous substances, are observed throughout the decades. An example is the regulatory process concerning glyphosate in the EU [29]. Its use as an active substance was approved until 15 December 2022, with pending regulatory decisions regarding the renewal of approval [30]. There is no consensus regarding the adverse health effects related to glyphosate exposure [31,32]. The International Agency of Research on Cancer classified glyphosate as “probably carcinogenic to humans” (Group 2A) in 2015 [33], while both European Chemicals Agency and the United States Environmental Protection Agency concluded that glyphosate does not meet the criteria for classification as a carcinogen [34–36]. Despite several lawsuits about glyphosate exposure-related adverse health effects, awarding multi million dollars damages to customers in the US, the enduring belief in the safety of Roundup (i.e., glyphosate-containing weed and grass killer) by its manufacturer continues to be unwavering [37].

The practice of “risk assessment of chemicals”, where a mere comparison with selected reference values is misused to represent or characterize actual health risks [38], has become common in the research area [39–41] and its application for administrative and regulatory purposes is even required [42]. Generic regulatory approaches to risk assessment, as adopted by the REACH legislation [42], have strayed from the basic HRA concepts [9] by focusing primarily on the intrinsic properties of substances (i.e., hazard identification) and less on exposure assessment [43]. Failing to reflect actual exposures in specific settings (e.g., working conditions) [44], such assessments can lead to misleading or wrong conclusions about safety.

Factors contributing to the effective consideration of HRA findings in public health policy remain understudied and insufficiently understood [45,46]. The multitude of different risk assessment processes, for example, as applied in practice by the US federal government, makes it difficult to understand the relation of risk assessment to environmental protection, environmental health policy, occupational health, and regulation [47]. In this context, it is important to expose continuous international efforts coordinated by the International Atomic Energy Agency (IAEA) and OECD Nuclear Energy Agency (NEA) to link basic concepts, standards, methods, tools, and best practice in the area of risk assessment and risk-informed decision-making [48–51]. Efforts to consolidate the RA area [52] are often ignored by “self-styled risk analysts” [53]. The authors have experienced this recently on multiple occasions during their involvement in several EU-funded projects that dealt with HRA in the context of making improvements to public health policies or guiding decisions for reduced exposures to hazardous substances, such as HBM4EU (https://cordis.europa.eu/project/id/733032, accessed 29 March 2022), HERA (https://cordis.europa.eu/project/id/825417, accessed 29 March 2022), ICARUS (https://cordis.europa.eu/project/id/690105, accessed 29 March 2022), and NEUROSOME (https://cordis.europa.eu/project/id/766251, accessed 29 March 2022). It remains to be seen whether the European partnership for the assessment of risk from chemicals (PARC) [54] will succeed in changing the REACH legislation's "risk of chemicals" approach toward returning the HRA methodology to its origins [9].

In summary, the lack of understanding of the HRA process and its application causes HRA and risk management frameworks to oversimplify complex scientific assessments, resulting in misunderstandings and hindering risk management decision-making, its success, and confidence in it [2,53]. Constant development of HRA practice is necessary to keep up with the advancing knowledge of relevant scientific fields [55,56]. However, advances in specific disciplines with potential usefulness for specific HRA elements (e.g., use of human biomonitoring [57], modeling, in vitro, and in vivo/in silico exposure/dose-effect/response studies [55]) alone cannot ensure improvements in HRA's effectiveness in informing public health decisions without the wide recognition and consolidation of fundamental HRA principles and concepts.

1.2. Brief Summary of Issues with a Research Look Ahead

Table 1 provides an overview of fundamental HRA concepts and related issues assumed to influence the basic understanding, i.e., the theory of HRA on one side and the practice, specifically the effectiveness of HRA results in informing risk management decisions, on the other. The table does not provide a complete list of issues in the RA area but focuses on those assumed to influence the impact of HRA in informing public health decision-making. We believe that these issues deserve full research and policy consideration, with proper intervention to secure HRA from further conceptual erosion.

Table 1. Selected HRA concepts and comments on recognized issues.

Concept	Comments
Terminology and narrative	Interdisciplinary communication and collaboration are crucial in health risk assessment (HRA). Clear, consistent, and efficient terminology and narratives among all involved in HRA are essential. Experienced scientists with deep knowledge should be willing to patiently explain terms and definitions to less experienced ones.
Probability (uncertainty) and "HRA for chemicals"	The core of HRA is the probability (likelihood or frequency) of exposures and consequent health impacts. Contact with hazardous substances during human activities/habits and the physiological responses to these contacts (intakes) are subjects of probability (uncertainty), while the properties of hazardous substances are not subjects of probability but are deterministic (probability equal to 1). It is poor science to apply probability to deterministic parameters (substances and their properties) and, consequently, to calculate risk for them.
Hazard vs. Risk	These two concepts are too often interchanged. "Renaming" hazard into risk seems the easiest way to avoid probabilistic risk issues and related transparent calculations. Such reasoning has become widely adopted, particularly in using the hazard index and/or the risk characterization ratio as measures of risk.
No exposure no risk	This concept is clear, yet exposures are unknown, uncertain, and/or unjustified in many attempts to conduct HRA. "Inventing" exposure by applying unjustified assumptions, especially for wider populations, such as at national or regional levels, is inappropriate, particularly in the context of risk management. Such praxis leads to misinforming risk management. Consequently, inappropriate, non-justified societal decisions can be made. Invented, improperly justified exposures are inappropriate, even for teaching and training purposes. Trainees misuse training examples and exercises in their daily work, which allows for the wide dissemination of erroneous concepts.
HRA leading to or led by risk management?	The main reason for wanting to assess risks is to manage them by either reducing or removing their causes or the consequences, or both. Management decisions often involve balancing the advantages and disadvantages of the environment, human health, and the consequences for other social benefits of different options. This complex situation has led to the need for comprehensive decision analysis and should emphasize how the management context and criteria can, or indeed should, influence the HRA context.

Table 1. *Cont.*

Concept	Comments
Fitness for purpose	HRA performed without a clear purpose cannot provide clear information and scientific basis for informing actions that aim at specific improvements of health in a selected population. The purpose should reflect the expectations of the users of HRA results, which, in turn, influence all other elements of the HRA methodology and process.

The research behind the above-described challenges is mostly descriptive (i.e., observational) and as such does not include specific attempts, guidance, or proposals for searching solutions, neither do any other accessible publications deal with concrete ways of stopping the further detrition of fundamental issues and the spread of inconsistencies within HRA. It seems, therefore, that targeted intervention studies, which are common in the area of community-based participatory research (CBPR) and especially in CBPR public health that lead to improvements [58,59], should be performed in the HRA area as well.

The study presented here has both observational and interventional elements and is pioneering in its call for thorough consideration and the re-establishment of an overall understanding of the effectiveness of HRA for decision-making. Its interventional contribution is provided in the form of proposals and recommendations, as given in the following section.

2. Materials and Methods

In consideration of the broader concepts presented in Table 1 we derived the following three more focused assumptions as a basis for our study and for designing the two questionnaires used in the survey:

1. The informing potential of HRA results is limited because some of the various types of results may not conform to or properly fit the area/policy of their application.
2. HRA is not applied in a consistent and integrated manner; rather, only some elements of HRA are practiced because of a limited understanding of the overall process of HRA, particularly its purpose.
3. There are diverse understandings of the importance of different elements of HRA for public health decision-making. This is evident from the interpretation of HRA results, especially in cases when consultation with the users of HRA results is poor or is missing, so the interpretation is biased by, for example, assessors, or in the opposite case, when the users of the results are consulted; however, a deeper exploration of their different understandings is missing.

To evaluate the validity of the assumptions, we administered a survey to different stakeholders to ascertain their understanding of fundamental HRA concepts and principles. We used their responses to evaluate the distribution of inconsistencies and inadequacies in their understanding of selected topics in the decision-making context. These findings formed the basis for developing proposals and recommendations to improve the impact of HRA on environmental and public health decisions.

The targeted stakeholders were four carefully selected groups of professionals from various backgrounds (i.e., research, administration, public health, and economy) (Table 2). Before administering the survey, the stakeholders were checked for their involvement in the RA area based on their expertise, previous work, or interests. Because of the multidisciplinary nature of professionals involved in RA, the limited availability of resources, the anonymity of the collected responses, and potential questionnaire biases, we restricted our sample to professionals who were willing to respond to the survey and who were reasonably easily accessible, for example, involved in the same projects or other activities as the authors and with publicly accessible contact information.

Table 2. Survey information.

	Target Group	Area of Work or Interest	Time Period	Level	Size	Responses
1.	Participants of the CRP V3-1722 [1] workshop	Administration, economy, public health, research	November 2019 to December 2019	National(Slovenia)	19	11
2.	Researchers involved in the NEUROSOME project [2]	Research	December 2019 to June 2020	Regional(Europe)	29	15
3.	Participants in the "Environmental Health Risk: Analysis and Applications" educational activities [3]	Administration, economy, public health, research	March 2020	Regional(United States)	38	21
4.	Established risk analysis and decision analysis professionals	Administration, economy, public health, research	November to December 2020	Global	49	12

[1] Project title: Attempt at interpretation of biomonitoring results in connection with environmental pollution monitoring data, with the emphasis on air pollution and assessment of potential impacts of these pollutants on the health of inhabitants"; funded by the Slovenian Research Agency. [2] Principal investigators, early-stage researchers, and other researchers involved in the NEUROSOME project (https://www.neurosome.eu/, accessed 29 March 2022). [3] Organized by the Harvard T.H. Chan School of Public Health, 9–12 March 2020.

The first group comprised participants in a workshop organized by the Slovenian Research Agency-funded project. The participants were from the industry, the Department of Environmental Sciences at Jožef Stefan Institute, Chemicals Office of Republic of Slovenia, Slovenian National Institute of Public Health, and the Faculty of Health Sciences of the University of Ljubljana. Several follow-up interviews with the respondents were conducted to clarify the questions and ambiguous responses. The group was relatively heterogeneous in terms of the participants' backgrounds, fields of work/expertise, and usage of HRA results for their specific involvement in decisions, and included well-experienced professionals. The second group comprised early-stage researchers (ESRs) and other researchers involved in the NEUROSOME project. ESRs were selected and asked to participate in the survey since their knowledge of HRA and perceptions of relations between HRA results and decision-making were still under development. The distribution of their answers to the questionnaire was expected to show some inconsistencies, which, after comparison with the responses of the first group, could be attributed to their inexperience in both HRA practice and involvement in decisions. The third group comprised participants in Environmental Health Risk: Analysis and Applications educational activities organized by Harvard T.H. Chan School of Public Health in 2020. The participants were professionals from regulatory agencies, such as the United States Environmental Protection Agency and the United States Food and Drug Administration, from universities, private consultant companies, and industries in the US, Europe, and Asia. The fourth group comprised established RA and decision analysis professionals, including notable members of the Society for Risk Analysis (SRA), and authors of prominent publications in the areas of RA and decision analysis. This group acted as a reference group in the context of the survey (see more in the Discussion section). Invitations to respond to the questionnaire were distributed by email and through internal SRA pages.

We distributed the same 15-item questionnaire in English or Slovenian to the first three groups and a more focused seven-item questionnaire to the fourth group of professionals, either through email or by sharing the link to the questionnaire on Google Forms. The aim of the more focused questionnaire, which was modified based on responses from the first three groups, was to provide more transparent and justifiable stand-points of the esteemed experts regarding the key issues about HRA in the decision-making context. Besides comparison of the understanding of selected topics with the professionals from the other three groups these were expected to act as a guidance and additional argumentation for recommending ways of improving the impact of HRA on decision-making. This prevailing focus of the second questionnaire had a consequence of leaving out questions about health impact assessment (HIA) and differences between HIA and HRA, which were included in the first questionnaire. The responses from all groups were collected anonymously or were anonymized before the analysis.

The survey was non-probabilistic. It was judgmental—all four groups were carefully targeted as mentioned above. Non-probabilistic type of sampling meant that the use of probabilistic statistical tests (for which conditions were not met) are not applicable. Consequently, the statistical analysis included calculations of proportions, mean values, and standard deviations, which were intended for qualitative relative comparisons, such as between the four groups or in relation to the responders' background. The responses with three-point Likert scales (first three groups) were assigned values of 1, 3, and 5 for a more straightforward comparisons of their responses with the responses from the fourth group that used a five-point Likert scale. This should be regarded with caution when interpreting results, and should only be done when comparing the relative differences between the options and not for comparing their absolute value, since it increased the apparent gap between the absolute values of different responses. Open-ended (i.e., other) options in the multiple-choice questions were intended for comments or explanations and not to restrict the responses only to the options specified. Since the responses to open-ended questions served as a source of additional information, their detailed analysis did not seem practical and beneficial.

The supplementary file includes both questionnaires and a summary of the responses.

3. Results

The responses confirmed our first assumption that the informing potential of HRA is limited because some of the various types of results may not conform to or do not properly fit the area/policy of their application. Responders understood HRA as being important for decision-making, but did not show a consistent understanding of how HRA should influence decisions. More than two-thirds (68%) of the respondents in the first three groups answered that HRA improves the transparency of the decision-making process, and 55% regarded HRA results as direct and the most important basis for decision-making. Similarly, 67% of the respondents in the fourth group regarded HRA and its results as important in influencing a wide range of decision-making considerations. However, respondents in the fourth group showed a coherent understanding that HRA results are not the direct and most important foundation for decision-making. In answers to open-ended options, they pointed out a decision context, i.e., concrete situation, as well as needs of the decision-makers which determine appropriate types of HRA results or endpoints.

The question about the most useful types of HRA results for decision-making aimed to assess whether there are specific types of HRA results that are generally preferred The HRA results expressed probabilistically were understood as being only slightly more useful in decision-making (Figure 1). As in the first three groups, no clearly preferred type of HRA results that would be the most useful in informing decision-making was identified in the responses of the fourth group. The responses from group 3 were more similar to the responses from group 4 compared to the responses from groups 1 and 2. "Other" types of useful HRA results were only specified by the fourth group. This group again stressed the importance of a decision context for determining most useful HRA results. Analysis of responses from the first three groups in relation to the respondent's background showed only small differences (Figure S1). Next, we attempted to identify whether specific types of HRA results were preferred in different decision-making settings, such as the economy, public health policy, and health protection actions. Only small differences in the types of HRA results that were understood as useful in these areas were observed. Types of HRA results that included costs were understood as being slightly more useful for the economy.

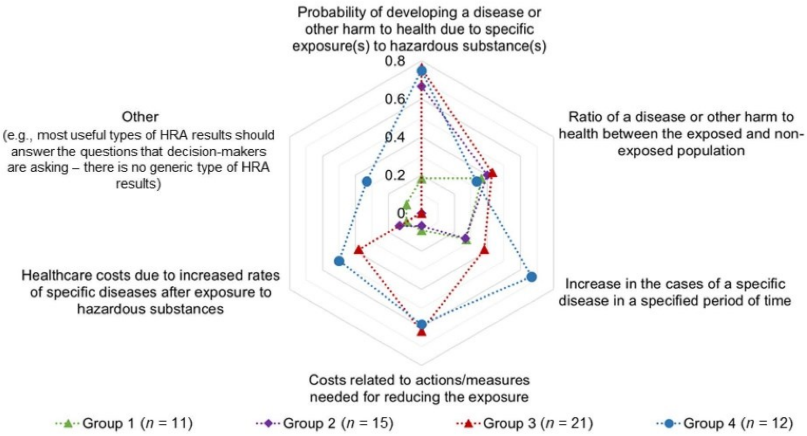

Figure 1. Most useful types of HRA results for decision-making—proportions of responses from the four groups.

In addition to the questionnaire responses, the interviews and discussions were performed during the survey within the first three groups. These showed that responders who claim to perform HRAs often follow a certain type of HRA procedure and select a certain type of HRA results (e.g., comparison with reference values, standards, guidance values) without being actively involved in a decision-making process from the beginning until the end. HRAs performed in this way can be lacking in understanding and consideration of expectations regarding the HRA results in the decision-making context. If so, this raises two fundamental issues. One is about assessment context (what is to be assessed, how to be assessed and why), which may not be considered thoroughly. The other is that a situation of "throwing results over the fence" in the RA arena [60] may occur, where risk assessors expect that their results will be used by others without any consultation, collaboration, and checking the "fitness for purpose" principle.

Our second assumption that HRA has not been applied in a consistent and integrated manner, and that only some elements of HRA have been practiced, was confirmed by responses about HRAs based on comparisons with standards, guidance values, reference values (e.g., hazard index or quotient), or tolerable daily intake values, and by a lack of understanding about the similarities and differences between HRA and HIA. Almost all respondents in the first three groups (93%) understood comparisons with standards, guidance values, or reference values as important in interpreting HRA results. This indicates that even in case when HRA is not performed in a consistent and integrated manner, the results of comparison with reference values are perceived important in interpreting the results. Such understanding, similar as mentioned above, exposes the issue of weak consideration of the assessment context. However, none of the established professionals from the fourth group selected hazard indexes or quotients among the most useful types of assessment endpoints in decision-making. The majority of the respondents (55%) in the first three groups answered that comparisons with guidance values improve decision-making, but the meaning of violation of guidance values is not clearly understood. About one-third (38%) of the respondents in the first three groups answered that the violations of guidance values should lead to the prohibition of the substances/activities causing violation, and one-third answered that it is not clear what actions should be taken. Less than half of the respondents in the fourth group answered that such comparisons are important for informing risk communication regarding decision-making, with one-third answering that such comparisons are not necessary and may mislead decisions toward radical attitudes.

The third assumption that there are diverse understandings of the importance of different elements of HRA for public health decision-making was also confirmed by inconsistent and dispersed responses. Elements such as HRA procedure, participants in the assessment process, reasons for conducting HRAs, and the reputation and credibility of the risk assessor were understood as additional important types of information in the decision-making, but were understood as relatively less important compared to the importance of other HRA elements. The survey respondents in the first three groups understood all HRA elements as being very important or of medium importance. Relatively less importance was ascribed to uncertainty, coordination of HRA procedures, and the type of HRA results, regardless of the responders' backgrounds (Figure S2). The responses of the fourth group showed that decision alternatives for mitigating exposure, uncertainty of HRA results, and transparency and clarity of the assessment process—the latter, contrary to perception of the first three groups, emphasizes proper consideration of the assessment context—were evaluated as more useful in informing decision-making than other elements.

A detailed summary of all responses from the four groups is included in the supplementary file.

4. Discussion

4.1. Comments on Survey Responses

While respondents considered the influence of HRA on decision-making important, it can be concluded that the perception of its importance may be biased. This bias is clearly evident from the responses that evaluated the importance and impact of HRA in decision-making based on standards and reference values. According to the observed perception, HRA should be done as a comparison with reference values, which, if viewed from the risk management perspective, suggests that decision-making without reference values is not possible. This perception is inappropriate and is not in accordance with the generally accepted theory, definitions, and processes of HRA [9]. Many responders in the first three groups either did not clearly understand the core RA subjects [52] or did not respond consistently, which supports the recognized need to consolidate the fundamental principles and core subjects of RA among relevant scientific and nonscientific communities [1,3]. This consolidation can be done in a variety of ways, such as through educational activities and university programs and workshops. Consolidation is also needed with regard to the overall process of HRA.

No clearly preferred type of HRA results was identified that would reflect a consistent understanding of the main RA concepts and would acknowledge probability and severity as key determinants of risk [1]. Threshold-based types of HRA results (i.e., comparisons with guidance values) are promoted by authorities and regulatory bodies [61,62], and are often reported as the only measure of risks [63,64], even though they are actually arbitrary measures of concern [65]. Furthermore, guidance values are not only science-based but are defined in an administrative process that determines acceptable risk and considers scientific uncertainty, risk management options, economic benefits and costs, relevant laws, and social norms [62]. Underlying characteristics, including the strength of the knowledge applied in setting each guidance value, and clear evaluation of the case-specific applicability of selected guidance value-based HRA, are often not transparently reported or considered in publications [63,66]. Such practice blurs the delineation between science and judgments [2] and encourages the abandonment of the fundamental exposure–response concept of HRA [67]. There is too much focus on the simple fact of exposure (e.g., contact with hazardous material) rather than the way (situation), duration, mode, and amount of exposure [53] with epidemiological data, and a lack of understanding that regardless of the existence or nonexistence of guidance values, even modest exposure reductions can benefit public health [67].

The types of HRA results incorporating probability were identified as more useful in decision-making (Figure 1), while the uncertainty was not consistently understood among the more important elements of HRA (Figure S2), indicating a lack of acknowledgment that uncertainty and variability are inherent characteristics of HRA [27,68]. By contrast, the responses of the fourth group showed better consistency with basic RA concepts (Figure S3). Since probability is often difficult to communicate, it does not influence decision-making and decisions as it should. An inadequate understanding of probability can lead to its reduced or discarded consideration in favor of the magnitude of risk, which leads to cognitive biases [69] and poor decision-making. When certain elements of HRA are less known or understood, biases seem to point to the area of the analyst's expertise [70].

4.2. Opportunities for Consolidating Understanding and Improving the Utility of HRA

Besides general recommendations, such as more focused education opportunities or academic discussions [3,71], there is a lack of concrete recommendations on how to improve the situation related to a particular HRA issue or to the HRA process as such. There is also a lack of targeted, intervention studies that would provide a solid background for concrete improvements. In this view, our study could be seen as an attempt to fill this gap.

An analysis of the survey showed that there are no clear patterns or causes for the inconsistent, dispersed, and diverse understanding of HRA. Confusion between HRA and HIA further supports the conclusion that there is a lack of consistent understanding about why and when to perform specific assessments, how they fit in the context of specific public health problems and decisions, and how they can meet the expectations of the decision-makers and other stakeholders. Dispersed inconsistencies with no clear patterns or causes limit the potential of targeted efforts aiming to improve the understanding of HRA in decision-making. Therefore, instead of focusing on particular or only some HRA elements, we address the observed inconsistencies and foundational challenges in the RA discipline [1], such as those presented in Table 1 by highlighting opportunities for procedural improvements of HRA praxis (Figure 2) that aim to encourage and ensure overall improvements in the effectiveness of HRA in environmental and public health decision-making. The concepts behind the framework in Figure 2 are consistent with other recognized HRA frameworks [7,9,27,55]. The framework does not aim to replace them and should not be considered an all-inclusive guide on how to perform HRA. Its purpose is more focused—to highlight how the risk-informing potential of HRA can be clarified and improved.

Apart from a few open-ended i.e., "other" responses to several questions (e.g., that the selection of the assessment endpoints or the importance of other important information depends on the assessment or decision context), most of the survey responses indicated a lack of understanding of the fit-for-purpose concept of HRA [7]. It is not reasonable, or even wrong, to assume the credibility or relevance of the specific findings of an HRA without assuring that the assessment is fit for its intended purpose. Fitness for purpose is crucial for improving the utility and effectiveness of HRA in informing decisions and should be ensured from the earliest stages of the assessment process. The origins of every HRA are in the initiation phase, which should gain full attention from risk analysts and assessors. It should be recognized, however, that the initiation phase requires a lot of consultations, tolerability, respect, and patience among the stakeholders involved, since there are often unclear and vague or unspecific expressions and issues that need to be clarified, consolidated, and eventually approved (blurred cloud in Figure 2). Such issues include perceived health concerns in different population groups. Therefore, the initiation phase must support the active participation of stakeholders. This can be facilitated by decision analysis tools and methods [72,73] that improve the understanding of stakeholders' concerns and values, help identify and clarify the actual decision problem and its most important components, and determine whether and how detailed assessments of health risks are actually needed and how they should be performed [73–76].

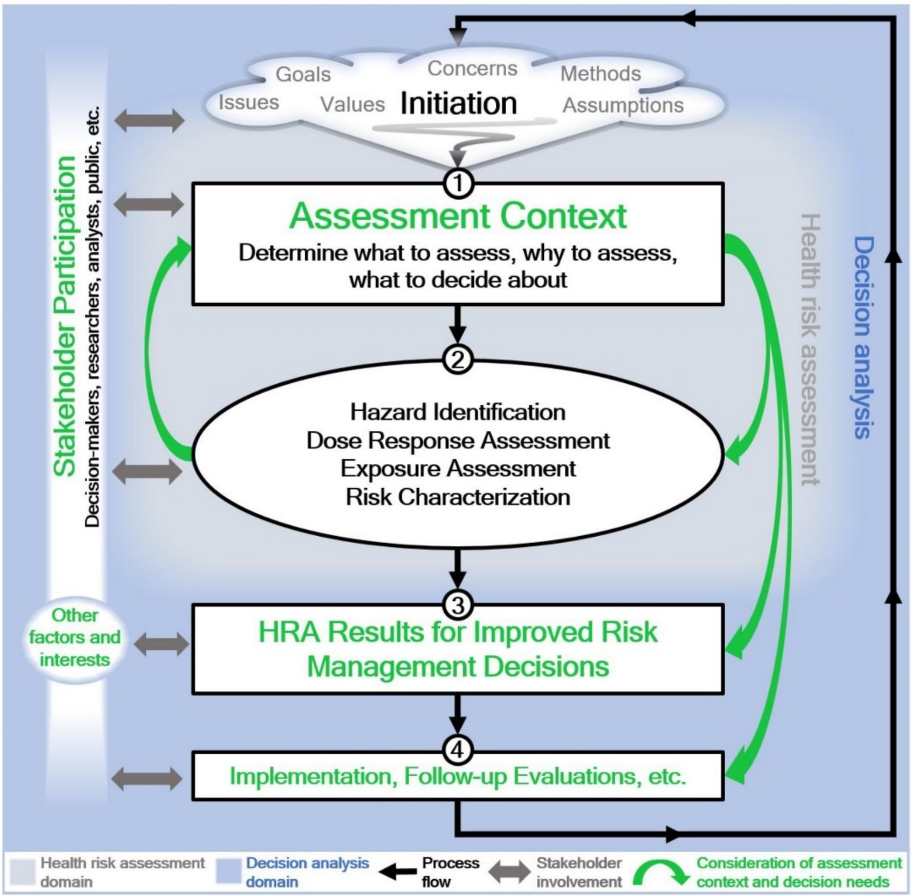

Figure 2. Opportunities for improving the utility of HRA.

"It is impossible to create meaning about risks without defining the context in which it is created" [77] (p. 4). Systematic, consolidated, and consistent discussions during the initiation phase are expected to generate the first formal step of HRA, which must clarify the assessment context (Figure 2, step 1) [78]. The assessment context reinstates the importance of planning, scoping, and problem formulation [7], which have not yet been acknowledged sufficiently as a regular and necessary step in HRA practice [56,63], as also shown by our survey. It clarifies the understanding and expectations regarding the assessment process, the results of HRA, and the context of their use among all involved in the assessment process before more technical steps of the assessment are conducted [27]. The broader context of a decision problem should be distinguished from the more specific context of the assessment. Decision analysis tools and methods are proposed to address the practical challenges related to complex processes of planning, scoping, and problem formulation. Clarification is especially needed in situations with diametrically opposed interests of stakeholders and where different options for solving a problem at hand are considered. The assessment context should be linked to the context of the decision problem and should clarify if the HRA is needed for addressing the decision problem and in what scope. There are cases and decision contexts which do not require full HRA and where only exposure or hazard assessment suffice decision needs. After establishing a clear need for HRA, the assessment context should determine the purpose of the HRA by clarifying what is going to be assessed, why it is to be assessed, the assessment's scope and plan (methods, tools, staff, financing, duration, etc.), and the decisions to be supported by the results of the HRA [27,79]. The concepts behind the assessment context step are consistent with the recently published recommendations for decision-first modeling for emerging risks [80], with an emphasis on a continuous and much broader inclusion of stakeholders, e.g., risk assessors, relevant subject matter experts, decision-makers at different administration levels, those affected by health risks, concerned citizens, and non-governmental organizations (NGOs), which is to ensure that the results of HRA are effectively addressing the concerns of as many stakeholders as reasonable.

Only after the assessment context is clear should the assessment process continue with "classical" HRA steps, including the four that often receive too much attention without a clear link to expected decisions [81]: hazard identification, dose-response assessment, exposure assessment, and risk characterization (Figure 2, step 2). These four steps, described in detail elsewhere [7,61,62], should be performed in consideration of the previously clarified assessment context. Based on the availability or non-availability of information required for specific estimates (e.g., exposure estimates, dose/exposure–response relationship), a need may arise for re-evaluations and modifications of the assessment context, considering new information coming from most recent relevant studies or decision needs. The continuous participation of stakeholders, whose importance was underacknowledged, improves the understanding of health risks, as well as the basic concepts of risk, hazard, and probability, which are often confused with each other [53]. Their participation can also address the issue of the often limited amount of information about assumptions and uncertainty factors in numerical estimates of hazards and risks received by risk managers and stakeholders [82].

To improve the understanding of the value of HRA for public health decisions and its contribution to reducing undesired health outcomes, it is necessary to monitor the decisions and their implementation with various follow-up post-decision evaluations, such as monitoring and auditing [83,84] (Figure 2, step 4). Follow-up evaluations should evaluate the success of HRA—for example, if objectives set in the assessment context are met—and must utilize tools and measures that are compatible with those used in HRA [24,85,86]. Such evaluations should also assess all relevant technological advances that could contribute to additional exposure reductions and are relevant in decision-making on various levels [24,25]. The findings of follow-up evaluations must be subjected to stakeholders' scrutiny, which contributes to building confidence in the overall assessment and decision process, provides trust and respect among the parties involved, and could eventually be a factor in the initiation stage of a fresh HRA process.

Proposed opportunities for improving the utility of HRA for decision-making are applicable generally, despite being based on authors' experience in HRA and HIA in the area of non-infectious diseases caused by activities leading to exposure to hazardous substances. Additional information about improvement opportunities within the HRA framework is provided in the supplementary file (Supplementary Figure S4), which also includes additional information that supports our recommendations.

4.3. Comments on Similarities and Differences between HIA and HRA

We observed a poor basic understanding of HIA and HRA and of the differences between them. As a response, we list some of the key differences between HRA and HIA as guidance for reaching consistency on the topic:

1. WHO's Gothenburg consensus paper defines HIA as "a combination of procedures, methods and tools by which a policy, program or project (i.e., a development proposal) may be judged as to its potential effects on the health of a population, and the

distribution of those effects within the population" [87] (p. 4). In this context, the HIA is part of a formal procedure, either an environmental impact assessment (EIA) or a strategic environmental assessment (SEA), which are required and determined by the EIA and SEA directives, respectively. The role of the HIA is to consider whether a development proposal could be improved in terms of protecting public health [88]. Methods and tools applied in HIA include expert opinion, historical data application, interaction matrices, scenario analyses, and other desk studies. Specific measurements and epidemiological studies are usually beyond the scope of HIA due to time constraints and limited financing. However, if applicable study results exist (including possible HRA results), they could be used.

2. HRA "is the process to estimate the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media, now or in the future" [89] (first paragraph). Methods and tools applied in HRA include laboratory experiments, comprehensive modeling, specific measurements, and epidemiological studies.
3. HIA is triggered by a new development proposal [90], while an HRA can be initiated in response to a specific health concern by citizens, researchers, public health professionals, NGOs, administrators, etc.
4. Despite some similarities, HIA and HRA should be distinguished [91]. The inconsistent use of HIA and HRA terminology creates confusion not only among the scientific community but also among potential users of the results of an HRA or HIA. While HRA provides a set of types of results, as we discuss in this paper, HIA's ultimate results are in the form of recommendations for changing/improving a development proposal to cause the least health issues during its implementation and subsequent utilization.
5. HRA can be a part of HIA but not vice versa.

4.4. Recommendations

The following is a summary of the recommendations:

1. A careful, technically sound narration in HRA should always be applied. The term 'risk' applies to the quantitative, probabilistic expression of the occurrence of specific health damage as a consequence of a certain exposure. Its interchange with the term "hazard" [13] is to be strictly omitted. Vague, unclear, populistic, and otherwise non-specified and non-quantified usage of the term 'risk' is neither appropriate nor valid. The adequacy of other derived expressions depends on the area of application, e.g., in the economy—probable additional costs due to workers' absenteeism associated with health consequences as assessed in the specific HRA.
2. Comparative evaluations using reference or guidance values of environmental pollution, human biomonitoring data, exposure, etc., could be used to evaluate the level of health concerns (e.g., for prioritization purposes). However, these semi-quantitative and qualitative evaluations should not be recognized, whatsoever, as a limited HRA or as actually characterizing specific risks.
3. Any HRA should start with a clarification of the decision and assessment contexts, which must guide all subsequent steps of the assessment. The decision adopted and implemented based on HRA results should be monitored for the success and expectations of the concerned stakeholders.
4. All HRA steps, as shown in Figure 2 or other frameworks, Ref. [7], should be practiced (and not only the four "classical" HRA steps). Types of HRA results should follow measures and indicators applied in epidemiological studies (i.e., addressing actual health concerns in a population of interest). Consideration of the results of relevant epidemiological studies is inevitable during the quantification and characterization of health risks (in environmental and public health areas).

5. Inconsistent, free narrative use of "health risk assessment" or "health impact assessment" phrases, contrary to their established meanings, procedures, and differences, brings additional confusion in the area [92–94] and should be avoided.
6. HRA is not HIA, and HIA is not HRA; however, HIA can involve HRA results. A distinction between the two is crucial for consolidating HRA practice and for avoiding its further erosion.
7. Targeted research efforts are needed to show possible ways out of the existing swamp of HRA inconsistencies and inadequacies. These would also deal with a thorough reconsideration and reevaluation of the applicability of toxicological or epidemiological approaches to HRA in specific situations [95–98]. Transparent addressing of the pros and cons of both approaches, and especially their uncertainties to improve the fitness for purpose, trustworthiness, confidence in, and credibility of the HRA process and its results, is inevitable.
8. The idea and a need for distinguishing between facts (science) and values in planning and decision-making, despite being an old and repeatable subject of discussion [72,73,76,99,100], have either not been implemented, or they have, but with no better success in convincing stakeholders than the assessments that were missing them. An exploration of this with targeted research would be beneficial and interesting.

4.5. Limitations of the Study

The survey was limited in scope and depth. It focused on HRA elements in the decision-making context and not on a broad understanding of all RA principles and elements. The main limitations of the survey were the selection and representativeness of the target population groups and the response rate (between 24% and 58% in all groups). Higher response rates from the first three groups could be related to the authors' and responders' involvement in the same activities. Non-probabilistic judgmental sampling limited the use of advanced (probabilistic) statistical methods, which can limit the inference of our findings to larger populations (e.g., groups of professionals in the HRA, HIA, or decision analysis areas). While the formulation of certain questions and response options differed slightly between the two questionnaires, their meaning stayed the same. Therefore, this was not expected to contribute considerably to uncertainties when comparing the results between the groups. The largest proportion of the responders from the first three groups had a background in research, while the backgrounds in public health or economy were not represented in a comparable manner. More than half of all respondents in the first three groups declared having previous experience or involvement in decision-making cases that required the assessment of health risks or impacts. However, despite declaring this, our findings suggest that the respondents were not yet involved or lacked experience in risk-informed decision-making. Actual decision-makers who had been using the results of the HRA were not represented in the survey as much as the other groups were. Despite our efforts to involve professionals with knowledge and practical experience in risk and decision analysis, the findings of this study cannot represent a broad understanding of the survey topics. In addition, the study may have missed important HRA elements, although the respondents identified none. In-depth interviews with the majority of survey participants would be necessary to obtain deeper and more detailed insights into their understanding of the topics covered by the survey, which remains a topic for future research efforts in this arena. Nevertheless, the findings of our study provide valuable and rare insights into the understanding of links between HRA results and decision-making.

5. Conclusions

The paper addressed recent alerts on inadequate understandings and practices of HRA with a focus on the pressing erosion of confidence in the risk informing value of HRA in public health decision-making. Based on the survey results among different stakeholders involved in risk assessment and decision-making, which show inconsistent distribution of the responses, we highlight the need for procedural opportunities to improve the overall understanding and the interaction between HRA and environmental and public health decision-making. It is vital that clarification of the assessment and decision contexts among all relevant and involved stakeholders is done at the beginning of the HRA process. Additionally, a decision follow-up step is needed at the end of the process to evaluate the implementation of decisions and identify the actual success and benefits of the HRA. While more targeted research on various foundational and procedural RA issues is essential to show potential ways for dealing with them, the immediate effective consideration of the assessment context in all steps of HRA can already contribute to improvements in risk-informed decision-making in environmental health, public health, and beyond.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/ijerph19074200/s1, Supplementary file, which includes both questionnaires and a summary of the responses, Figure S1: Most useful types of HRA results for decision-making—responses from groups 1 to 3 according to the background of the responders, Figure S2: Perceived importance of HRA elements by the background of responders, Figure S3: Perceived importance/usefulness of HRA elements for decision-making—comparison of responses of the four groups, and Figure S4: Opportunities for improving the utility of health risk assessment (expanded).

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Chapter 5

Discussion

The five publications provide an extensive discussion of the doctoral research results, including but not limited to the discussion of my results in the context of other research in the field and the discussion on future research needs. Additionally, this discussion chapter addresses the main goals and hypotheses of the dissertation (Chapter 2).

Potential health effects of development proposals are not adequately considered in management/policy decisions

The first hypothesis guiding my doctoral research that the potential health effects of development proposals are not adequately considered in management/policy decisions was addressed in Bizjak et al. (2020), Bizjak & Kontić (2019) and Kontić et al. (2022). The key finding in the Bizjak et al. (2020) research and related paper was that environmental health indicators are not fit for purpose – e.g., evaluating the effectiveness or success of implemented actions. Inadequacy of environmental health indicators defined in the policy implies that actual health effects related to policy actions, which could identify appropriate indicators, were not considered adequately. This first hypothesis is also supported by the RŽV case study (Kontić et al., 2022), where risk assessment results are expected to influence management decisions concerning the mill tailings at Boršt, but it is not yet clear how would such results be used in the decision-making and which stakeholders will the decision-making process involve.

Inconsistencies exist between available and related environmental and health data applied for policy development and decision-making purposes

The research and findings on second hypothesis, i.e., that there are inconsistencies between available environmental and health data used for policy development and decision-making purposes, is summarized in my article that demonstrates the benefits of auditing in the public health domain (Bizjak et al., 2020). The findings suggest that the environmental health indicators, as defined by the actual policy for monitoring purposes, cannot adequately evaluate the policy’s success since their goals and intended uses are unclear, supporting the second hypothesis's validity. Despite being developed for supporting public health and environmental policies, the internationally comparable Environmental and Health Information System (ENHIS) indicators (WHO Regional Office for Europe, 2010) seem of limited value when evaluating success of a specific public health policy. The auditing also highlighted the issue of inconsistent and indirect associations between environmental quality data and assumed exposures leading to specific health outcomes. In addition, the paper by Bizjak, Capodiferro, et al. (2022) assesses the current risk assessment practice applying HBM data through core risk analysis principles, i.e., the fourth main goal of the doctoral dissertation. Its finding supports my second hypothesis, confirming that HRA concepts lack clarity and consistency in emerging scientific fields like HBM and exposome studies.

There is a lack of experience with currently available tools such as HIA and HRA to inform public health or other developmental decisions

The validity of the third hypothesis (that there is a lack of experience with currently available tools such as HIA and HRA for to inform public health or other developmental decisions) is supported by the observations of Kontić et al. (2022), Bizjak, Capodiferro, et al. (2022), and Bizjak, Kontić, et al., (2022). The case studies on NORM and nuclear legacy sites illustrate a framework for risk-informed decision-making that integrates risk assessment with decision-making (Kontić et al., 2022). Notably, the RŽV case illustrates a lack of transparent involvement of relevant stakeholders and unclear articulation of how the risk assessment findings could be used in decision-making, despite being designed for decision-making purposes. As demonstrated, decision analysis tools such as DEXi and GiSdT facilitate future discussions regarding using risk assessment findings and managing the mill tailings site at Boršt.

HBM can provide undeniable proof of exposure but usually only has a minimal value in providing different types of important exposure assessment information when conducting HRA to inform targeted risk management interventions, i.e., exposure sources, exposure pathways, and why are individuals/populations exposed (Stackelberg & Williams, 2020). Several studies included in the review (Bizjak, Capodiferro, et al., 2022) did not specify the underlying uses and usefulness of HBM data for HRA purposes before collecting HBM samples. Such practice can lead to an increasing amount of HBM information that will remain archived but unexploited in terms of their expected, even promised, yet unrealized usefulness for HRA and related risk-informed decision making. It also supports the conclusions of the NRC (2006, p. 2) that "*the ability to generate new biomonitoring data often exceeds the ability to evaluate whether and how a chemical measured in an individual or population may cause a health risk or to evaluate its sources and pathways for exposure*".

The survey results also confirm a lack of understanding and experience of HRA and HIA (Bizjak, Kontić, et al., 2022). The terms HIA and HRA have often been used interchangeably. The inconsistent and improper use of HIA and HRA terminology creates confusion among the scientific community and the lay public, including potential users of an HRA or HIA results. Despite some similarities, HIA and HRA are not the same (CDC, 2016). Compared to the HIA, HRA describes a narrower approach used to estimate risks related to the exposure situations. The broader HIA process can include the HRA or the findings of the already completed HRA during its analytical risk appraisal stage.

There are inconsistencies in the understanding and differentiation of HRA and HIA, especially regarding their potential use in informing decision-making

The fourth hypothesis that there are inconsistencies in the understanding and differentiation of HRA and HIA, especially regarding their potential use in informing decision-making, is supported by the survey's findings targeting four distinct groups of professionals involved in the HRA and decision-making areas (Bizjak, Kontić, et al., 2022). The survey addresses the various understandings of differences and similarities between HRA and HIA observed among selected professionals through comments on similarities and differences between HIA and HRA. These comments aimed to improve the general understanding of HIA, HRA and their key concepts, focusing on their differentiation and application in policy development and the decision-making context; i.e., the third goal of the dissertation.

HRA may also be initiated by scientific interest or the need for new knowledge about how specific exposure to a particular hazardous substance influences health. In contrast, HIA initiation always needs to be triggered by a new policy or a project proposal, such as an investment that requires a permit that is granted in a formal, legally defined process and related requirements of the decision-makers (planners and authorities) about the potential health impacts of their decisions (Gulis, 2017). If there is no need for such decisions, there can be no HIA. In this context, HIA can be a part of a formal procedure, either an EIA or a strategic environmental assessment (SEA), which are required and determined by the two directives: the EIA Directive (Directive 2014/52/EU) and the SEA Directive (Directive 2001/42/EC). In this process, HIA contributes to whether an investment, i.e., development proposal, could be improved to protect public health.

Methods and tools often used in HIA include expert opinion, historical data application, previous experience, common sense, specific and limited modeling, interaction matrices, scenarios analyses, and other desk studies. Evaluation in HIA focuses on activities introduced by new investments in a specific environment and the changes they may cause, such as land use, population habits, and exposures. Specific measurements and epidemiological studies are usually not performed in the framework of HIA due to various limiting factors such as legal restrictions, time constraints, and limited financing. For example, it is not reasonable to expect an investor to finance a long-lasting epidemiological study as a potential investment before a permit is obtained for the investment (i.e., a “chicken and egg” scenario).

Additionally, according to EIA, or SEA, and related legislation no initial environmental survey or measurements could be performed by an investor on the other people's land/property before the investor acquires that land for the investment. This survey consequently, cannot happen before a permit for the investment is obtained; it is important to note that in such cases an HIA together with EIA or SEA is already concluded when the permit is granted. Therefore, the HIA needs to be finished rapidly based on the existing data and applying the appropriate methods and tools. HRA can also be initiated in response to a specific health concern. However, without an association with a development proposal, the HRA has no legal background (similar to HIA within EIA). The initiators of HRA can include concerned citizens, researchers, public health professionals, NGOs, and administrators.

Finally, there is a substantial difference between the results of HIA and HRA. HRA results should estimate the probability and severity of possible adverse health effects. In contrast, HIA’s ultimate results are recommendations for changing/improving a development proposal to cause minimal health issues during its implementation and subsequent utilization. Such recommendations may be related to changing a site where a development is proposed or the materials used in the proposed production process; establishing recreational, and sports areas when a development proposal deals with land-use planning, or in the case of a more strategic development may relate to resolving issues regarding energy supply strategy at the national level. Without exception, all such recommendations are aimed at health prevention and health improvement of the population that is somehow associated with the development proposal. The basis for HIA recommendations is a comprehensive analysis of activities related to the development proposal and population characteristics/habits which may suffer health issues and not, for example, expected or predicted incidence rate of specific health damage to the population as a result of some rapid, specific, unclear HRA.

Unclear, inconsistent, and improper uses or understanding of core risk analysis terminology, its definitions, and principles can inevitably lead to ineffective use, confusion and misunderstanding of different types of assessments, such as HRA and HIA. Also, the use of established terminology and concepts, as accepted by the risk analysis community (SRA, 2018a, 2018c), in new and inappropriate contexts causes HRAs to lose their principal meaning and identity, which reduces their potential for supporting decision-making that otherwise effectively contributes to positive changes in various areas of application.

The understanding of key risk analysis concepts (e.g., hazard, risk, exposure, dose, and uncertainty) is not coherent among the broader scientific community

The validity of my fifth hypothesis that the understanding of key risk analysis concepts (e.g. hazard, risk, exposure, dose, uncertainty) is not coherent among the broader scientific community was supported by the findings of my review (Bizjak, Capodiferro, et al., 2022). Here I assessed the current risk assessment practice based on the HBM data through the context of core risk analysis principles, i.e., the fourth main goal of the doctoral dissertation. Additionally, the fifth hypothesis was also supported by the findings of Bizjak, Kontić et al. (2022) that focus on the understanding of HRA in the decision-making context. Both papers contributed specific clarifications of the scientific foundations of risk analysis, i.e., the second goal of the dissertation. The review concluded that there are apparent inconsistencies in understanding fundamental risk analysis principles in the publications about HBM in HRA. Despite stating otherwise, most of the reviewed publications were not actual examples of HRAs but HBM based exposure assessments and only included a limited assessment based on various threshold value approaches. The confusion in terminology, persisting in the HRA area (Serraino, 2014), was also observed in HBM.

The survey results also support the recurring foundational challenges in the risk analysis area (Aven & Flage, 2020), which include the lack of acknowledgment of the main purpose of HRA to inform risk management decisions. While still requiring future attention (Hansson & Aven, 2014), consensus about the core risk analysis subjects can be reached among the professionals involved in the risk analysis area (SRA, 2018b, 2018a). During the COVID-19 pandemic, the public widely used risk analysis terms without adequately considering their meaning. For example, the term risk is often used interchangeably with probability or hazard (Bizjak, Kontić, et al., 2022). This finding supports perhaps an even more pressing need for consolidating core subjects of risk analysis among the broader scientific (and non-scientific) community, which would help improve the recognition of risk analysis as a separate discipline.

Understanding the importance of different HRA elements in informing risk management decisions seems to be inconsistent and dispersed (Bizjak, Kontić, et al., 2022). Most of the HRA elements were perceived as important or very important; however, the uncertainty, coordination of HRA procedure, and the type of HRA results were perceived as relatively less important, regardless of the background of the responders from the first three groups targeted by the survey. This indicates a slight difference compared to previous research revealing that the biased perception of the importance of certain HRA elements is usually focused on the area of the professional's expertise (Slovic, 1999). The established risk and decision analysis professionals (the fourth group in the survey) perceived the decision alternatives for mitigating exposure, uncertainty of HRA results, and transparency and clarity of the assessment process as relatively more useful for informing decision-making.

Chapter 6

Conclusions

As observed over the past two decades and more recently during the COVID-19 pandemic, the role of HRA or HIA in informing public health decisions continues to be unclear or is diminishing. My findings confirm the confusion between HRA and HIA, highlight a limited utility of HBM in general, unsuitable and misleading HRA praxis based on HBM data (e.g., when there is a lack of relevant epidemiological evidence), and show that inconsistencies in the understanding of the risk-informing purpose of HRA, and the core risk analysis terms and principles are widespread and unclear. It is crucial to improve the science to public health policy interaction to ensure that the most relevant scientific knowledge improves population health. The extent of observed issues is a clear warning that more has to be done to address the swamp of inconsistencies and inadequacies in HRA area resulting in misunderstandings and hindering risk-informed decision-making and confidence in it. The main contributions of my doctoral research to the improvements of the HRA praxis are:

(1) The clarification of the assessment and decision contexts among all relevant and involved stakeholders at the beginning of the HRA process (Figure 4), which the decision analysis tools or methods can facilitate, can improve the overall understanding of the interaction between HRA and environmental and public health decision-making.

(2) The improved understanding and contribution of the assessment context and stakeholders' participation in informing decision-making to improve public health policies (i.e., the fifth goal of the doctoral dissertation) should improve S2P interaction in HRA (i.e., the first goal of the dissertation).

(3) A decision follow-up step at the end of the process is crucial for evaluating the implementation of decisions and identifying the success and benefits of the HRA. As a type of follow-up evaluation, auditing can help evaluate the implementation, compliance, and adherence to selected public health policy on one side and the accountability and honesty of those involved in policy development and implementation on the other. Increasing the overall transparency of the auditing and regular re-auditing is imperative if auditing is to contribute to improved S2P interaction.

(4) Auditing can also provide evidence about the satisfaction of the stakeholders involved in terms of their effective participation and contribution to the decisions, which can, in turn, contribute to the overall credibility of the assessment process, decision making and policy implementation.

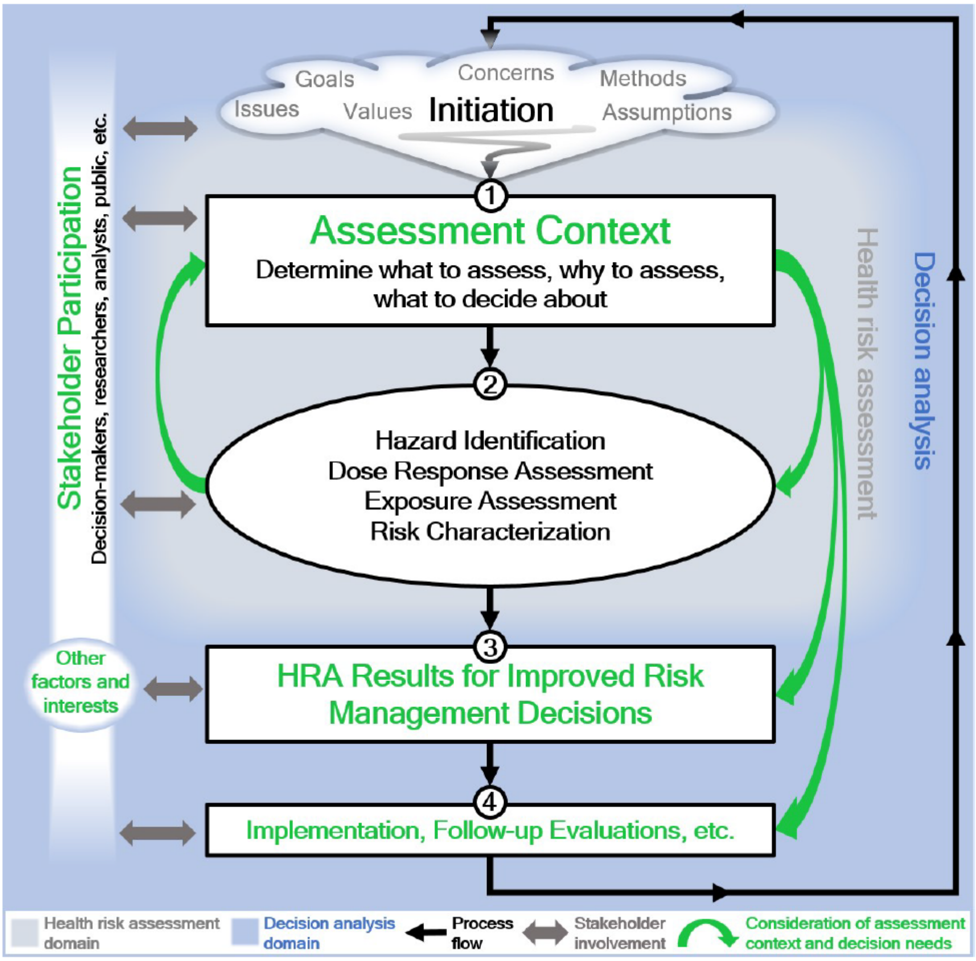

Figure 4: Opportunities for improving the utility of HRA.

(5) Besides general efforts such as study programs offering courses on risk analysis, HRA would benefit from targeted interventions. The advances in specific disciplines, including HBM, modeling and *in vitro* studies that can potentially be used for HRA purposes, cannot improve the HRA's science, process, and impact on public health decisions without wider recognition and consolidation of core HRA principles and concepts. More targeted research on various foundational and procedural risk analysis issues should also be performed to show potential ways of dealing with them. Such targeted research efforts should deal with a thorough reconsideration and reevaluation of the applicability of different HRA approaches (e.g., using toxicological or epidemiological approaches) in specific situations. There is a need to build on the findings of review that assessed the clarity of HBM in HRA with a more comprehensive investigation, which would have to include more professionals. There is also a need for more (continuous) evaluations of the success of national or international public health policies and for (re)evaluations of applicability of environmental and health indicators in terms of their actual informing value in policy development. Additionally, there is a lack of evidence about the actual benefits of stakeholder involvement in the decision-making processes. However, despite further research needed in many areas, the clarification of the assessment context among all stakeholders and its effective consideration in all steps of HRA can immediately improve risk-informed decision-making in environmental health, public health, and beyond.

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Biography

Tine Bizjak passed his Matura examination with distinction in 2007 after attending the Poljane grammar school in Ljubljana, Slovenia. During the first years of his studies at the Faculty of Medicine at the University of Maribor, he discovered his interests lie in the environmental health research area. He obtained his Bachelor's degree in Environmental technology at the University of Nova Gorica, School of Environmental Sciences in 2016. His Bachelor's thesis focused on the evaluation of an Aethalometer based black carbon emissions source apportionment model. He has also completed a 6-month Erasmus+ applied ecology traineeship at the Faculty of Applied Ecology and Agricultural Sciences Hedmark University College, Norway. After graduating, he completed a second 6-month Erasmus+ traineeship at the Department of Environmental and Biological Sciences, University of Eastern Finland, making the first evaluation of the microplastic pollution in Finnish lakes. He later obtained his Master's degree in General Toxicology and Environmental Health Risk Assessment at the University of Eastern Finland in 2018, having received the Ad Futura scholarship for studying abroad. His Master's thesis focused on the comparison of chemical and optical methods for the measurements of black carbon emissions from wood combustion. Afterwards, he became a research assistant at the Fine Particle and Aerosol Technology Laboratory, Department of Environmental and Biological Sciences, University of Eastern Finland. Between October 2018 and October 2021 he worked as an MSCA ITN early stage researcher within the NEUROSOME project (Grant agreement No. 766251) at the Department of Environmental Sciences at the Jožef Stefan Institute In Ljubljana, Slovenia and as a research assistant at the same department between October 2021 and March 2022. In 2018 he also enrolled in the Ecotechnologies doctoral program at the Jožef Stefan International Postgraduate School.

During his doctoral research work, he was also involved with several other Slovenian and international projects: including HERA (Integrating Environment and Health Research: a Vision for the EU), working on the evaluation of the key topics in policy and practice in the environment, climate and health nexus in Slovenia and other European countries; in SciShops where) he gained knowledge and experience about the community based participatory research; in MODARIA II (Modelling and Data for Radiological Impact Assessments) performing decision analysis related to the closing-down of the RŽV; and the HBM4EU (European Human Biomonitoring Initiative) and the Slovenian Research Agency's CRP V3-1722 projects where he contributed to the understanding of HBM data (on Cd, and As and its compounds) in HRA.

The author presented his work at BIONANOTOX 2019 and 2021 conferences, the SciShops symposium, the Fourth Technical Meeting of MODARIA II, and the 13th Students' Conference of the Jožef Stefan International Postgraduate School and the 15th Researchers' Day of chemistry, Material Science, Biochemistry and Environment in 2021. He has also participated in the 2nd HBM4EU training school in 2018, in the training session on NORMALYSA tool for safety assessment & Uranium residues management organized by the IAEA within MODARIA II programme in 2019, several workshops and summer schools organized within the NEUROSOME project, and in the *Environmental Health Risk:*

Analysis and Applications educational activities at Harvard T.H. Chan School of Public Health in March 2020. During his doctoral research the author also held three lectures at the University of Ljubljana on environmental impact assessment, strategic environmental assessment and the difference between assessments of health risks and health impacts as part of Landscape Architecture Master Degree course Environmental Protection and Fundamentals of Environmental Science.