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# Extending and improving current frameworks for risk management and decision-making: A new approach for incorporating dynamic aspects of risk and uncertainty

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#### ABSTRACT

In recent decades, there has been a growing recognition of the importance of risk-informed decision-making, and the use of risk assessments to support decisions is a core principle in current frameworks and standards for risk management and decision-making. While considerable efforts have been directed towards clarifying the role of risk assessment as input to decision-making, less attention has been paid to the follow-up of the risk assessment once a decision has been made. However, new knowledge, as well as changes in systems, phenomena or values, could alter the underlying premises of the initial risk assessment. Many of the current frameworks for risk management and decision-making lack suitable approaches for reflecting these issues, leaving important aspects of risk unaddressed. In this paper, we present an adjusted approach to risk management and decision-making in which the need for new risk assessments is evaluated, focusing on three main criteria: i) the introduction of new decision alternatives, ii) changes in risk, and iii) changes in context/values. Acknowledging the challenge of determining the appropriate timing for the evaluation, we emphasize that striking a balance between remaining responsive to challenging circumstances and avoiding the use of unnecessary resources on excessive evaluations, is a key task. By providing the basis for a more dynamic approach to risk assessment, the paper aims to strengthen the foundation for risk-informed decision-making.

#### 1. Introduction

Decision-making under conditions of risk and uncertainty is a fundamental issue within risk analysis and decision analysis. Several frameworks and standards have been developed to provide guidance on this issue. Some of these frameworks and standards take a risk management and governance perspective (COSO, 2017; IRGC, 2017; IRM, 2002; ISO, 2018; NRC, 1983; PMI, 2017), while others are founded on decision analysis theory (Clemen & Reilly, 2013; Howard & Abbas, 2015). Although the risk management and decision analysis frameworks differ with respect to which concept is considered predominant (risk or decision-making, respectively), the main purpose of the frameworks is the same: to provide a systematic approach for generating information about risks and uncertainties to be used as a basis for decision-making.

Within the field of risk management and decision-making, there are two main perspectives on how to use risk assessments in the decisionmaking process. One perspective, commonly known as risk-based decision-making, involves a prescriptive approach where the output of the risk assessment directly determines the chosen course of action (e.g., by using predetermined criteria or thresholds). On the other hand, riskinformed decision-making follows the idea that information generated by the risk assessments serves as input to the decision-making process, but should be considered in conjunction with a broader range of evaluations and considerations (Apostolakis, 2004).

While the role of risk assessment as input to decision-making is an unequivocal principle in a majority of the most commonly applied standards and frameworks, the various approaches present different perspectives on how the process should be structured once a decision has been made. According to some frameworks, the decision is seen as an end state, indicating that the process is considered complete after the decision has been made (Howard & Abbas, 2015; Clemen & Reilly, 2013; National Research Council, 1983). Other frameworks refer to the relationship between risk management and decision-making as a loop, in which the choice of decision alternative(s) is followed by a stage (often referred to as 'monitoring and review') where information succeeding the decision is fed back into another risk assessment iteration (e.g., IRGC, 2017; IRM, 2002; ISO, 2018). This way of structuring the process provides the basis for adopting a dynamic perspective on risk assessment, allowing for changes in risk and uncertainty to be captured and incorporated into the decision-making process. However, the 'monitoring and review' stage is mainly restricted to assessing the effectiveness of the chosen decision alternative. For example, according to the

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Received 1 June 2023; Received in revised form 10 September 2023; Accepted 13 September 2023 Available online 21 September 2023 0925-7535/© 2023 The Author(s). Published by Elsevier Ltd. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/). risk management standard produced by the Institute of Risk Management (IRM), a key purpose of the review process is to "determine whether the measures adopted resulted in what was intended" (IRM, 2002, p. 11). A similar notion is found in the ISO 31000 standard, which states, "The purpose of monitoring and review is to assure and improve the quality and effectiveness of process design, implementation and outcomes" (ISO, 2018, p. 14). Although this provides useful reflections on the influence of decision-making on risk, the decision could also have impacts beyond this. Furthermore, there could be changes in the premises underlying the initial risk assessment that could have a significant impact on judgments of risk and uncertainty. To illustrate the issue, consider the following example:

At the beginning of March 2020, many governments worldwide decided to implement strict lockdown policies in an attempt to mitigate the risk associated with an uncontrolled spread of the COVID-19 disease. Although these policies can be seen as successful in relation to their initial purpose, which was to protect the population against the emerging disease, the lockdowns gave rise to new risks and vulnerabilities, i.e., for the economy, public health, business and industries (Bonaccorsi et al., 2020; Elleby et al., 2020; Kuckertz et al., 2020; Kumar et al., 2021; Shafi et al., 2020). The case illustrates an example of socalled risk-risk trade-offs, a concept in which a decision to reduce one risk leads to the generation of new risks (Graham et al., 1995; Lofstedt & Schlag, 2017). Some of the risk-risk trade-offs related to the lockdown were known and anticipated yet (implicitly or explicitly) accepted in order to reduce the spread of the disease, for which the risk was judged to be higher. An example is the significant losses for businesses that were required to close when the lockdowns were imposed. Other effects were unforeseen, such as the increased vulnerability against cyberattacks following the extensive adoption of new platforms and technology for working remotely (Buil-Gil et al., 2021). Hence, the decision to implement lockdowns served to decrease the disease risk yet, at the same time, had rippling effects that gave rise to new risks and vulnerabilities. Furthermore, the decision to implement the lockdown policies was taken in a context in which the knowledge about the virus, the disease and the population's immunity was limited and evolving rapidly. As the pandemic unfolded, new knowledge emerged regarding such aspects as the virus's transmission and the efficacy of the implemented measures, altering many of the assumptions underlying the initial risk assessments. In addition, the consequences of the lockdowns became more evident, and the initial focus on reducing the spread of the virus and protecting the population's health gradually expanded to also incorporate the economic and social impacts of the lockdown policies, causing a shift in the underlying values and objectives of the risk assessment (Coccia, 2021; Lewis, 2022).

As illustrated by the above example, a risk-informed decision-making process must be seen in light of the specific context in which it was performed. This context could change, influencing both the prerequisites of the risk assessment, as well as the results and how they are evaluated and used. Capturing this aspect in a risk management and decision-making context requires clear guidance on how these effects and changes can be identified and addressed. The present paper aims to show how the review/monitoring stage of current frameworks and standards can be extended and improved to better reflect the dynamic features of risk and uncertainty by presenting a systematic approach for evaluating the need for the initial risk assessment to be reviewed and new risk assessments to be conducted, using three main criteria:

- 1) The introduction of new decision alternatives
- 2) Changes in risk
- 3) Changes in context/values

The evaluation builds on general ideas and principles for risk assessment adopted in the frameworks and standards referred to above, in which the risk assessment produces a risk description containing a set of specified events, outcomes and a measure of the associated uncertainties (typically expressed using probabilities). However, following contemporary perspectives on risk conceptualization and characterization (SRA, 2015; SRA, 2018), the evaluation extends beyond these principles to also incorporate aspects of uncertainty that go beyond the assigned probabilities, including judgments on the knowledge supporting the assessment. Furthermore, by taking into consideration potential changes in the context and values that the analysis is built on, such as objectives, priorities, public opinion and attitudes towards risk, the evaluation is intended to capture aspects that are not an integral part of the risk assessment but which could influence how the risk assessment results are evaluated and used. Employing these principles as a foundation, we present a systematic approach for evaluating the need for new risk assessments, in which the introduction of new decision alternatives, as well as changes in risk and changes in values, are used as the main criteria for the evaluation. The aim of the proposed approach is to strengthen the ability of the frameworks and standards to capture and integrate new information as it becomes available, ensuring that the risk assessments are up-to-date, and that the risk management and decisionmaking process remains relevant and effective.

The remainder of the paper is organized as follows: In Section 2, we conduct a review of current standards and frameworks, focusing on the degree to which the structure and contents of these take into account dynamic aspects related to risk assessment. In Section 3, we outline the general set-up of the suggested approach and present the proposed criteria for evaluating the need for new risk assessments, using a case example. The approach is discussed in Section 4. Finally, some concluding remarks are made in Section 5.

#### 2. Review of current frameworks and standards

Several frameworks and standards exist, with the purpose of providing guidance on how to make decisions in the presence of risk and uncertainty. These frameworks and standards typically outline a general structure and description of the risk management and decision-making process, using a set of guidelines and principles that can be applied to a wide range of contexts. In this section, we will take a closer look at current frameworks and standards, particularly focusing on the structure of the risk management and decision-making process, and their ability to consider potential changes and developments of relevance to risk and uncertainty that may occur after a decision has been made. The aim of the present section is not to be exhaustive, but to provide an overview of defining ideas and principles that underpin some of the most commonly applied frameworks and standards for risk management and decision-making. For this purpose, the following were selected:

- The enterprise risk management framework by the Committee of Sponsoring Organizations of the Treadway Commission (COSO, 2017)
- The risk management standard by the Institute of Risk Management (IRM, 2002)
- The ISO 31000 Risk management principles and guidelines (ISO, 2018)
- The risk assessment framework presented in the 'Red Book' by the National Research Council (NRC, 1983)
- The framework for risk governance by the International Risk Governance Centre (IRGC, 2017)
- The project risk management framework by the Project Management Institute (PMI, 2017)
- The decision analysis framework by Clemen and Reilly (2013)
- The decision analysis framework by Howard and Abbas (2015)

In the frameworks and standards listed above, the risk management and decision-making process is structured as a sequence, consisting of several steps or stages. Although the description of the steps and their components is influenced by differences in main perspective and terminology, the approach outlined by the various frameworks and standards includes a set of main steps that are broadly similar:

- 1. Establishing a context: Identifying and defining the scope and objectives of the process
- Risk assessment: Identifying key events/hazards, their potential outcomes and the uncertainties associated with the events and outcomes
- 3. Evaluation: Evaluating the results of the risk assessment and prioritizing options
- 4. Decision: Selecting and initiating the implementation of options

The second step, sometimes referred to as 'risk analysis', focuses on establishing an overview of the relevant risks and uncertainties that could affect the objectives or values defined in the first step. While the risk assessment procedure is described using different methods and terms, the basic elements of the process are generic: identifying the events that could occur, specifying potential outcomes (consequences) and describing the associated uncertainties. The uncertainties related to the events and outcomes are typically described using likelihood/ probability. The frameworks for decision analysis do not refer to the term 'risk assessment' explicitly. However, they include an assessment of potential outcomes and uncertainties that follows the same procedure as the risk assessment process outlined above, the main difference being that the outcomes and uncertainties are seen in relation to some specified decision alternatives.

The contents and scope of the third stage (evaluation) determine the degree to which the decision-making process can be considered risk-based or risk-informed. When the decision-making is risk-based, the evaluation stage is typically limited to comparing the results of the risk assessment to some predefined thresholds or criteria. In a risk-informed approach, however, the evaluation takes into account a wider range of factors, including social, cultural, economic, and ethical dimensions, which may not have been explicitly addressed in the risk assessment. While the frameworks and standards above vary with respect to the scope and contents of the evaluation stage, the main idea is that the risk assessments do not prescribe what to do – decision-making needs to be supported by a broader evaluation that extends beyond the results of the risk assessment alone.

The decision stage (sometimes referred to as risk treatment in the above frameworks and standards), involves choosing among the various decision alternatives and initiating the implementation of the chosen alternative. The main intention of the stage is to address the risks identified in the risk assessment. The choice of alternatives is based on various strategies for handling risk, including risk avoidance, risk reduction, risk acceptance or transferring/sharing risk.

With the exception of the framework presented by the National Research Council (NRC, 1983), all of the frameworks and standards

feature a feedback-loop, which entails the return of information from a later stage in the process to earlier stages. There are, however, variations with respect to where the feedback-loop is placed in the risk management and decision-making structure, and what information is fed into it. Table 1 provides a summary of the placement and interpretation of the review and feedback processes in the various frameworks and standards.

In the decision analysis frameworks by Clemens and Reilly (2013) and Howard and Abbas (2015), the feedback-loop is inserted from the stage preceding the decision, leading back to the initial stage of the process, the main purpose being to ensure that the quality and the relevance of the information leading up to the decision are sufficient. According to these frameworks, the dynamic aspects of the process are addressed by capturing the potential for new information or changes in circumstances arising during the risk assessment and evaluation stages that could impact decision-making. However, once a decision is reached, the process is considered complete, and no further evaluations are included.

In some of the frameworks and standards, the risk management and decision-making process is described as a cycle in which the feedbackloop runs from the end of the structure and back to the initial stage. The loop is fed by information generated after the decision has been made, in what is referred to as a 'review' or 'monitoring' stage. The frameworks by COSO and PMI do not explicitly include the feedback loop in the flowchart representation of the risk management and decision-making process. However, the frameworks both include a review stage subsequent to the decision, implicitly assuming the existence of some sort of feedback mechanism. In the ISO 31000 standard, the review and monitoring stage serves as an iterative feedback loop which continuously draws from and provides feedback to all stages of the risk management and decision-making process.

When studying the stated purpose and contents of the review and feedback stages, three main aspects can be identified: i) the performance or effectiveness of current measures or decision alternatives, ii) the quality of the risk management and decision-making process and iii) the need for adjustments in response to changing circumstances.

The guidance provided by the various frameworks and standards differs with respect to which aspects are focused on, and how the scope and contents of the review and feedback processes are understood and presented. Furthermore, the frameworks and standards differ in their degree of specificity and detail in the guidance provided. While the ISO, IRGC and IRM frameworks take a more general perspective, offering some overall recommendations to guide the process, the frameworks by COSO and PMI concretize a set of characteristics or tools that can be used in the assessment of the various aspects. For example, the PMI framework refers to the use of risk audits as a key tool for evaluating and documenting the effectiveness of both risk responses and the overall process. The framework by COSO points to a set of characteristics to consider in the assessment of substantial changes, including changes in law/regulation and how changes in senior personnel affect risk. Although these tools and

#### Table 1

Structure and contents of the review and feedback steps.

| Framework/<br>standard | Contains<br>feedback loop | Stage providing input to<br>feedback-loop | Stated interpretation/purpose of review and feedback process  |
|------------------------|---------------------------|---|---|
| COSO                   | Yes                       | Review and revision                       | Assess substantial change, review risk and performance and pursue improvement in enterprise risk management   |
| IRM                    | Yes                       | Monitoring                                | Ensure that risks are effectively identified and assessed, and that appropriate controls and responses are in place   |
| ISO                    | Yes                       | Monitoring and review                     | Assure and improve the quality and effectiveness of process design, implementation and outcomes   |
| IRGC                   | Yes                       | Monitoring and control                    | Establish a link between the outcome of risk management and the need to revise the initial assessment and the management decisions, if conditions have changed or if performance is lower than expected |
| NRC                    | No                        | _   | -   |
| PMI                    | Yes                       | Monitoring and control                    | Monitor the implementation of risk response plans, track identified risks, identify and analyse new risks and evaluate process effectiveness  |
| Clemen & Reilly        | Yes                       | Sensitivity analysis                      | Capture changes in the decision-maker's perception of the problem, including judgments of likelihoods and uncertainties, and preferences for outcomes not previously considered                         |
| Howard & Abbas         | Yes                       | Appraisal (evaluation)                    | Refine the analysis if new information is required or becomes available   |

characteristics provide a direction for the evaluation, they do not offer specific guidance on how these elements should be assessed. For example, when considering changes in law/regulation, the framework does not specify which changes are relevant to the analysis or how their impact on risk and uncertainty can be evaluated.

Several of the frameworks and standards recognize the need for revision or adjustment, specifically in response to the information generated by the assessment of the effectiveness/performance of current measures (i) as well as the changes in circumstances (iii). For example, the latter aspect is emphasized in the IRM framework, stating that "Changes in the organisation and the environment in which it operates must be identified and appropriate modifications made to systems". Similarly, the IRGC framework highlights the "need to revise the initial assessment and the management decisions, if conditions have changed or if performance is lower than expected" (2017, p. 25), referring to the output of aspects iii) and i), respectively. Despite this acknowledgement, the frameworks and standards do not provide clear guidance with respect to when the output of the evaluation requires further action. For example, the COSO and PMI frameworks consider updating risk assessments as a task to be performed on a periodic basis rather than as a direct result of the review process. In the frameworks related to decision analysis, changes in circumstances are addressed (iii) but restricted to the context of the assessment/analysis and evaluation stages.

According to some of the standards and frameworks, the quality of the risk management and decision-making process (ii) is considered an important part of the review and monitoring stage. An example is the COSO framework, in which a stated goal of the review is to assess the overall performance and effectiveness of the risk management program. This includes the use of benchmarking and internal audit procedures to ensure that current practices are under continuous scrutiny and improvement. A similar notion can be found in the ISO standard, in which a key purpose of the review and monitoring process is "to assure and improve the quality and effectiveness of process design, implementation and outcomes" (ISO, 2018, p. 14).

To summarize the above review, the notion of risk management and decision-making as a continuous, iterative process is integral to the majority of current frameworks and standards. This notion is operationalized by incorporating review and feedback mechanisms in the structure of the risk management and decision-making process. However, there are some issues when it comes to the interpretation and use of these mechanisms. The main concerns relate to the lack of clear criteria for evaluating the need for new risk assessments. While the effectiveness of current measures and decision alternatives is highlighted as an important part of the evaluation, changes in relation to risk, values and other circumstances are covered only to a limited extent. Furthermore, current approaches do not provide clear guidance when it comes to determining when adjustment or revision is justified. However, if the purpose of the review is to evaluate the need to revise or adjust the initial assessment, it is necessary to clarify the conditions under which the results of the evaluation should trigger such a response.

In the following section, we propose an adjusted approach for evaluating the need for new risk assessments that aims to rectify these issues and provide current frameworks and standards with a stronger foundation for implementing a dynamic perspective on risk management and decision-making.

## 3. Adjusted approach for evaluating the need for new risk assessments

#### 3.1. General set-up

The set-up presented in this section places the approach within the context of the risk management and decision-making process, which follows the stages outlined in Section 2.

The first stage, 'establish context', includes defining the objectives and scope of the risk assessment. In this stage, the main purpose of the risk assessment is identified. Laws, regulations, policies and guidelines that constitute the frames and boundaries for the risk assessment are identified and taken into consideration. Furthermore, the stage includes specifying the relevant stakeholders involved, as well as their values, interests and concerns.

In line with the basic ideas presented in current frameworks and standards, the risk assessment stage involves generating a risk description that contains a set of specified events, potential outcomes (effects, consequences) and a measure of the uncertainties associated with the events and outcomes, typically expressed using likelihood/probability. However, we extend current thinking by incorporating ideas and principles from contemporary risk science that emphasize the importance of considering aspects of uncertainty that go beyond the assigned probabilities (see, e.g., Aven, 2012; Renn, 2017). In line with these ideas and principles, the characterization of uncertainty needs to reflect assessments related to the strength of the knowledge that the description of risk (including the specified events, outcomes and the assigned probabilities) is conditional on. Knowledge is here understood as justified beliefs (SRA, 2015), often formulated as assumptions supported by inter alia data, models, information and argumentation.

In the following stage, referred to as 'evaluation', decision-makers deliberate over the results of the risk assessment. However, in order to acknowledge the leap between the risk assessment and the decision, the evaluation goes beyond considerations of the description of risks and uncertainties, also incorporating judgments on the limitations of the assessments, as well as addressing the potential for uncertainties and knowledge gaps that may not have been captured by the assessments. In addition, decision-makers need to take into account aspects that are not reflected by the risk assessments, such as risk perceptions, reputational issues, organizational factors and political, social and strategic concerns. This process, sometimes referred to as managerial review and judgment, or broad risk evaluation, is essential in order to ensure that risk and uncertainty aspects not covered by the risk assessments are given sufficient weight (Hansson & Aven, 2014; Hertz & Thomas, 1983; Renn, 2017).

Among the limitations that decision-makers should reflect on, is the suitability of the methods and models used in the analysis. For example, do the methods and models align with what can be considered best practice? Are they well understood, or could there be potential 'black box' issues in which the complexity of the models exceeds the understanding of the analysts and decision-makers? Furthermore, the resources and knowledge supporting the analysis should be taken into consideration. For example, do the analysts have the required competence for conducting the analysis? Have they conferred with relevant experts on the subject matter? Addressing these factors, and how they could influence the output of the risk assessment, constitutes an essential part of the evaluation.

Similarly, the managerial review and judgment should take into account organizational factors that could have an impact on decisionmaking, including the structure of the organization, its values, limitations and constraints. The importance of aligning decisions with strategic values is highlighted by Thekdi and Aven (2018) who stress the potential consequences of misalignment, including a degrading reputation and long-term damage to the organization. They also offer insights into how evaluations of organizational factors can be incorporated into the managerial review and judgment process.

Another fundamental issue that should be addressed in this stage, is the potential for cognitive biases and heuristics that could influence how decision-makers interpret and deliberate over the results of the risk assessments. For example, confirmation bias may lead decision-makers to focus on the information that support their preconceived notions, while ignoring potentially contradicting information. Similarly, the availability heuristic could prompt decision-makers to draw conclusions based on the most recent, or easily retrievable data, rather than conducting a comprehensive assessment of all relevant information (Kahneman, 2012; Montibeller and von Winterfeldt, 2015; Tversky & Kahneman, 1974). The managerial review and judgement process serves as a pivotal platform for decision-makers to recognize how these cognitive pitfalls come into play, and to employ debiasing strategies to address them (Fischoff, 1982; Larrick, 2004; Montibeller and von Winterfeldt, 2015).

The scope and boundaries of the risk and uncertainty assessments largely determine the content of the evaluation process. A narrow, probability-based approach to risk and uncertainty characterization requires a broader managerial review and judgment, and vice versa (Aven & Zio, 2014). The results of the decision-makers' review and judgment are used as input to support the decision, which constitutes the next stage in the process. The stage includes choosing among a set of decision alternatives, and initiating the implementation of the selected option.

Once a decision has been made, the process enters the 'review/ monitoring' stage. In the adjusted approach, the main purpose of the review/monitoring stage is to assess whether the information generated from the previous risk assessment process remains up-to-date or new risk assessments are needed. In the adjusted approach, the need for new risk assessments is evaluated based on three main criteria: the introduction of new decision alternatives (1), changes in risk (2) and changes in context/values (3). The proposed approach is intended to serve as a supplement to the existing review and monitoring stage, extending and improving the current evaluation criteria and scope. As illustrated in Fig. 1, the review/monitoring stage is followed by a decision point which determines the need for new risk assessments, using the results from the evaluation of criteria 1, 2 and 3 as input. If the answer is 'no', the process returns to the review/monitoring stage. However, if the answer is yes, the process enters a feedback loop, whereby information is extracted from the evaluation of criteria 1, 2 and 3 and fed back into the initial stage of the process. What triggers the evaluation of the need for new risk assessments is context dependent. In some cases, the evaluation may be conducted as part of a regular or periodic review process, while, in other cases, it may be triggered by external events, such as technological advancements or changes in the legal or regulatory landscape. In addition, information obtained through signals and warnings could indicate gaps in the existing risk assessment, triggering an evaluation of the need for new risk assessments using the proposed approach. Such signals and warnings include the occurrence of unexpected and surprising events, shifts in stakeholders' attitudes and concerns, or feedback from frontline workers, experts or professionals involved in the implementation or management of risk management policies and strategies. By actively monitoring and analysing these signals and warnings, decision-makers can detect when potential shifts in the risk landscape or contextual factors warrant further investigation.

An overview of the relevant actors and their roles and responsibilities for each of the steps in the process is provided in Table 2.

The main aim of the adjusted approach is to rectify the issues identified in Section 2. The approach extends and improves the scope and contents of the review/monitoring process by introducing three main criteria for evaluating the need for new risk assessment and specifying how the criteria should be evaluated in a structured and systematic way, ensuring that relevant aspects of risk and uncertainty are taken into consideration. Furthermore, by showing how the output of the evaluation can be used to assess the need for new risk assessment iterations, the approach provides guidance on when adjustment or revision is justified.

#### 3.2. Evaluation criteria

The output of the risk management and decision-making process depicted in Fig. 1 is contingent on the conditions under which it was conducted. For instance, when establishing the context, judgments are made regarding the main objectives of the risk assessment and the values at stake. Similarly, evaluating the results generated by the risk assessments requires assessments on which aspects to prioritize (environmental, social, economic, etc.), how to weight different concerns, including ethical concerns and public perceptions of risk, and which levels of risk should be considered tolerable or acceptable. The risk assessment stage produces a risk description that is rooted in the current state of the activity, system and phenomena considered, as well as the knowledge/information used to support the assessment. Furthermore, the risk management and decision-making process builds on a defined set of decision alternatives, often formulated as a "choice between various concepts, design configurations, sequence of safety critical activities, risk reducing measures, etc." (Ersdal & Aven, 2008, p. 201). However, once a decision has been made, new decision alternatives could arise, potentially altering the underlying premises of the initial risk assessment. These new alternatives may emerge due to factors such as technological advancements, shifts in available resources or new data/information. For example, the development of new technology could open up for previously unexplored approaches or tools. Similarly, the acquisition of new data or information about the system or phenomena at hand could reveal challenges or opportunities that were not captured in the initial process, leading to the formulation of new options to be considered.

In order to assess whether the initial risk assessment remains relevant, an evaluation needs to be made concerning the degree to which the conditions underlying the initial risk assessment have changed. The criteria for evaluating the need for new risk assessment are designed to capture potential changes in these conditions by reflecting the following main aspects:

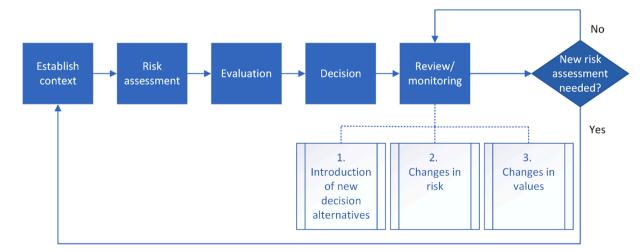


Fig. 1. Outline of risk management and decision-making process, including the adjusted approach for evaluating the need for a new risk assessment iteration.

#### Table 2

Overview and description of roles and responsibilities.

| Step              | Relevant actors           | Roles/responsibilities  |
|-------------------|---------------------------|---|
| Establish context | Managers                  | Providing overall direction and guidance for the risk management and decision-making process, and allocating the necessary resources.   |
|                   | Decision-makers           | Setting the priorities and determining the goals and objectives to be achieved.   |
|                   |                           | Specifying relevant stakeholders.   |
|                   | Stakeholders              | Contributing to establishing the context by providing input on relevant perspectives, concerns and values.  |
| Risk assessment   | Analysts                  | Conducting the risk assessment  |
|                   | Subject matter<br>experts | Providing specialized knowledge and expertise on subjects relevant to the analysis  |
| Evaluation        | Managers                  | Participating in the evaluation process, reviewing the results of the risk assessment and considering how they align with organizational policies and strategies.   |
|                   | Decision-makers           | Leading the evaluation process, deliberating over the results of the risk assessment and its limitations, also taking into consideration<br>input from managers and stakeholders on other relevant aspects. |
|                   | Analysts                  | Contributing with elaborative and detailed information concerning the analysis, its contents, background and supporting data/   |
|                   | Subject matter            | knowledge.  |
|                   | experts                   |   |
|                   | Stakeholders              | Contributing with concerns and perspectives relevant for the evaluation of the risk assessment results and the specification of decision alternatives.  |
| Decision          | Decision-makers           | Utilizing the results of the risk assessment and the subsequent evaluation to select and implement the appropriate decision alternative(s).   |
| Review/           | Managers                  | Overseeing the review/monitoring stage, allocating the resources needed to support the evaluation of the need for new risk assessments.   |
| monitoring        | Decision-makers           | Considering the results of the evaluation criteria, and determining the need for new risk assessments.  |
|                   | Analysts                  | Responsible for conducting the assessment of the evaluation criteria, analysing data, assessing the impact of changes and providing   |
|                   | Subject matter<br>experts | information to support decision-makers in determining the need for new risk assessments.  |
|                   | Stakeholders              | Identifying and communicating shifts in contextual factors that could warrant an evaluation of the need for new risk assessments.<br>Providing feedback and input to the evaluation.                        |

1. The introduction of new decision alternatives

2. Changes in risk

3. Changes in values

A brief description of the proposed evaluation criteria for assessing the need for new risk assessments is presented in Table 3.

It is important to emphasize that there could be strong interrelationships between the criteria for evaluating the need for new risk assessments. Changes in risk (criterion 2) could subsequently lead to changes in context/values (criterion 3) or the introduction of new decision alternatives (criterion 1) For example, the identification of potential new events occurring (criteria 2) may prompt stakeholders to reevaluate their priorities and risk tolerance (criteria 3). Consequently, stakeholders might seek alternative courses of action that align with their updated values or preferences, triggering the introduction of new decision alternatives (criterion 1).

The following section provides an outline of the suggested approach, using the COVID-19 pandemic as an illustrative example.

#### 3.3. Outline of the adjusted approach using a case example

In response to the outbreak of the COVID-19 pandemic in March 2020, the authorities in a specific country X initiate a risk assessment. The process follows the stages outlined in the general set-up from Section 3.1.

#### **Establishing context**

The main objective of the risk assessment is to support decisionmaking on how to confront the disease and mitigate its impact. The values to be protected are human lives and public health, and the main stakeholders identified are the government, public health authorities, health professionals and healthcare providers, elderly and vulnerable populations and the general public.

At the time, the decision alternatives considered are:

Keep society open and allow the virus to spread at precedent speed. Introduce non-binding public health recommendations to reduce the spread of the virus, including face masks and social distancing. Implement strict lockdown measures, such as closing schools and non-essential businesses, and restricting travel and social gatherings.

#### **Risk assessment**

A risk assessment is conducted, identifying the main events/hazards, the potential consequences/outcomes and the associated likelihood/ probability. In line with the outlined approach in Section 3.1, judgments on the knowledge supporting the probabilities are included.

The main events identified are:

A1: The disease spreads among vulnerable parts of the population.

A2: The capacity of the healthcare system is exceeded.

The probabilities of events A1 and A2 (P(A1) and P(A2)) are judged to be very high. The consequences of the specified events are assessed in terms of loss of human lives. For both A1 and A2, the expected consequences are considered to be very large. The knowledge base supporting the assigned probabilities is weak, as there is a significant lack of knowledge concerning the disease and its potential development and impact – the uncertainties involved are considerable. The knowledge

Table 3

| Over | Overview and description of evaluation criteria. |   |  |  |  |  |
|------|--|---|--|--|--|--|
|      | Criteria   | Description   |  |  |  |  |
| 1    | Introduction of new decision alternatives        | Evaluating changes that occur in the set of decision alternatives after a decision has been made, which may affect the premises of the initial risk assessment  |  |  |  |  |
| 2    | Changes in risk                                  | Evaluating changes in risk that occur after a decision has been made, including the effects of the chosen decision alternative, new knowledge/information changes in the activity, system and phenomena considered, as well as changes in frames/constraints and stakeholders |  |  |  |  |
| 3    | Changes in values                                | Evaluating changes in the values that underpin the initial risk assessment, including changes in prioritizations, ethical concerns, levels of risk tolerance/acceptability, attitudes towards risk and changes in public perceptions of risk                                  |  |  |  |  |

supporting the analysis is based on a wide range of key assumptions. In addition to assumptions concerning the virulence and severity of the disease, the following key assumptions are made:

K1: The assessment assumes a 'business-as-usual' scenario, with no restrictions on social interaction and movement

K2: The level of immunity in the population is very low

K3: The healthcare system has limited capacity to handle patients requiring intensive care

K4: People who recover from COVID-19 will have permanent immunity

K5: The elderly and those with underlying health conditions are particularly vulnerable to having a severe outcome of the disease

K6: The virus is mainly spread by individuals showing symptoms

K7: The virus is mainly spread through surface contact

The results of the risk assessment, as well as the knowledge base (including key assumptions, data, etc.) on which it is based, are presented to decision-makers.

#### Evaluation

Decision-makers conduct an evaluation of the results of the risk assessment. The process includes reflecting on the risks and uncertainties highlighted in the assessment, acknowledging the limitations of the assessment, and making judgments on how to weight different concerns, including social, political and ethical concerns, as well as public perceptions of risk. Furthermore, decision-makers take into account the various stakeholders' values, goals, criteria and preferences. In the present situation, decision-makers prioritize protecting the health of the population and ensuring that the capacity of the healthcare system is not overwhelmed. Because of the large uncertainties, decision-makers choose to give stronger weight to cautionary/precautionary thinking.

Decision

Based on the evaluation above, the third decision alternative is chosen, and a national lockdown is implemented in the country.

#### **Review/monitoring**

As part of a regular review process, an evaluation is conducted in June 2020 to consider the need for new risk assessments, using the criteria specified in Section 3.2.

#### 3.3.1. Evaluation of criterion 1: Introduction of new decision alternatives

In order to evaluate the need for new risk assessments based on the introduction of new decision alternatives, decision-makers need to consider i) whether new decision alternatives have emerged since the previous decision was made and ii) whether the new decision alternatives have an influence on risk.

As a starting point, decision-makers in country X review the initial set of decision alternatives and identify whether any new alternatives have emerged since the national lockdown was implemented in March 2020. In light of the significant social and economic impact of the current measures, decision-makers are focused on considering options that balance the objective of controlling the spread of the disease with the need to minimize the social and economic burden on the population and society as a whole. A new decision alternative identified is the gradual reopening of society, which involves easing restrictions on businesses, schools and social gatherings, while developing systematic approaches for testing, isolation and contact tracing.

The new decision alternative could have a significant influence on risk. For example, lifting restrictions on businesses, travel and social gatherings could lead to an increase in transmission rates, resulting in a potential increase in the number of infections, hospitalizations and deaths. The possible resurgence of cases increases the likelihood that the capacity of the healthcare system is exceeded. Strategies for testing, isolation and contact tracing could potentially contribute to strengthening the knowledge base concerning the disease, for example by providing a more accurate picture of the level of immunity in the population. Furthermore, by tracking and monitoring the spread of the virus, health authorities can identify risk factors that may be associated with severe outcomes, such as age and pre-existing health conditions. The uncertainties associated with the initial risk assessment concerning the impact and development of the disease still apply but with the addition of new uncertainties related to the effectiveness of the new measures introduced. The easing of restrictions could potentially lead to new vulnerabilities, such as increased transmission in certain populations, while effective testing, isolation and contact tracing measures could increase resilience.

Based on the above evaluation, it can be concluded that the introduction of the specified decision alternative justifies the need for new risk assessments to be conducted. As a result, the information obtained from the evaluation is extracted and fed into the initial stage of the risk management and decision-making process, initiating a new risk assessment iteration.

#### 3.3.2. Evaluation of criterion 2: Changes in risk

The second evaluation criterion is intended to capture any changes in risk that have occurred since the previous decision was made, which are not accounted for in the initial risk assessment. There are a range of factors that could give rise to changes in risk. To ensure a structured approach for evaluating changes in risk that capture these potential triggers, the criterion is evaluated using a set of sub-criteria. The sub-criteria reflect a set of main factors that could alter the output of the risk assessment. The altering effects could include a shift in the underlying assumptions or probability judgments supporting the assessment. An overview of the sub-criteria with illustrating examples is given in Table 4.

Each of the sub-criteria are evaluated with respect to their effect on risk, covering the following aspects:

- *The potential for new events to occur* Assessing the degree to which the changes give rise to the potential for new events to occur that were not identified in the initial risk assessment.
- *Probability* Assessing the degree to which the changes have an influence on the assigned probabilities of the events and/or consequences specified in the initial risk assessment.
- *Knowledge strength* Assessing the degree to which the changes affect the judgments concerning the strength of the knowledge supporting the initial risk assessment.
- *Knowledge base* Assessing whether the changes alter key assumptions or evidence contained in the knowledge base.
- Vulnerability/resilience Assessing how the changes impact aspects of vulnerability and resilience, including the system's ability to recover from, and adapt to, disruptions.

The latter point builds on contemporary perspectives on the need to integrate risk management and resilience and vulnerability management (e.g., Aven, 2017; Logan et al., 2022; Zio, 2018). This acknowledgement has gained momentum in recent years, as the increasing complexity and interconnectivity of current systems is making the identification and anticipation of events a challenging task. According to these perspectives, prudent risk handling extends beyond ensuring that systems are capable of withstanding and responding to events, to also focus on their ability to adapt and recover from events, including those that are unanticipated. Vulnerability refers to the consequences for a system (e.g., an individual, a business, the society) in the case of a disruptive event occurring, and the uncertainties related to these consequences (SRA, 2015). While the vulnerability concept is in some cases restricted to situations where the event is known, recent perspectives open up for broader interpretations of the concept in which vulnerability can also be seen in relation to unknown events (Aven, 2022). Resilience is understood as the ability of a system to sustain or restore its functionality following an event (even unknown) (SRA, 2015). Resilience is an aspect of vulnerability when interpreting vulnerability in the broad sense as referred to above, covering the full extent of the potential consequences following an event. Vulnerability then extends beyond considerations of resilience; for example, a system could have high

#### Table 4

Overview and description of sub-criteria for evaluating changes in risk.

| Subcriteria                      | Illustrating example  |
|----------------------------------|---|
| Effects of the previous decision | The impact of previous decisions made in response to the COVID-19 pandemic, including the implementation of a national lockdown, travel restrictions and social distancing measures   |
| Changes in activity/system       | Changes in societal structures and processes that could affect the spread and impact of COVID-19, such as changes in the capacity of the healthcare system, changes in the immunity levels of the population and changes in the availability of vaccines or treatment options     |
| Changes in phenomena             | Changes in the virus or the disease, including the emergence of new variants with altered characteristics in terms of virulence, severity of disease, etc.  |
| New information/<br>knowledge    | The consideration of new knowledge or information concerning aspects of relevance, such as the immunity of the population, the effect of treatment options and characteristics of the virus and the disease, obtained through, for example, research or data from previous events |

resilience (i.e, strong ability to quickly recover after an event), yet, the system could still be highly vulnerable because of the severity of the potential consequences following the event.

Based on an assessment of the effect on the aspects listed above, a judgment is made on the overall impact on risk.

In the COVID-19 case example, an evaluation is conducted for each of the sub-criteria in Table 4. The evaluation is performed as a brainstorming session, taking into account the collection of available and relevant data and information, as well as the current context in which the evaluation is conducted, including the status of the pandemic, public views and opinions and restrictions in place. The primary objective of the evaluation is not to be all-inclusive but to provide a general overview of relevant changes and effects that have occurred since the previous risk assessment was conducted in March 2020. Key results and findings from the evaluation are summarized in Table 5.

For each of the sub-criteria, there could be a range of effects or changes that are relevant to consider. These could differ with respect to how they affect the output of the initial risk assessment. To distinguish between the various changes and effects and their respective effect on risk, the evaluation contains a description of the specific changes/effects that have been considered. The evaluation takes a broad perspective, not only addressing changes and effects directly related to the events and consequences identified in the initial analysis but also capturing potential changes and effects that have arisen outside the scope and context of the previous risk assessment. When assessing the effects of the previous decision, for example, it is relevant to address the immediate effects, such as the reduced social interaction and movement caused by the implemented restrictions. However, effects that may have emerged as indirect or unforeseen effects of the implemented lockdown should also be considered, such as the emergence of new technology for working remotely, an effect which came as a consequence of the need for businesses and education institutions to adapt to the changing circumstances and create solutions for working from home. Another unforeseen effect of the lockdown identified in the evaluation is the reduction in people seeking medical attention for non-COVID-related health problems, causing concerns about delayed diagnosis and treatment of serious health conditions, such as cancer.

The former effect (reduced social interaction and movement) was considered to be among the desired effects of the implemented lockdown, intended to confront events A1 and A2 specified in the initial risk assessment. The latter effects, however, followed more or less unexpectedly as a consequence of the restrictions. While the former effect could have an impact on the assigned probabilities of events A1 and A2, the latter effects would not alter the output of the initial risk assessment but could give rise to the potential of new events occurring that were not considered in the initial risk assessment, including cyberattacks and a rise in cases of undetected cancer.

When it comes to changes in the system/activity, an essential change to consider is increased immunity against the disease. When the initial risk assessments were conducted in March 2020, available data concerning the level of immunity among the population was scarce. A main assumption supporting the analyses was that the population's immunity was very low, contributing to a judgment of the probability of events A1 and A2 as very high and the expected outcomes of these events as severe. In June 2020, a significant part of the population had gained immunity through infection, and more data had been collected concerning the level of immunity in the population. Consequently, the probabilities of events A1 and A2 occurring are judged to be lower, their expected outcomes are judged to be less severe and there is an increased amount of relevant data strengthening the knowledge support for these judgments.

Another relevant change that is considered in relation to the activity/ system is the improved capacity of the healthcare system. The increased availability of resources, including personnel, equipment, systems and facilities, indicates a significantly reduced probability of event A2 occurring. The change also contributes to a decrease in the expected consequences, as there will be more resources available to handle severe cases. It is, however, worth noting that the effect could also introduce the potential of new events occurring, including shortages or disruptions in other areas of healthcare, due to the mobilization of healthcare workers and resources.

In the present case example, changes in the phenomena refer to changes in the virus/disease. Relevant changes to consider in this context could be the emergence of new variants of the virus with altered characteristics, such as increased transmissibility, virulence or the potential for immune escape. These changes would have a significant impact on the risk assessment results, as they could lead to a higher judged probability for events A1 and A2, as well as an increase in the judged probability of these events leading to severe outcomes. However, no new variants were detected between March 2020 and June 2020; thus, changes in the virus/disease were not considered in the present evaluation.

The evaluation of changes in information/knowledge provides valuable insights into the dynamic aspects of risk and uncertainty. In the case example, the new data obtained on the transmission of the disease, effective treatment options and disease characteristics contributed to strengthening the knowledge foundation supporting the probability assignments and rejecting or altering the assumptions underlying the initial risk assessment. For example, the data collected from testing and contact tracing contributed to strengthening the knowledge supporting the assigned probabilities of events A1 and A2. On the other hand, new data on the potential for asymptomatic infections introduced a knowledge gap that weakened the knowledge supporting the probability judgments and reduced the validity of assumption K6 (the virus is mainly spread by individuals with symptomatic disease). Additionally, data on effective treatment options strengthened the knowledge supporting the probability assignments related to the severity of outcomes. The collection of data from those who recovered from the disease provides more information concerning the course of the disease, which populations are more prone to getting severely ill, and the duration of immunity among infected patients. As a result, the knowledge strength supporting the probabilities of events A1 and A2, and the expected outcomes of these events, increases. Furthermore, the information concerning waning immunity indicates that assumption K4 (people who recover from COVID-19 will have permanent immunity) does not hold. Finally, the new data on potential risk factors necessitates the addition of new vulnerable populations to those specified in assumption K5.

The consideration of vulnerability and resilience in the assessment highlights how various changes can impact the system's susceptibility to adverse events and outcomes. For example, higher levels of immunity 9

Evaluation scheme for assessing the need for new risk assessments based on criteria 2: changes in risk.

| Sub-criteria                     | Description of changes/  | Potential for new events occurring   | Probability  |  | Strength of knowledge  | Knowledge base  | Vulnerability/resilience   | Overall           |
|----------------------------------|--|--|--|--|--|---|--|-------------------|
|                                  | effects considered   |  | Specified events   | Specified outcomes   |  | (key assumptions, data, etc.)   |  | effect on<br>risk |
| Effects of the previous decision | Reduced social<br>interaction and<br>movement  | Potential for new events<br>related to the socio-<br>economic impacts of<br>restrictions (e.g., mental<br>health issues, financial<br>loss for businesses, etc.) | A1: Lower<br>probability of the<br>disease spreading<br>among vulnerable<br>parts of the<br>population | No impact  | Less movement and adherence to<br>public health recommendations<br>allows for more precise modelling of<br>the disease spread and impact –<br>stronger knowledge concerning the<br>probability of events A1 and A2 | Assumption K1 no<br>longer holds  | Could decrease<br>vulnerability for society<br>by limiting the spread of<br>the virus  | Moderate/<br>high |
|                                  |  |  | A2: Lower<br>probability of<br>exceeding the<br>capacity of the<br>healthcare system                   |  |  |   |  |                   |
|                                  | Emergence of new<br>technology for working<br>remotely   | Potential for new events<br>related to the use of new<br>technology platforms (e.  | A1: No impact<br>A2: No impact   | No impact  | No impact  | No impact   | No impact  | Low/<br>moderate  |
|                                  | Decrease in number of<br>medical consultations<br>for issues not related to<br>COVID-19              | g., cyberattacks)<br>Potential for new events<br>related to undetected<br>cases and delayed<br>diagnosis of serious health<br>conditions, such as cancer         | A1: No impact<br>A2: No impact   | No impact  | No impact  | No impact   | No impact  | Low/<br>moderate  |
| Changes in activity/<br>system   | Higher levels of<br>immunity among the<br>population   | No impact  | A1: Lower<br>probability<br>A2: Lower<br>probability   | Lower probability of<br>severe outcomes<br>(hospitalizations,<br>deaths) | More data on population immunity –<br>stronger knowledge concerning the<br>probability of events A1 and A2   | Validity of<br>assumption K2 is<br>reduced                                    | Higher immunity<br>decreases vulnerability<br>among the population<br>against the disease, as<br>well as the health care<br>system       | Moderate/<br>high |
|                                  | Higher capacity in the healthcare system   | Potential for new events<br>related to the mobilizing<br>of healthcare workers (e.<br>g., shortages or<br>disruptions in other areas<br>of healthcare)           | A1: No impact<br>A2: Lower<br>probability  | Lower probability of severe outcomes                                     | No impact  | Validity of<br>assumption K3 is<br>reduced                                    | Could reduce<br>vulnerability and<br>enhance resilience for<br>society against the<br>disease by preventing<br>health care overload      | Moderate∕<br>high |
|                                  | Implementation of<br>systems for testing,<br>isolation and contact<br>tracing                        | Potential for false<br>positives/false negatives,<br>events related to strain on<br>healthcare systems, and<br>privacy issues                                    | A1: Lower<br>probability<br>A2: Lower<br>probability   | No impact  | Data from testing and contact tracing<br>– stronger knowledge about the<br>probability of events A1 and A2   | No impact   | Reduces vulnerability for<br>the population and<br>strengthens healthcare<br>resilience by identifying<br>and isolating cases<br>quickly | Moderate/<br>high |
| Changes in phenomena             | No changes concerning the virus or the disease   | -  | -  | -  | -  | -   | -<br>-   | -                 |
| New information/<br>knowledge    | New knowledge<br>concerning transmission<br>(asymptomatic<br>transmission, airborne<br>transmission) | No impact  | A1: Higher<br>probability<br>A2: Higher<br>probability   | No impact  | Lack of knowledge concerning the<br>extent and impact of asymptomatic<br>infections – weaker knowledge about<br>the probability of events A1 and A2  | Validity of<br>assumption K6 is<br>reduced<br>Validity of<br>assumption K7 is | No impact  | Moderate/<br>high |

(continued on next page)

| Sub-criteria | Description of changes/                              | Description of changes/ Potential for new events | Probability      |   | Strength of knowledge  | Knowledge base                   | Vulnerability/resilience                 | Overall           |
|--------------|--|--|------------------|---|--|----------------------------------|--|-------------------|
|              | effects considered                                   | occurring  | Specified events | Specified outcomes                      |  | (key assumptions,<br>data, etc.) |  | effect on<br>risk |
|              | New knowledge about No impact<br>effective treatment | No impact  | A1: No impact    | Lower probability of<br>severe outcomes | More data on effective treatment<br>ontions – stronger knowledge about | No impact                        | Could reduce<br>vulnerability and        | Moderate/<br>hioh |
|              | options  |  | A2: Lower        |   | the probability of having severe                                       |                                  | enhance resilience by                    |                   |
|              |  |  | probability      |   | outcomes   |                                  | improving the outcome                    |                   |
|              | New knowledge about                                  | No imnact  | A1. Hioher       | No imnact                               | More data collected from those who                                     | Data indicates that              | or treatments<br>Increased vulnerahility | Moderate/         |
|              | the disease (risk factors.                           |  | probability      |   | recovered from the disease – stronger                                  | assumption K4 no                 | among individuals who                    | high              |
|              | duration of immunity for                             |  | •                |   | knowledge about the probability of                                     | longer holds                     | are exposed to the risk                  | 5                 |
|              | recovered patients, etc.)                            |  | A2: Higher       |   | events A1 and A2   | ,                                | factors                                  |                   |
|              |  |  | probability      |   |  | More data on risk                |  |                   |
|              |  |  |                  |   |  | factors - new                    |  |                   |
|              |  |  |                  |   |  | vulnerable                       |  |                   |
|              |  |  |                  |   |  | populations added                |  |                   |
|              |  |  |                  |   |  | to assumption K5                 |  |                   |

Fable 5 (continued)

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among the population significantly decrease vulnerability for both event A1 (disease spread among vulnerable groups) and event A2 (healthcare system capacity exceeded), as the likelihood of widespread transmission is reduced. It is important to emphasize that these assessments are grounded in the context of the initial analysis, addressing vulnerability and resilience with respect to the identified events. However, as illustrated by the case example, the evaluation could reveal changes that introduce new aspects of vulnerability and resilience not previously considered. For instance, the emergence of new technologies for working remotely, while enhancing business resilience, may simultaneously introduce the potential for cyber-risk attacks, representing a new dimension of vulnerability for both businesses and individuals.

An overall evaluation of the four sub-criteria suggests that the need for new risk assessments can be justified. The effects of the previous decision and changes in the system/activity indicate that several of the assumptions underlying the initial risk assessment are no longer valid. While the new information/knowledge contributes to strengthening the knowledge base for the probability judgments, it also reveals areas of weaker knowledge. In addition, several of the changes and effects were found to give rise to the potential of new events occurring that were not considered in the previous risk assessment process.

The information obtained from the evaluation is incorporated into the feedback loop and used as a starting point for a new risk assessment iteration, in which the findings from the evaluation are more thoroughly evaluated.

#### 3.3.3. Evaluation of criterion 3: Changes in context/values

The evaluation of the third criterion aims to capture changes in the context and values underlying the initial risk assessment that could affect the premises of the assessment or the evaluation of its results.

The context of the risk assessment covers the frames, constraints and limitations under which the assessment is conducted, including the scope of the analysis, the tools, methods and resources at hand, organizational/governmental structures and systems, as well as legal, regulatory and political aspects. In the COVID-19 case, the risk assessments conducted in March 2020 were based on a scope in which the main perspective was at the national level, focusing on the impact of the pandemic for the country as a whole. However, as the pandemic progressed, it became evident that there were large differences across the various regions, with respect to the spread and impact of the disease, highlighting the need for more localized risk assessments that could account for the specific contexts and challenges of different regions. Another important consideration is the changes with respect to the resources and knowledge supporting the risk assessment process. In March 2020, the analyses were conducted under severe time constraints and with limited access to resources, information and tools. By June 2020, however, significant improvements had been made in terms of the resources and knowledge available for performing the risk assessments. For example, the establishment of expert task forces and scientific committees contributed to strengthening the foundation of the risk assessments, by providing additional resources, knowledge and skills, and improving the coordination of the processes.

Values play an important role in the risk management and decisionmaking process, as they constitute the baseline for prioritizing, determining how to weight different concerns (ethical, environmental, economic, etc.) and establishing which levels of risk are considered tolerable or acceptable. The goals, objectives and values-at-stake specified in the initial phase of the risk management and decision-making process influence which events and consequences are considered of importance in the subsequent risk assessment. Because these goals and objectives are largely determined by the values, preferences and goals of relevant stakeholders, changes related to these stakeholders would have a significant effect on the established context of the analysis. Such changes could be caused by the introduction of new stakeholders or changes in the values, goals, preferences and concerns of existing stakeholders.

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During the establishment of the context supporting the risk assessment of March 2020, the relevant stakeholders identified were the government, public health authorities, health professionals and healthcare providers, elderly and vulnerable populations, as well as the general public. However, as the pandemic situation evolved, new stakeholders emerged. These new stakeholders included industry and business owners who were concerned about the economic impacts of restrictions and lockdowns, as well as schools and universities that had to make decisions about remote learning and campus closures. Additionally, new vulnerable populations, such as minorities and immigrant populations, emerged as groups that were disproportionately affected by the pandemic. The values, concerns and preferences among these stakeholder groups could influence the premises for the risk assessment. For example, the introduction of industry and business owners as stakeholders could lead to a stronger focus on economic concerns and the need to balance public health measures with the need for businesses to remain operational. Similarly, schools and universities highlight the importance of maintaining education quality and offering satisfactory solutions for distance learning. The inclusion of new vulnerable populations indicates a need for more targeted interventions and a recognition of the disparities and inequities exacerbated by the pandemic. Incorporating these values and concerns into the risk assessment context would expand the initial focus on public health to include a broader range of social and economic factors, requiring an adjustment of the stated goals and objectives of the risk assessment. An adjustment of the context could affect which events/outcomes are considered important in the risk assessment, as well as how the risk assessment results are evaluated. For example, by incorporating economic values as a value-atstake alongside human lives and health, the set of events specified in the risk assessment may be extended to include events that could lead to a loss of economic stability, such as business closures, unemployment and reduced economic activity. Furthermore, in the evaluation process, the increased concerns among stakeholders about the potential impacts of the lockdown for the economy could prompt decision-makers to focus on prioritizing options and policies that balance public health concerns with economic interests.

Changes in trust, risk perception and attitudes towards risk are also considered as part of the evaluation of the present criterion, as such changes could impact the weight given to certain values and how decision-makers prioritize options. In the COVID-19 case example, there were strong concerns among the public regarding the severity and impact of the pandemic at the beginning of the outbreak. The high perceived risk, and the large uncertainties involved, lead decisionmakers to give stronger weight to cautionary/precautionary policies. In June 2020, the uncertainties regarding the impact of the disease had been reduced through observations and studies, while new uncertainties had emerged concerning the long-term effects of the lockdown. In combination with an increasing fatigue among the population with respect to the implemented restrictions, this led to a shift in the attitudes towards risk, in which the population became more willing to accept the risks related to the pandemic but less tolerant of the risks and uncertainties related to a prolonged lockdown. These changes could influence which values and concerns decision-makers choose to focus on in the evaluation. For example, decision-makers may give less weight to the uncertainties related to the disease and prioritize options aimed at reducing the socio-economic impacts of the lockdown. Furthermore, changes in the level of trust are taken into account. The rapid development of the pandemic caused inconsistencies and confusion regarding the recommendations and guidelines provided by the authorities, resulting in eroded trust among parts of the population. Eroded public trust towards the government and authorities could affect how decisionmakers prioritize options, which values and concerns are given weight, as well as which policies are implemented and how. For example, decision-makers may prioritize policies that serve to maintain public trust, at the expense of options that would be more effective in reducing risk. Furthermore, decision-makers may need to invest more time and

effort into ensuring that there is a clear understanding of the rationale behind the choice of decision alternative, including how the risk assessment results are evaluated and which values and concerns are given weight, as well as other aspects influencing the choice of policy (political, reputational, etc.). An overview of key results from the evaluation of criteria 3 is provided in Table 6.

#### 3.3.4. Overall assessment

Based on the evaluation of the three criteria (the introduction of new decision alternatives, changes in risk and changes in context/values) it is concluded that the need for new risk assessments can be justified. In line with the outlined approach in Section 3.1, a new risk assessment iteration is initiated, in which the results obtained from the above evaluation are incorporated and refined.

#### 4. Discussion

The previous sections illustrate an approach for evaluating the need for new risk assessments, using the COVID-19 pandemic as a case example. The approach extends current frameworks and standards, by providing a systematic framework for capturing dynamic aspects of risk and uncertainty, using three main criteria as a basis for the evaluation: the introduction of new decision alternatives, changes in risk and changes in context/values.

An important implication of the suggested approach is that it provides a structured foundation for revisiting policies and decisions that were implemented in contexts characterized by significant uncertainties. In such situations, decision-making is often supported by cautionary/precautionary thinking, giving strong weight to protecting the values-at-stake and reducing risk. The cautionary/precautionary principles are invoked with limited knowledge as a main rationale. However, knowledge is a dynamic concept; thus, the basis for implementing cautionary/precautionary measures will change over time. Recognizing when the underlying conditions supporting the policy have changed to the degree that the initial rationale no longer holds is not straightforward. By conducting a systematic evaluation of the effects of changes in risk, context and values, decision-makers can identify when the knowledge gaps that initially justified cautionary/precautionary measures have been sufficiently addressed, and the need for revoking or modifying existing policies and measures should be considered.

A fundamental issue in relation to risk management and decisionmaking is capturing the potential for currently implemented measures to introduce new risks or exacerbate existing ones: referred to as risk-risk trade-offs. Anticipating risk-risk trade-offs requires a comprehensive understanding of the activity, system and phenomena involved, their dynamics and the interrelations between them. However, gaining such insights is particularly challenging when dealing with complex systems, where there is limited knowledge and the uncertainties are large. The lack of knowledge about the system's behaviour and causeeffect-relationships makes it difficult to capture the potential for inadvertent effects of the chosen decision alternatives or interventions. Additionally, many systems operate in dynamic environments where conditions could change rapidly, further complicating the identification of potential risk-risk trade-offs. The proposed evaluation scheme addresses this issue by incorporating an assessment of the effects of the decisions that were made in the previous risk management and decisionmaking iteration, and whether these effects could give rise to the potential for new events to occur. As illustrated in the previous section, using COVID-19 as a case example, the suggested evaluation scheme allows decision-makers to see beyond the immediate and anticipated effects of the decisions made, and consider the broader implications of policies and measures, also taking into account that these could have ripple effects that extend beyond the scope of the initial risk assessment.

Several authors highlight the limitations of conventional risk management and decision-making approaches when it comes to dealing with systems and organizations that are growing increasingly complex and

## Table 6 Evaluation scheme for assessing the need for new risk assessments based on criteria 3: changes in context/values.

| Subcriteria  | Description of changes/effects considered   | Effect on risk assessment                               |                                      | Overall           | Comments  |  |
|--|---|---|--------------------------------------|-------------------|---|--|
|  |   | Effect on context<br>(goals, values-at-<br>stake, etc.) | goals, values-at- evaluation of risk |                   |   |  |
| Changes in frames/<br>constraints  | Shift from focusing on the risks for the country as a whole,<br>to more local and regional perspectives   | Moderate  | Moderate                             | Moderate          | The shift in scope introduces a moderate effect on the context, as it adjusts the<br>boundaries and focus of the risk assessment to address variation in the spread of the<br>disease across regions. A more detailed understanding of the impact of the<br>pandemic on specific regions could have an effect on the evaluation process,<br>opening the door to more tailored interventions and resource allocation |  |
| Changes in stakeholders  |   |   |                                      |                   |   |  |
| 2.1. New stakeholders considered   | Industry and business owners  | High  | High                                 | High              | The inclusion of new stakeholders has a high effect on the context, as it expands the range of values and concerns that need to be addressed in the risk assessment   |  |
|  | Schools/universities  | High  | High                                 | High              | process. It also affects the evaluation by requiring that the interests, goals and  |  |
|  | New vulnerable populations (immigrant populations)  | Moderate/high   | Moderate/high                        | Moderate/<br>high | preferences of these stakeholders are taken into account in the decision-making<br>process, implying a stronger focus on balancing public health interests with other<br>relevant concerns that have emerged  |  |
| 2.2. Changes in stakeholders'<br>priorities, concerns, goals<br>and values               | Shift in focus of authorities and the general population<br>from public health concerns to economic recovery  | High  | High                                 | High              | The shift in focus alters the priorities and considerations underlying the risk<br>assessment, giving stronger emphasis to socio-economic concerns. It also requires a<br>recalibration of the evaluation of the risk assessment results, as decision-makers  |  |
|  | Increased concern among public health experts about the<br>rise in mental health issues related to lockdown measures  | Moderate  | Moderate                             | Moderate          | need to ensure that their judgments are aligned with current values and concerns among stakeholders   |  |
| <ol> <li>Changes in trust, risk<br/>perception and attitudes<br/>towards risk</li> </ol> | Lower perceived risk concerning the virus/disease   | Moderate  | Moderate                             | Moderate          | The effect on the context of the risk assessment is low/moderate, as it requires that<br>altered public perceptions and concerns are considered when defining goals and<br>values-at-stake. The effect on evaluation is high, as the changes in trust, risk   |  |
|  | Pandemic fatigue: People becoming more accepting of the<br>risks associated with the virus and less willing to comply<br>with public health recommendations | Low   | Moderate                             | Moderate          | perception and attitudes towards risk could have a strong influence on how<br>decision-makers interpret and use the risk assessment results. The changing<br>landscape of public sentiment and trust may lead to a reassessment of the weight   |  |
|  | Decreased trust in authorities' recommendations and guidelines  | Moderate  | Moderate                             | Moderate          | given to the various risks, concerns and the trade-offs between different options,<br>requiring decision-makers to strike a balance between effective risk management<br>and maintaining public trust and support   |  |

interconnected (e.g., Brocal et al., 2019; Dekker et al., 2011; Helbing, 2013; Katina et al., 2014; Komljenovic et al., 2019). A key issue is the rapid pace at which these systems and their surrounding environments change and develop, making long-term predictions at micro and macro levels a challenging task (Komljenivic et al., 2019). Helbing (2013) points to two typical properties of highly complex and interconnected systems: Firstly, changes tend to occur at a pace that exceeds humans' ability to understand the system behaviour or react to it. Secondly, events often trigger cascading effects that extend far beyond the impact of the initial event. Under such conditions, there is a need for risk management and decision-making approaches that are able to address the continuous changes in risk and the underlying context, also capturing the potential for rippling effects of previous events or decisions that may not have been anticipated in the initial risk management and decision-making process. By proposing a structural framework for how to identify and assess the changes and effects that could occur, the present paper aims to strengthen current risk management and decision-making processes to better account for the dynamic and complex environment under which current systems and organizations operate. Furthermore, the approach incorporates the aspects of vulnerability and resilience, acknowledging that these concepts constitute an essential part of handling risk in systems that are characterized by high complexity and large uncertainties.

It is important to acknowledge that the proposed evaluation scheme serves as a coarse assessment rather than providing detailed descriptions of all the risks, effects and changes involved. Its primary purpose is to act as a trigger for new risk assessments, prompting more thorough and comprehensive evaluations to be conducted when indicated. The suggested approach provides a framework that encourages iterative and feedback-driven risk management and decision-making, ensuring that the current strategies and policies for handling risk are based on the most current knowledge and understanding of the context and the associated risks and uncertainties. A key challenge associated with the application of the adjusted approach is determining when an evaluation of the need for new risk assessments is necessary. This requires a balance to be struck between remaining responsive to evolving circumstances, while avoiding the expenditure of time and resources on premature or excessive review processes. The appropriate timing for evaluating the need for new risk assessments depends on the context at hand and requires taking into account factors such as the level of uncertainty, the complexity of the systems and phenomena involved and the degree to which the circumstances are subject to rapid change.

#### 5. Conclusions

The need for effective risk management and decision-making processes is widely recognized, and several frameworks and standards have been developed to guide decision-makers in handling risk and uncertainty. However, a closer look at these frameworks and standards shows that there is room for improvement when it comes to their ability to capture and incorporate dynamic aspects of risk and uncertainty. To address this issue, the present paper proposes an adjusted approach to risk management and decision-making. The main purpose of the approach is to enhance the review and monitoring stage, by incorporating a systematic evaluation of the need for new risk assessments. The evaluation is divided into three main criteria: the introduction of new decision alternatives, changes in risk and changes in context/values. The output of the evaluation serves as a basis for determining whether a new risk assessment iteration should be initiated. The approach aims to provide a structured framework which takes into account the dynamic environment in which the risk management and decision-making process takes place. In addition to assessing changes and effects with respect to risk, the evaluation takes a broader perspective, also incorporating aspects related to the scope and context of the risk assessment, as well as factors that influence how the results of the risk assessment are evaluated. By recognizing that the premises, results and evaluation of the risk

assessment may change over time, and providing guidance on how these changes can be captured and addressed, the suggested approach can strengthen the ability of current frameworks and standards to ensure that risk management and decision-making processes remain relevant and effective in the face of changing circumstances.

In the present paper, we have illustrated the proposed approach, using the COVID-19 pandemic as a case example. However, the approach is adaptable to a wide range of application areas, and the evaluation of the criteria can be tailored to suit the specific context and nature of the risk assessment. Different industries, sectors or domains may require different assessments of changes and effects, based on their unique characteristics and challenges. Therefore, decision-makers should customize the factors addressed in the evaluation to align with their specific risk management needs and organizational context.

#### CRediT authorship contribution statement

**Ingrid Glette-Iversen:** Conceptualization, Methodology, Writing – original draft, Writing – review & editing, Visualization. **Roger Flage:** Conceptualization, Methodology, Validation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Project administration. **Terje Aven:** Conceptualization, Methodology, Validation, Writing – original draft, , Writing – review & editing, Visualization, Supervision, Project administration. Supervision, Project administration.

#### **Declaration of Competing Interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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