The precautionary principle and regulatory impact assessment: on the need for initial screening of hazards in regulatory work with examples from transport

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Abstract

To achieve effective regulation, the OECD and the European Commission recommend the use of regulatory impact assessment (RIA). The full RIA process has however not been implemented in Sweden. There is for example a lack of established practices at the national level for the analysis of risk in regulatory work. Instead, soft law in the form of management by objective systems is guiding transport and environmental policy. These systems were introduced in the end of the 1990s following the international discussion on the precautionary principle. According to findings in other countries, policy making based on the precautionary principle may result in unexpected and unwanted consequences and therefore, based on a literature review and an assessment of current practices in transport regulation in Sweden, we suggest the use of an initial screening of hazards in regulatory work. We also apply the proposed method to four transport related case studies to illustrate how an initial assessment can provide the basis for an informed discussion on what hazards to counteract with regulation and on what grounds.

Keywords: Precautionary principle, risk assessment, Hazards, Regulatory impact assessment

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Introduction

According to the OECD, effective regulatory governance involves regulatory policies, tools, and institutions. To achieve effective regulation, the OECD (2012) argues for the use of regulatory impact assessment (RIA) and this approach has also been adopted in the EU with risk assessment as an integral part. In Sweden however, the full RIA process has not been implemented (Nerhagen and Forsstedt, 2016; Radaelli, 2010). Wahlgren (2013) for example states that risk assessment methods are generally lacking in legal work in Sweden and he argues for their increased use. The reason for these types of analysis not being used appears to be policy making traditions (Hansson and Nerhagen, 2017) but also the influence of the precautionary principle. It is manifested through "soft law" such as the Vision Zero and the 16 Environmental Quality Objectives, as well as the Environmental code, all established in the end of the 1990s. More recently, the precautionary principle has also been discussed in relation to the new Climate Act that entered into force on 1 January 2018[1]. That the precautionary principle appears to result in a lack of practices such as RIA and risk assessment is the motivation for this paper. We explore how the principle has been interpreted and how it has influenced policy making in regulatory work in the Swedish transport sector. Based on the findings in the literature we also develop a method for how the precautionary principle can be accounted for in a systematic way in the regulation of transport.

The precautionary principle was introduced with the Rio Declaration as a new general principle in international environmental policy and law (United Nations, 1992). Internationally, the principle achieved wide acceptance when it was launched in the 1990s. However, how to actually interpret and implement it has over the years attracted interest from scholars in different disciplines (Sandin, 1999; Gollier et al., 2000; Kriebel et al., 2001; Tait, 2001; Farrow and Hayakawa, 2002; Sandin et al., 2002; Gollier and Treich, 2003; Sunstein, 2002; Sunstein, 2003b; Farrow, 2004; Hahn and Sunstein, 2005; Gardiner, 2005; Sandin, 2007; Trouwborst, 2007; Hartzell-Nichols, 2013 and Hansson, 2016). Farrow and Hayakawa (2002) for example discuss the need for a bounded degree of precaution in regulatory work. Another discussion is that is has been applied to other policy areas than the environment, for example human health (Trouwborst, 2007), while other researchers argue that RIA has replaced its use in the EU (Löfstedt, 2004). Nowadays in the EU, the principle is mentioned in Article 191 of the Lisbon Treaty on the Function of the European Union, which relates to the environment. It is also mentioned in the better regulation toolbox with reference to a communication from the European Commission (COM, 2000). From this communication its relationship to risk analysis is clear: "The precautionary principle should be considered within a structured approach to the analysis of risk, which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk".

The precautionary principle, in a very general sense, means that measures against some hazard should be implemented no matter what. There are two motivations for this this, one practical and one moral. In some cases, risk cannot be estimated due to lack of knowledge, but one might want to take action anyhow. This is for example the case with climate change where the consequences are global and very far reaching. This is the kind of reasoning on which the new Climate Act in Sweden is based. In other cases, one might consider it to be morally/ethically/politically obliged to avoid the hazard even if risk is small. An example here is the current discussion in Sweden on banning smoking in public places which, according to an assessment by Folkhälsomyndigheten (2014), is expected to have minor impacts on public health. What is known is that in more crowded surroundings, such as

[1] http://www.government.se/articles/2017/06/the-climate-policy-framework/

public bars, there appear to be an impact. Hence, from the discussion in the media it is clear that the main motivation is to use regulation in order to establish a non-smoking norm for public behavior.[2] However, implementing the precautionary principle without regard to assessments of costs and benefits will, if the principle is used excessively, result in policies with unexpected and unwanted consequences. Regarding smoking in public places for example, there is the question of who should control and enforce this regulation and what the related cost of this will be?

The idea behind this paper is that to avoid unwanted outcomes, regulators need established practices for initial screening of hazards to help them differentiate between situations where actions based on precaution is motivated and situations where a fuller risk assessment or RIA should be undertaken. We believe that one reason for the lack of such practices could be, as discussed in a recent paper by Dudley et al. (2017), that policy makers are not always acquainted with these types of analysis. To allow for an informed discussion about risk with non-specialists, our main question is therefore how to define and implement the precautionary principle in risk related regulatory work in practice? To answer this question, in the paper we describe the current state of art on how the principle could be interpreted. Based on this, current practices in the Swedish transport sector, and with examples provided by four case studies, we develop a method for how to account for the principle in an initial screening of risk in regulatory work to allow for a categorization of different types of hazards and their consequences.

The outline of the paper is as follows. First, we provide a brief description of the current Swedish policy making context in the area of transport and environment, with a focus on the influence of the precautionary principle. We then review the discussion in the scientific literature on how to implement the precautionary principle in practice. Thereafter, we describe current practices regarding risk assessment in regulatory work in the transport sector in Sweden and develop a method for initial screening of hazards. We also apply it to four cases, illustrating different types of hazards currently assessed by the Swedish Transport Agency. The hazards considered are: accidents in roundabouts, falls when walking in public streets, , health impacts from air pollution in tunnels and the need to secure infrastructure constructions for impacts of climate change. Some concluding remarks ends the paper.

"Soft law" governing Swedish environmental and transport policy

Environmental protection, and in particular climate change, is at the forefront of the current governments policy in Sweden[3]. This focus on sustainable development has been guiding Swedish policy for over two decades. It has also had a considerable influence on transport policy which the existence of the consideration goal ‑ safety, environment and health care - adopted by the parliament illustrates. Sweden is therefore by many considered a frontrunner in these areas. In contrast, Sweden has not implemented the full RIA process. As described in Nerhagen and Forsstedt (2016), a reason for this is the focus of the legal framework (Ordinance 2007:1244) on reductions of administrative burdens of enterprises. This lack of established practices on the use of RIA including risk assessment, which is of high relevance in the case of the aspects covered by the consideration

[2] This government agency also has a goal stating: Reduce all kinds of tobacco use and prevent that those under age, minors, start using tobacco in all its forms (https://www.folkhalsomyndigheten.se/ accessed 20180130)..

[3] "It is the firm desire of this Government that Sweden be a global role model, in our development, our equality and our leadership on climate change adaptation. A country whose hallmarks are the equal worth of all people, self confidence, solidarity and the belief that it is possible to change the future." http://www.government.se/government-policy/

goal, may therefore unintendedly impose inefficient or costly policies. [4] Without the full RIA process in place there is currently a lack in Sweden of what Sunstein (2002) refers to as safeguards to prevent probability neglect in policy-making, i.e. that hazards are regulated despite the expected negative consequences being close to non-existent.

The influence of the precautionary principle on current environmental and transport policies in Sweden dates back to the end of the 1990s and a Government Communication on Ecological sustainability to the Parliament (1997/98:13).[5] One outcome of this was the establishment of the Environmental Quality Objectives system (Government bill 1997/98:145)[6], where for example the Clean air goal states: "The air must be clean enough not to represent a risk to human health or to animals, plants or cultural assets". The system was established based on suggestions presented by the Swedish Environmental Protection Agency. The precautionary principle is mentioned as one of several strategies to reach the established goals (Government bill 1997/98:145, appendix 1). For transport, the so-called Vision zero policy, that strongly influences current decision making, was outlined in Government bill 1998/98:56. Also in this case a management by objectives system was introduced. It is clearly stated that Vision zero should be the basis for the development and functioning of the transport system and the following goal for traffic safety is established: “that ultimately no one should be killed or seriously injured by traffic accidents and that the system should be developed so that it meets this goal”. As discussed by Farrow and Hayakawa (2002), with reference to papers authored by the key architect of the Swedish Vision Zero policy (Claes Tingvall), this policy could be viewed as precautionary even though the term is actually not being used.

The legal manifestation of the precautionary principle is found in the Environmental Code (prop. 1997/98:45), adopted by the parliament in 1998. Chapter 2 includes general rules of consideration. In section 3 in this chapter it is stated that “Persons who pursue an activity or take a measure, or intend to do so, shall implement protective measures, comply with restrictions and take any other precautions that are necessary in order to prevent, hinder or combat damage or detriment to human health or the environment as a result of the activity or measure”. However, from section 7 it is clear that some assessment of the expected damage and the cost of imposing measures should be done. The latter however does not apply in relation to the policy instrument environmental quality standards, something that has had an important influence over the years on the reluctance to use impact assessments and estimates of the external costs of transport air pollution in policy making (Pyddoke and Nerhagen, 2010; Nerhagen, 2018).

It has been two decades since the above-mentioned communication (1997/98:13) was written and the bills were passed. During this time modifications have been made when new governments have come into office, but the basic framework based on management by objectives remains. Hence, the Vision Zero is still a guiding principle for the development of the transport system as well as the

[4] According to Sunstein (1996), the use of cost-benefit analysis was formally introduced in regulatory work in the US in 1981 as a way to control the work done by government agencies. It was introduced following a “rights revolution” of the 1960s and 1970s when new government agencies were created designed to protect against threats to life, health, and safety but without established mechanisms to evaluate regulatory performance.

[5] The Swedish government system in the area of environmental policy differs substantially from that in the United States as described by Sunstein (2018). OECD has in several national report about Swedish environmental policy highlighted the problem on the ambitious objectives not being supported by the Environmental Code.

[6] How to reach these ambitious objectives has been a question for governments and government agencies ever since. This has also been an issue discussed in both public media and the academic literature, not the least in relation to transport policy (Edvardsson, 2004; Sundström, 2005; Härdmark, 2006; Brännlund, 2008; Eckerberg et al., 2012; Edvardsson Björnberg, 2013; Azar et al., 2014; Hysing and Olsson, 2011; Nordén, 2015).

Environmental Objectives System and the Environmental Code with the general rules of consideration for the environment and for society as a whole. Recently, in September 2016, the current government established a restart of the work with the Vision zero, for example including a greater focus on traffic modes other than road and on unprotected road users (Ministry of Enterprise and Innovation, 2016). However, in relation to the implementation of the Environmental Code, it has become evident that its requirements raise questions in practical implementations.[7]

Regarding the use of CBA, the only central government agency in Sweden with a long tradition of using this kind of analysis is the Swedish Transport Administration (STA). To provide a scientific basis and establish basic principles for CBA calculating, transport agencies and researchers have cooperated for over ten years in the group *Arbetsgruppen för Samhällsekonomiska Kalkyler* (ASEK). However, the CBA method developed by the STA is mainly used to evaluate transport investments and its main influence appears to be as a screening tool (Eliasson and Lundberg, 2012; Andersson et al., 2018). Regarding environmental policy on the other hand, it was only in 2010 that the Swedish Environmental Protection Agency was given the responsibility to develop the use of economic analysis in the EQO system (following the Governmental Official Report 2009:83 and the Government Bill 2009/10:155). This is to be done in collaboration with other agencies. For this purpose, a "platform" for agency cooperation has been established where a number of agencies participate. So far however the impact this has had on the use of CBA in practice appears to be limited (Wallström and Söderqvist, 2016).

The precautionary principle in practice – literature review

Researchers from different disciplines gave the precautionary principle much attention in the beginning of the 21 century. By scholars from the social sciences, much thought has been given to moral and ethical aspects in relation to (environmental) risks, but without clear guidance on its implementation in practice. In this line of research Sandin and other Swedish scholars have been very active and influential (Sandin, 1999; Sandin et al. 2002; Sandin, 2007). Sandin et al. (2002) gave the principle a wider definition than in the Rio Declaration stating: "on some occasions, measures against a possible hazard should be taken even if the available evidence does not suffice to treat the existence of that hazard as a scientific fact". They call this a case of precaution which is separate from a situation where the scientific evidence is conclusive. The latter is referred to as prevention. Regarding the principle's use in practice, distinctions are made between an *argumentative* and a *prescriptive* version as well as an *absolutist* versus a more *reflected* use. They also conclude that it could be a problem if the principle is used in an unreflected manner because policy makers may focus too narrowly on single threats.

In a more recent paper, Hartzell-Nichols (2013) gives an overview of this literature. In response to arguments put forth by some writers that the principle is a mode of legal reasoning rather than a rigid rule, Hartzell- Nichols (2013) argues that a distinction needs to be made between a principle used to guide decision making to take steps to protect the environment for its own sake, because of

[7] Many questions have been raised regarding the practical implementation of the Environmental code in general and the environmental quality standards in particular. As discussed in the Government Official Report 2002:107, environmental quality standards were a policy instrument not previously used in Swedish law. For Swedish transport, how the limit values in the EU air quality directive should be interpreted in relation to particulate matter from road wear was for example investigated in a recent public inquiry (Government Official Report 2015:27). In another recent project, how to implement the paragraphs in Chapter 2 of the Environmental Code has been analyzed. An output from this project is a guidance on how section 7 in chapter 2 should be applied (Nordzell, Scharin and Söderqvist, 2017). It describes how to undertake cost-benefit analysis of prevention measures but without guidance on how to include risk analysis.

intrinsic value, and a principle used to protect human health from possible harmful effects of, for example, food production. Of particular interest for the purpose in the present paper is therefore the discussion on "moral precautionary principles that capture *prima facies* moral obligations". It is concluded that there is a need for a decision-making framework to enable decision-makers to determine when precautionary measures are morally warranted. It is also discussed that in these cases there needs to be interaction between scientists and analysts and the policy-making process, hence these situations also need to involve the political level.

Trouwborst (2007) instead discusses the legal scope of the principle. The purpose of his paper is to reduce some of the confusion and what he refers to as "the polemic nature in the academic debate" related to its interpretation[8]. According to the author, the principles primary purpose is adequate protection of the environment, even for its own sake. Hence, in policy making a distinction needs to be made between precaution, which has been part of health law and policy for a long time, and application of the precautionary principle. This should be based on the best information available, and the required action should be effective and proportional. The latter implies that adoption of excessively strict measures should be avoided. According to the author in practice this implies that the principle *does not apply* in the following cases:

- When anticipated environmental effects are either not adverse or not significant
- When reasonable grounds for concern are lacking.

Contrary to the previous writers, Trouwborst (2007) concludes that under international law the principle includes situations of quantifiable risk, uncertainty proper and ignorance. Therefore, if the threshold of harm and likelihood is crossed, effective and proportional action may or must (depending on the gravity or harm) be taken, whether there is uncertainty or not. He therefore argues for abandoning the theoretical distinction between prevention and precaution. As for socio-economic considerations, Trouwborst (2007) concludes that the principle delimits the freedom of States to balance environmental, social and economic interests. It does not however imply that all risk of harm be avoided at any cost. Instead, the proportionality requirement imposes that the size of the risk determine the need for action. A duty to take effective precautionary measures, even if socio-economic costs are high, exists exclusively in situations where reasonable grounds for concern indicate that serious and/or significant irreversible harm may result.

From these sources we can conclude that the principle is given different interpretations by different writers. That it is a problem for decision making that the principle comes in many forms is the issue raised by Sunstein (2003b). He makes a distinction between a strong "better safe than sorry" version, which he argues may result in a safety margin being built into all decision making, and a weak version which states that a lack of decisive evidence of harm should not be a reason for refusing regulation. His argumentation relates to the problem raised above about the principle being used in an unreflected manner. According to Sunstein, this is likely to happen since people and policy-makers have limited cognitive capacities and that decision-making is influenced by many things, ignorance, emotions or imperfect information for example (Sunstein 2000, 2002, 2003a; Hahn and Sunstein, 2005)[9]. Therefore decision-makers in general use heuristics which may result in what he calls

[8] Although admitting in the conclusions that also the definitions presented and discussed in the paper are susceptible to varying interpretations.

[9] A reflection we have made when reviewing the literature is that this research is not seemless. There are few cross references between studies done by scholars in social sciences and economists, and possibly also between scientists in Europe versus scientists in the US. Examples are Sandin et al. (2002), Gardiner (2005), Gollier and Treich (2003), with Farrow and Hayakawa (2002) and Hahn and Sunstein (2005) being exceptions to the rule.

probability neglect. This in turn may be harmful if there is a focus on the strong version or on low-probability hazards in regulatory work (Sunstein, 2003b). To avoid this, he points at the need for *institutional safeguards,* such as analytic requirements on the use of CBA and institutional checks. He also discusses normative issues, for example when people have strong emotions such as fear. Here he argues for information and education, but in some cases also risk reduction.

Economists finally have focused on what Sunstein (2003b) refers to as analytical requirements and how the principle can be implemented in a benefit-cost analysis framework. Examples are Farrow and Hayakawa (2002), Gollier and Treich (2003) and Farrow (2004) who base their analysis on option theory. According to Farrow and Hayakawa (2002) real option theory focuses on uncertainty and the size of irreversible costs to develop a bounded degree of precaution. Another interesting aspect raised by Gollier and Treich (2003) and Farrow (2004), which is also discussed by Hansson (2016), is the dynamic aspects of decision making and that learning improves scientific knowledge over time. Gollier and Treich (2003) make a distinction between the notion of prevention and precaution. The former aims at managing risk while the latter aims at managing the wait for better scientific information. One conclusion is that when long-term effects of risks are unknown, it may be optimal to be more prudent at the initial stage of the risk management process. They also discuss that the presence of scientific uncertainty drastically complicates the decision-making process. One reason is that politicians with strong career concerns may prefer to select the risk policy that the public believes is good. They conclude that this kind of political inefficiency will cause the regulator to depart from social welfare maximization.

The central findings from this literature review can therefore be summarized as follows:

- Central to the interpretation of the precautionary principle is the scientific level of knowledge in relation to a possible hazard. It is also clear that in practical applications, situations with low probability or uncertainty of the potential dangers should be treated differently in the analysis from situations where there is scientific evidence.
- Regarding precaution, this sometimes involves moral aspects which may need to be assessed by politicians.
- Another important aspect in practice is that the information on scientific evidence is interpreted by individuals (civil servants in the case of a government agency) which, for various reasons (public pressure, emotions, imperfect information), may result in exaggerated judgements of probable harm.
- Several aspects make assessments of hazards and risks in RIA s very difficult in practice. One is that the scientific knowledge can be large or small, and in addition the possible consequences - in the worst case irreversible damage- as well as the cost of protective measures need to be accounted for.
- It is also described that real option theory can be used in a CBA to arrive at a bounded quantitative degree of precaution.
- Last but not least, the state of knowledge may change over time which in turn implies that regulations may have a need for mechanisms for revisions and adjustments.

Risk assessment and initial screening of risk

There are internationally recommended methods for risk assessment, as described in the European Commission (2010) for example. The following definitions are commonly used. A *hazard* is a potential source of harm. *Harm* is the possible injury or damage on humans, property, the environment or on society in general. *Probability of occurrence* is the likelihood of the harm occurring. *Risk,* finally, is the combination of the probability of occurrence of a hazard and the

severity of the harm resulting from the hazard, i.e. the consequences. This methodology is also the basis for the guidelines developed in Sweden (Torstensson and Wallin, 2001; Räddningsverket[10], 2003). When combined with monetary values, it can also be used to calculate the expected cost of a certain harm when the probability of occurrence is known. What aspects to consider when using this kind of approach in practice is discussed in two projects on how to perform national risk assessments in Sweden (Nerhagen and Hultkrantz, 2013; Nerhagen, 2014).

One question raised in several reports in Sweden is what is to be considered an *acceptable risk* from society's point of view (Davidsson et al., 1997; Persson et al., 1998; Räddningsverket, 2003). These authors provide several examples on how such criteria for acceptability or tolerance levels are established and used in other countries. In one report it is clearly stated that there is a general dissatisfaction with Swedish politicians' lack of interest for discussing these issues and that it is a problem that politicians tend to focus on aspects raised in the media or discussed among the general public (Persson et al., 1998). It is also stated that a reason for this could be that the analytical tools used by professionals are not easy to understand by politicians.

Regarding transport planning, we have found two Swedish studies outlining methods for this kind of risk assessment. Both discuss the question of tolerance levels and for what situations that risk assessment based on calculations of probability and consequence can be of use. Löfling (2005 a,b) outlines an approach to be used for assessments of road sections and also gives examples of how it can be implemented. This work was done for Vägverket[11] following the requirements placed on the administration by Ordinance 2002:472 § 3 on crisis management. Löfling (2005a) provides an example of how the approach can be applied but underlines that more work is needed on what classifications of risks, "tolerance levels", that should be used when deciding on policy measures in practice. He also concludes that other aspects, such as legislation, may require policy measures to be implemented irrespective of the results from a risk assessment.

In a more recent research project financed by the Swedish Transport Agency, Häggström et al. (2016) use this kind of assessment to discuss safety goals for tunnels. The authors make a distinction between "normal" tunnels for which standard requirements apply and others for which an in-depth risk analysis is required. They also discuss which risks should be included in the analysis and conclude that single deaths can be excluded. Their reason for this is that they are frequent events for which experience and empirical relationships exist and which are therefore covered by already established rules. The second extreme they discuss is events that rarely occur but with major consequences in the form of, for example, a large number of fatalities. In the case of tunnels, they propose an upper limit of 300-500 fatalities. They also note that for accidents with very low probabilities and extremely large consequences, another type of handling is required, for example through a public inquiry that highlights the risks.

Hence, these examples from the applications in Sweden confirm the findings in the literature review on the precautionary principle that calculation of risk may in some cases not be a useful evaluation criterion and is in other cases not possible. They also highlight the need identified by practitioners in government agencies of a discussion about what is to be considered as an "acceptable risk" from societies point of view. Therefore, based on our review of the literature and the findings from the Swedish studies presented here, we suggest an initial screening of the problem and the hazard at hand. The aim is to categorize the hazard and its possible consequences in an early stage in order to allow for the regulator to determine how to proceed with the impact assessment.

[10] The predecessor to the current Swedish Civil Contingencies Agency.
[11] The National Road Administration which is now part of the Swedish Transport Administration.

From the literature review, the following aspects need to be distinguished. First the scientific knowledge about the problem, the probability of a hazard, need to be assessed. If the probability is known and above a certain threshold, then standard practices on risk assessment and RIA can be used. In the cases of low-probability or uncertainty however, it has to be determined if precautionary measures are relevant and, in that case, on what grounds. Here, a separation needs to be made between what Sunstein (2003b) refers to as the strong and the weak version of the precautionary principle. The strong version is a case of "better safe than sorry" where there may be moral/ethical/political aspects involved which provide motives for regulation irrespective of the consequences (harm) or the size of the risk. Hence, this is a situation where we see the need for the political level to be involved in the evaluation. In the case of the weak version, where decisive evidence of harm is lacking, there may still be potential need for government action. Reasons for this could be to reduce fear among the general public or for the reason of collecting information to increase current knowledge on possible impacts. In the case of uncertainty, where there may be important consequences, it may also be relevant with a worst-case analysis in order to apply the so called maxmin criterion (Sunstein, 2003a).

To be able to make a separation between different situations of risk in regulatory work, we suggest that the aspects outlined in Table 1 are used in an initial screening. We believe this will provide enough information to allow for an informed discussion on whether a certain hazard is acceptable or not, and the need for additional analysis. The first six will provide an overview of the hazard and the regulatory context while the last four are included since they are recommendations presented by the EU in COM (2000).

Table 1. Aspects to consider in an initial screening of risk in a RIA

Aspects to consider in an initial screening
1. Describe the hazard
2. Assess the probability and how it may change over time
3. Assess and quantify the possible harm
4. Describe ethical/moral/political aspects that may prevent the application of a regular risk analysis
5. Describe possible regulations
6. Describe possible consequences for society as a whole of the possible regulations
7. Assess if a regulation is proportional to the chosen level of protection
8. Assess if a regulation is consistent with similar measures already taken
9. Assess the potential benefits and costs of action or lack of action, subject to review, in the light of new scientific data
10. Assess if a regulation is capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment

Results of the application of this initial screening to the four cases are presented in Table 2, low probability, and Table 3, uncertainty. In the tables we provide a summary of the main aspects outlined in Table 1 for each case. The two low-probability events in Table 2 are accidents when hitting something in a roundabout and falls in public streets. Our discussion here is based on current knowledge about the magnitude of the problem, but a caveat is the weakness in available statistics. The two cases with uncertain probabilities in Table 3 are possible health impacts of air quality in tunnels and climate change adaptation of infrastructure. Based on the information in each table, we discuss the similarities and differences between the cases and how this will influence the recommendation on how to proceed in each case.[12]

Table 2. Application of the initial screening to the two low-probability cases

Aspect	**Vehicle accidents in roundabouts**	**Falls when walking in public streets**

[12] More details on methods for risk assessment and how the approach outlined in Table 1 have been applied to the cases, for example the data sources used, are provided in the project's report to the Swedish Transport Agency (Nerhagen, Forsstedt and Edvardsson, 2017).

1	Accidents happen where people drive into the circle of a roundabout the harm done that depends on the decorations and the construction.	People walking in public streets sometimes fall due to road design practices, especially the elderly.
2	Few accidents occur and many of them are due to drunken driving. With more roundabouts the probability for this hazard increases in society but others are decreased. With the introduction of new cars in the transport system having radars the probability will decrease.	According to the currently available statistics , the share of total accidents due to a fall in public streets is small relative to these kinds of accidents in other contexts. The probability of a fall in public streets is higher in wintertime. The current knowledge however is low and in addition, with an increasing share of elderly in the population and if the political ambitions with more people walking and biking are fulfilled, it becomes more important to understand the influence of current road design practices.
3	Death, hospitalization and injuries as well as property damage mainly inflicted on the individual involved in the accident.	Death, hospitalization and injuries for the population in general.
4	Contributes to the Vision Zero policy.	Contributes to the Vision Zero policy. With the political ambition of more people walking and biking, there may be a need to follow up the consequences of the policy.
5	Requirements on design. Light and signs indicating that there is a roundabout. Measures to reduce drunken driving.	Requirement on design. Road maintenance. Requirements on vehicles used. Aid to vulnerable groups. Require the municipalities to perform this kind of assessment in their legally manifested work on risk and vulnerability analysis.
6	The construction costs may increase, costs borne by municipalities or the Swedish Transport Administration.	Costs for measures of this kind will mainly be borne by the municipalities and may crowd out other safety enhancing measures.
7	From societies point of view the impact on probability and the consequences of measures are expected to be small although it may have an impact on single individuals.	Infrastructure planning has to be adapted to local conditions and may therefore be difficult and costly to regulate.
8	There are some general requirements in place.	There are requirements in place.
9	The expected benefit of regulation is likely to be very small and may be reduced over time with the introduction of “intelligent” cars.	The assessment of measures has to be undertaken on a case to case basis. Obtaining information is most important and a regulation should be aligned with the work and requirements imposed by other government agencies, for example the obligation placed on the municipalities to make assessments of risks and vulnerability.
10	More information is not likely to contribute to better knowledge since these are very irregular and case specific events.	Additional information is beneficial for better future impact assessments.

Regarding roundabouts, this is a low risk case relative to other risks in society. Therefore, implementing regulation could be considered a strong version of precaution and regulatory decisions should preferably involve the political level. Based on the information in Table 2, our suggestion is further analysis on the cost of undertaking measures and that the possible regulatory consequences of imposing this kind of regulation should be done. The latter refers to the discussion in Farrow (2004) of “having the right to continue the status quo”. He discusses that there can be a legal and a perceptual framing of a problem. Imposing a regulation may transfer the right of legal action from one party to another, and the consequences of this is also an important aspect to consider in regulatory work.

Regarding falls in public streets, the conclusion is that this is a low risk case according to available statistics but that it may increase over time due to an increasing share of elderly in the population and the political ambition to increase walking and biking. Hence, in this case the weak version of precaution applies. Our suggestion in this case is therefore that more information should be collected on how road design practices influence accident risk. Preferably, this could be included in

the work on assessments of risk and vulnerability that municipalities are required to do regularly since they have the main responsibility for both infrastructure planning and elderly care.

Table 3. Application of the initial screening to the two cases with uncertain probability

Aspect	Health impacts of air quality tunnels	Adaptation of infrastructure to climate change
1	Air pollution concentrations can become very high in longer tunnels and the question is what impact this may have on public health.	With increasing rainfall due to climate change the risk of flooding and shreds increases.
2	The probability of health impacts is not established empirically but some information can be obtained from other research on the impact from transport emissions. This suggests that the main problem is respiratory problems due to exposure to NO_2 but this is currently under investigation by The World Road Association-PIARC.	The probability is increasing but it is unclear where the impacts will be the largest. The probability should be assessed in environmental impact assessment in plans for new infrastructure. The National Transport Administration has recently established a strategy on how to work to identify risks in the transport system.
3	Marginal effect on long term health impacts in a population but may cause or contribute to acute problems for individuals with respiratory diseases.	There is no guideline on how to assess the size of risks, only on how to assess possible measures.
4	Contributes to the EQO Clean air.	Contributes to the EQO Built environment.
5	Requirements on the ventilation system. Information system signaling when the air pollution concentrations are high.	There is already cooperation established between government agencies and other public administrations, one focus being on helping the municipalities in their planning of the physical environment. Actual measures have to be based on a case by case basis.
6	The construction costs may increase, costs borne mainly by the Swedish Transport Administration. Surveillance will also imply maintenance costs.	The cost for municipalities may become large and a guide has been presented on ways to receive funding.
7	From societies view the expected health benefit is likely to be small. With information, sensitive individuals can choose other routes.	This is difficult to determine given the uncertainty related to the probability of a hazard.
8	There are some requirements in place regarding ventilation for the reason of fire safety for example. The question is to what extent they may be of use in reducing air pollution concentrations.	This needs to be determined on a case by case basis but in some areas there are already legislation in place that has to be considered in regulatory work.
9	Expected benefit is uncertain but ventilation is something that is required in longer tunnels, hence this may not be an additional cost. Installing an information system on the other hand would be an additional cost.	This also has to be determined on a case by case basis.
10	Data collection would increase knowledge about the pollution situation in tunnels and might improve future impact assessments.	This is an important aspect and data collection and modelling are therefore done by different government agencies.

Regarding air quality in tunnels, the consequences are in general expected to be low since the exposure time is very short. There are however distributional aspects to consider since there may be vulnerable groups. Hence, this is also a case of the weak version of precaution. Based on the information in Table 3, our conclusion is that there is a need to collect additional information on how the air pollution concentrations may vary before the work with the impact assessment is continued. Based on the results from such an analysis, measures such as requiring higher ventilation capacity or providing information when concentration levels are expected to be high could be considered. The latter to help individuals take precautionary measures such as using medicine or choosing to take another route.

In the case of infrastructure climate change adaptation, the probability of harm in society is very difficult to predict since the occurrence of flooding due to heavy rainfall for example can be experienced everywhere in Sweden. The problem here however is that the consequences can become very large involving harm to humans, property and vital services in society. Here we believe regulation is required but not on a one-size-fits-all basis. Again, this is an example of a weak version of precaution but in this case the minmax criterion could be relevant to apply. Our conclusion is therefore that a systematic approach to assess the consequences is needed based on some kind of

categorization. Although much work is already done in this area in Sweden, and there is an established network where several government agencies participate, we have not found specific methods on how to assess and quantify the consequences to allow for a ranking of the most vulnerable places where abatement measures should be prioritized.

Concluding remarks

The current regulatory and transport planning system in Sweden is influenced by the environmental quality objectives and the Vision Zero policy adopted by the parliament in the end of the 1990s. Currently, there is a lack of established practices on the use of impact assessments in regulatory work. An argument for the use of RIA, including risk assessment and CBA, is that it allows for a systematic analysis of the impacts of policy making in complex system and for the government to assess the performance of the governance system. In the scientific literature arguments are raised for the use of decision making based on assessments of benefits and costs particularly in situations involving environmental or other risks. It is argued that there is a need for this type of structured analysis since it is cognitively demanding to assess risks and the consequences of policy interventions in complex systems. Furthermore, policy makers need to make a more explicit analysis of the trade-offs involved in a particular situation, since it is difficult to make a general assessment of the cost of providing a certain level of safety. The need for making this kind of analysis when establishing goals and designing policy measures has also been raised by researchers in Sweden in recent years.

To provide an understanding of the reasons for and the problems with the current regulatory framework in Sweden, we have reviewed the scientific literature on the precautionary principle since it appears to have been very influential in the establishment of the EQOs and the Vision zero. Our finding is that there is a consensus on the need to have established practices on how to implement this principle and that due to resource constraints, not all risks in society can be eliminated. The Swedish government however has not established the institutions that the OECD consider necessary to support the use of RIA. Therefore, there is currently a lack knowledge and established procedures in the Swedish governance system on how to perform this type of analysis. Furthermore, the conclusion from the studies on risk assessment is that there are no criteria established on what is an acceptable risk. Hence, in practice Sweden appears to apply what Sunstein refers to as the strong version of the precautionary principle, i.e. better safe than sorry, even in cases where the probability for a certain hazard can be assessed and is found to be low. We believe that this may be an approach with unexpected and unwanted consequences and we have therefore suggested the use of an initial screening of risk in a RIA. We believe that this can contribute to an informed discussion on what risk to counteract with regulation and on what grounds.

Our final remark relates to the question of proportionality in the handling of different hazards in society. In the paper we provide four examples to illustrate the variety in hazards that a regulator in transportation may be required to assess. One of this is accidents in roundabouts which is an example with low probability and consequences imposed mainly on an individual level. A comparison here can be made with down-hill skiing which is an activity resulting in many accidents during a year, some leading to hospitalization, life-long handicaps and even death. The latter however is a much less regulated area; the use of helmets by children for example is not required nor extensive fencing to protect individuals from hitting a tree or a stone. The question here is if it is relevant for society to consider low-probability risks that individuals mainly impose on themselves in the transport system when other activities, with possibly higher probability of harmful accidents, are not being extensively regulated. Or, put differently, in what contexts does the Vision zero apply? Is there a reason for this discrepancy, such as the transport system being a publicly provided service, or is it simply an example of policy making being a cognitively demanding task where it is easier for decision makers to account

for aspects that they are well acquainted with and exposed to in their daily life? To us, this comparison illustrates the need for established practices to allow for "a whole of government approach" also to risk assessments.

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