Understanding and Applying the Precautionary Principle in the Energy Transition

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BETTER POLICIES FOR BETTER LIVES

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Foreword

Given the uncertainty surrounding the safety of certain technologies that can help significantly reduce carbon emissions and environmental degradation, it is important for regulatory frameworks and practices to reconcile these safety concerns with the need to harness innovation to address climate- and environment-related threats and risks of irreversible damage. Applying the precautionary principle (PP) is one way to do so. This report contributes to a better understanding of the conditions under which the precautionary principle can support effective decision-making, including the policy choices that are inherent to its use.

For example, as is the case for most nascent technology applications, the use of hydrogen still involves some imperfectly known safety risks. Hydrogen has been used industrially for several decades and much is already known about its behaviour in different scenarios. However, its application in residential use, such as for heating, requires more investigation into safety. Where technology applications involve several risk dimensions, as in the case with hydrogen, the PP should be applied in a way that factors in risk-risk trade-offs holistically. Addressing individual risks in isolation—for instance those relating to climate change, biodiversity loss, and pollution, or water needs in situations of water stress—can hamper useful technological innovation for the energy transition.

Despite its longstanding presence in regulatory discourse, the PP does not have a clear definition. Originally designed for environmental harm prevention, its application has extended to areas such as public and consumer safety. More recently, different regulatory responses to the COVID-19 pandemic showed that, despite similar levels of scientific knowledge and evidence across regulatory regimes, PP interpretation has been far from consistent. Enabling a constructive and appropriate application of the precautionary principle is critical to help bring about an energy transition in line with net-zero emissions policy goals. This report provides governments and regulators with a set of principles and practical guidance for that purpose. It does not imply that OECD members do or should subscribe to the PP. Rather, it provides analysis to rethink the PP in the context of the energy transition. Even for countries, which do not subscribe to the PP or incorporate "precaution" as a founding element of their policies, this report presents important elements regarding the management of conflicting risks and uncertainty in the context of the climate emergency and the energy transition, and as such contains findings and recommendations that are relevant in any case. Thus, while "precaution" and "PP" are kept because of their specific relevance in particular to EU countries, the report's contents can be read and used independently of this specific wording, as pertaining to risk trade-offs and risk uncertainty.

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Abbreviations and acronyms

AHP	Analytic Hierarchical Process
AI	Artificial Intelligence
BSE	bovine spongiform encephalopathy
CBA	Cost-benefit analysis
CCS	carbon capture and storage
CDSS	Clinical Decision Support Systems
DDT	dichlorodiphenyltrichloroethane
DG REFORM	Directorate-General for Structural Reform Support
EAP	Environment Action Programme
EC	European Commission
EDCs	Endocrine disruptors
EEA	European Environment Agency
EMFs	Electromagnetic fields
EPRS	European Parliamentary Research Service
EPA	Environmental Protection Act
ERF	European Risk Forum
EU	European Union
EPSC	European Political Strategy Centre
GE	Genetically engineered
GMOs	Genetically modified organisms
HPV	Human papillomavirus
IARC	International Agency for Research on Cancer
IEA	International Energy Agency
INAIL	Insurance Body for Work
IPCC	Intergovernmental Panel on Climate Change
IRGC	International Risk Governance Council
ISO	International Organisation for Standardisation
JRC	Joint Research Centre
MADM	Multiple-attribute decision-making
MCA	Multi-criteria analysis

MCDA	Multiple-criteria decision analysis
MCDM	Multiple-criteria decision-making
MDDM	Multi-dimensional decision-making
MMT	Methylcyclopentadienyl manganese tricarbonyl
MODA	Multi-objective decision analysis
NASEM	US National Academies of Science, Engineering, and Medicine
PP	Precautionary principle
RECIPES	REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders
RRI	Responsible research and innovation
SbD	Safe(r)-by-Design approaches
SDRs	Shared Data Repositories
SIA	Safe(r) Innovation Approach
TSI	Technical Support Instrument
UGC	Underground coal gasification
UK-ILGRA	UK Interdepartmental Liaison Group on Risk Assessment
UNFCCC	United Nations Framework Convention on Climate Change
UWWTD	EU Urban Wastewater Treatment Directive
WFD	European Water Framework Directive
WHO	World Health Organization
WTO	World Trade Organization

Executive summary

The precautionary principle (PP) has been an important aspect of regulatory delivery for nearly four decades. Although there is no universally accepted definition of the PP, several formulations centre around the following elements: 1) the need for (environmental or health) protection; 2) the presence of a threat or risk of serious damage; 3) the understanding that a lack of scientific certainty should not be used to avoid taking action to prevent that damage, and — in the case of stronger formulations — an obligation to act in the face of uncertainty, 4) the need to provide evidence of safety ("reverse burden of proof").

The PP was originally developed as a regulatory response for environmental protection and is now applied more broadly. It is usually applied when a given technology or activity has considerable uncertainties related to its environmental, health, and safety risks (i.e. uncertainties related to the probability, magnitude and long term effects of any possible harms). The PP envisages a scenario where a risk is known to exist, but its probability and magnitude of harm are uncertain or unknown. Now widely applied and with a global reach, the PP is often invoked whenever the scientific evidence surrounding the safety of a given technology is not conclusive. This report therefore strengthens the case that the PP supports — and is an important element of — risk-based regulation. A companion report is being published specifically on risk-based and risk-informed regulation of key hydrogen applications for the energy transition, and this latter report goes significantly more into specific technical details and decision-making issues. The two reports are complementary, with the current one being more at the level of principles and covering a broader range of issues and topics.

There are however different interpretations of the PP, notably regarding the burden of proof, or the responsibility to demonstrate safety. Given this diversity of interpretations across regulatory regimes, this report seeks to foster a better understanding of the PP to support prudent decision-making that enables the energy transition and contributes to the achievement of targets on net-zero emissions.

Often, the PP is considered relevant to regulatory decision making when alternative scenarios exist, each presenting different risks that need to be regulated. In the case of the energy transition - the structural shift from fossil fuels to renewable energy - the decision is between the risks stemming from new technologies, versus those of devastating climate change. The fundamental difference between the two set of risks is that while climate change impacts are being felt around the world today, the most disastrous effects of climate change are distant in time and diffuse — and therefore still insufficiently perceived as an immediate risk, whereas risks from new technologies may be perceived as more immediate and quantifiable. Historically, regulatory decision-making has often favoured short-term benefits while neglecting long-term harms (as observed in the cases of coal power, the railroads and hydropower). Indeed, long-term harms were often either fully unacknowledged or unknown, or at the very least unregulated (and indeed it was not until the 1960s that proper environmental regulation emerged). Furthermore, in earlier stages of the energy transition (from wood to coal, oil and gas), environment pollution tended to be the prevalent consideration as opposed to climate change. applying the PP remains crucial to prevent additional pollution generated by the energy transition.

The PP is commonly in the background of many risk management decisions, but it is complex to apply in practice. Yet, the safety risk of technologies supporting the energy transition is immediate. This can lead policy-makers or regulators to operate and apply the PP over-cautiously — sometimes to the extent of complete inaction — in a misguided attempt to protect public and environmental safety. At the policy level, the PP can be invoked rather than properly understood and applied, to justify inaction driven by the reluctance to run into opposition to disputed policy choices. At the same time, there are cases of regulators not applying the PP when it would be relevant, despite early warnings. This report examines how the PP can be used as a tool to support flexible decision-making, helping regulators and operators to manage risk through positive action. The PP should enable the identification of all key potential risks, including those related to environment, health, safety, and uncertainties associated with the use of a new technology. The PP should help regulators act without adding excess requirements for the sake of "playing it safe".

In the context of the energy transition, many regulatory choices are loaded with risks. However, this need not involve banning a given technology or action. Doing so can affect public opinion negatively and lead to a lower acceptance of it (even if eventually declared safe). When it comes to energy technologies, the PP has been invoked in several cases to justify decisions that arguably did not result from evaluative and deliberative processes, but instead were driven by socio-political factors and pre-existing perceptions of risk. A precautionary approach, in essence, means accepting the existence of uncertain risks and proceeding with caution through a range of measures also including pilot projects, international data sharing co-operation and dedicated scientific collaborations.

This report also explores the interplay between the PP and the innovation principle. Evidence suggests that, if applied overly rigidly, i.e. when an overly-cautious approach is taken without sufficient consideration for risk-risk trade-offs and potentially less restrictive regulatory solutions, the PP can thwart potentially beneficial innovation. Instead, governments and regulators should consider applying the PP in ways that help manage the introduction and deployment of these innovations in a safe and agile way. To do so, risks stemming from a new technology should be considered in the context of its concrete application, and weighed against its potential benefits. Moreover, the PP can help ensure that knowledge generated through experimentation and gradual upscaling is regularly and systematically fed into regulatory development and improvement.

This report also discusses the use of the PP regarding low-carbon hydrogen, which presents a concrete illustration of the potential practical application of the PP. Hydrogen has been in use for over a century, albeit mostly concentrated in industrial applications, and much is known about its physical behaviour, even though specific technologies used in the energy transition are largely new. This means that safety issues are mostly understood and do not warrant excessive precaution. Low-carbon hydrogen, which is seen as a key technology for the energy and climate transition, is produced through electrolysis using low-carbon electricity – with an environmental impact on water sources that can be meaningful, particularly while seawater electrolysis technologies are still being matured. This means a holistic and inclusive approach is necessary to understand the risk-risk trade-offs. Namely, all the risks should be looked at together rather than individually, following a "one risk at a time" approach. This notably involves striking the right balance between mitigating the potential negative safety or local environmental impacts of an innovation on the one hand, and addressing potentially devastating climate-related threats on the other hand.

1 Introduction: What precaution, and for what?

This chapter discusses the precautionary principle in the context of the energy transition to “net zero” emissions. It also provides guidance on applying the precautionary principle in the energy transition, including adopting holistic and transparent approaches to risk and precaution.

Key messages

- Questions surrounding risk, uncertainty and precaution play an important role in the energy transition to "net zero" emissions.
- The precautionary principle is one of the options available to regulators seeking to achieve public goals such as the energy transition while mitigating risks of using new technologies. This report provides guidance in applying this principle in the energy transition.
- Adopting holistic and transparent approaches to risk and precaution should be a central priority. Such approaches require:
  - a systemic consideration of risk-risk trade-offs,
  - an understanding of the socio-political context surrounding risk- and precaution-related decision-making, and
  - institutionalisation of periodic assessments.

Rethinking the precautionary principle in climate crisis times

This report discusses the relevance and applications of the *precautionary principle* (PP) in the context of the energy transition, i.e. the move to low-carbon sources and carriers of energy, and the deeper integration of carbon abatement initiatives that compensate for the CO2 already present or being emitted.

In the context of increasingly severe climate change and accelerating global warming, with very dangerous feedback-loop effects that further aggravate the situation, facilitating the transition to "net zero" (or even net negative emissions that reduce atmospheric CO2 levels) is a vital priority. However, it is one that is proving difficult to achieve; the replacement of current technologies by other, low-carbon ones, is hampered by many economic, social, political, and technical obstacles. For many of these challenges, the questions around risk, uncertainty, and precaution play an important role.

The precautionary principle (and precautionary approaches, more generally)[1] has generated significant controversy over the years, and the debate around its relevance and effectiveness remains polarised. This report does not intend to argue for or against the PP; instead, it acknowledges, as a starting point, that precautionary approaches are part of the options available to governments and regulators seeking to achieve public policy goals such as energy transition.

The report examines a selection of relevant research, empirical evidence, and existing practice with regard to the use of the PP in a range of policy areas including energy. It does so with a view to enabling a constructive and appropriate application of the principle. In this context, the report focuses particularly on contributing to an improved understanding of the conditions under which the PP can constitute an effective decision-making tool, including the political choices that are inherent to its use. The report focuses particularly on the need for approaching precaution holistically. This approach notably entails considering risk-risk trade-offs and reconciling the need to guarantee a sufficient level of safety with the imperative to capitalise on innovation that addresses climate risks and the irreversible damage it can cause.

As such, the report does not attempt to provide a comprehensive account of all relevant research or practical work pertaining to the PP. Instead, it highlights selected studies as well as concrete examples, draws a number of conclusions, and formulates guidance with a view to informing public policy decision-making.

The report's specific focus is on the energy transition and, more broadly, climate change mitigation, adaptation and resilience. Thus, while it looks at the construction, interpretation and application of the PP across a range of policy areas, it specifically tries to draw lessons that are relevant to energy and climate. Indeed, among the many difficulties slowing the roll-out of technology that could reduce current or future CO2 levels and potentially limit the increase in global temperatures, the question of precaution is important. Complexity related to applying the PP for the energy transition is particularly high given that the PP is typically used as a tool designed to assess a technology, sector or application. In contrast, climate change is a vastly broader phenomenon that can be considered the sum of global modernisation. As such, no single regulator may have a clear view of related risks. Many technologies are seen, rightly or wrongly, as too hazardous by large swathes of the public and decision-makers alike. A number of these technologies are also, again rightly or wrongly, criticised for having potential negative consequences that are too hard to predict. The report thus seeks to investigate and discuss which could be the "proper" applications of the PP, attempting to distinguish more clearly these from cases where risk-management is more relevant than "precaution" as such. Moreover, it attempts to help think through the issue of balancing risks and uncertainties that exist in both directions, i.e. acting / using the technology versus doing nothing / not using it. Indeed, one of the most important characteristics and challenges of the climate emergency is that "doing nothing" is often *not* the most "precautionary" approach.

The literature review and analysis presented in this report point to a number of conclusions and highlight the need to further help governments and regulators apply the PP constructively and appropriately — particularly with regards to guidance on the use of precaution in the specific context of the energy transition.

Guidance on applying the precaution principle

If the PP is to constitute a useful and practical tool for decision-making, its application needs to be guided by the identification of serious potential hazard. This, in turn, requires enhanced systemic readiness (including anticipatory approaches), adaptive learning, periodic assessment (built on an appropriate understanding of the state, pressures, and trajectory of the context), and review.

In addition, adopting holistic and transparent approaches to risk and precaution should be an overarching priority for policymakers and regulators. In this context, "holistic approaches" comprise two essential components. The first is a full and systematic consideration of risk-risk trade-offs, as well as the need to shift focus and available resources — to the extent possible — to actual regulatory and impact outcomes (as opposed to an exclusively "implementing the law" focus). The second essential component involves acquiring a sound understanding of the socio-political context surrounding risk- and precaution-related decision-making. This, in turn, requires extensive public deliberation and stakeholder engagement along the lines of the "concern assessment" notion.

This section puts forward a set of suggestions pertaining to the above-mentioned analysis and priorities. It includes consideration of their institutional implications.

Ensure the systematic consideration of risk-risk trade-offs through more holistic and inclusive approaches

The efforts of governments and regulators should focus -— as a priority — on risk-risk trade-offs, in addition to systemic and cumulative risks. This contrasts to a traditional focus on "individual silos of risk" (Baldwin, 2016[1]). Doing so will lead to better regulatory decisions that help reduce multiple risks in concert (Wiener, 2020[2]).

This refocusing notably involves ensuring that as systemic and informed-but-objective a view as possible is taken of the context in which precaution may be needed — something which requires careful and conscious multi-dimensional leadership overview. Given the resource implications (e.g. capacity building) of developing and implementing more holistic and inclusive approaches, effort should be concentrated on those technologies or innovations with the broadest scope of application and highest potential impacts.

A more holistic approach also involves considering the trade-off between precaution's potential negative consequence related to stifling innovation, and the need to actively encourage innovation that can deliver the solutions needed to help address major societal challenges such as climate change and the energy transition. Evidence suggests that, if applied overly rigidly, i.e. when an overly-cautious approach is taken without sufficient consideration for risk-risk trade-offs and potentially less restrictive regulatory solutions, the PP can thwart potentially beneficial innovation (Institute for Safety, 2021[3]) (Hydrogen Safety Innovation Programme, 2020[4]).

In addition, there is a strong need to make the tensions and contradictions between different goals and aspirations clear and visible (Blanc, F. et al., 2015[5]). Doing so involves targeting the factors driving the tendency by regulators "to focus on one risk at a time and neglect side effects" — despite existing methodological guidance for more holistic approaches, e.g. (Graham, J. and Wiener, J., 1995[6]). Drivers identified in the literature notably include: "mission-driven agencies, sometimes with narrow legal authority; fragmented institutions, with separate specialised domains; narrow or bounded thinking, driven in part by heuristic errors and in part by decision costs; and the omitted voices of those affected" (Graham, J. and Wiener, J., 1995[6]).

Additional analysis providing a deeper understanding of the reasons behind the limited effective application of available guidance and tools (as well as the potential steps that could be taken to address them), would therefore be valuable — notably with regards to the role of pre-existing structures, practices and philosophies of government, as well as other institutions such as insurance bodies. In addition, ensuring more holistic approaches to risk and precaution will likely require adapting the mandates of the institutions concerned. This could include introducing explicit requirements, so risk-risk trade-offs are better taken into account, as well as considering the way in which these institutions co-operate with each other. The objective of breaking down silos should drive this adaptation. In line with existing OECD recommendations, steps should be taken to strengthen co-operation across policy-making departments and regulatory agencies, as well as between national and sub-national levels of government. It may also be valuable to explore how regulatory oversight bodies can help to ensure that precautionary approaches are holistic and well-balanced.

Without doubt, ensuring the systematic consideration of risk-risk trade-offs through more holistic and inclusive approaches involves rethinking several strategic policy choices. It also requires strong leadership and high-level political endorsement. These efforts will, however, remain relatively ineffective unless they trickle down — in a coherent fashion — to operational, day-to-day regulatory decisions. Moreover, approaching risk and precaution holistically requires considering not only the potential negative consequences of a given activity or innovation, but also its potential benefits, including any contribution it makes to key public policy objectives such as reducing carbon emissions and combatting climate change.

Understand the role played by socio-political and psychological elements in precautionary decision-making — and act upon them

Much of the existing research and analysis regarding the PP revolves around the level of available scientific evidence and assessment, as well as related uncertainty regarding hazards and potential risks. Although frameworks and guidelines for using the PP have been proposed (e.g. by compiling lists of common circumstances when precaution might be warranted; scenario-based guidance or advice with regard to emerging risks (European Commission, 2017[7]), application remains inconsistent.

One key factor behind this inconsistency stems from the fact that socio-political and psychological elements play a determining role when it comes to precautionary decision-making. Those elements should thus be focused on as a priority. Doing so notably involves analysing factors such as the political economy and determinants of perceptions of, and responses to risk including risk perception studies. The analysis should extend to understanding what governments and regulators can do in order to facilitate successful outcomes.

Understanding the importance of the above-mentioned factors and their interplay also requires acknowledging that the PP is not meant to instantly confer "objectivity" to the decision-making process. Nor does it have the ability to trigger some sort of "automated" decision. Rather, it is a guiding principle that needs to be interpreted and applied in a specific context, under specific constraints and — to the extent possible — be based on evidence and careful judgment. Preventing the PP from being construed as a rigid or strictly prescriptive normative blueprint is all the more necessary given that the impossibility of achieving an "optimal" precision of rules has been convincingly demonstrated (as has the unavoidable distance between rules, compliance and results). Moreover, this impossibility of "optimal" rules means that risk-based, accountable and professionally-grounded discretion at the regulatory delivery and enforcement stage is essential if the desired regulatory objectives are to be met (OECD, 2021[8]) (Diver, 1983[9]). In the case of the energy transition, interpreting and applying the PP constructively and appropriately means comparing and prioritising regulatory options in a context of multiple trade-offs and uncertainty.

A key additional aspect in this context relates to the need for enhancing inclusion and promoting reasoned transparency through ongoing public engagement and participation — as well as the promotion of extensive public deliberation about the possible hazards and risk governance (Bellaby, P. and Clark, A., 2016[10]). Governments and regulators should attempt to further articulate the notion of "concern assessment" in their risk-related regulatory practice by reviewing existing processes from that perspective. This is in addition to fully implementing existing normative guidance on stakeholder engagement in regulatory policy and governance (e.g. principle No. 2 of the OECD 2012 Recommendation of the Council on Regulatory Policy and Governance), and drawing on evidence and tools from risk communication science.

This involves adopting a proactive, duty-based approach to enhance the level of understanding of hazards and risks on a wider population basis, while mitigating the risks of manipulation of public perception (e.g. by vested interests), including through online social networks. It also involves careful monitoring and analysis of any shifts in political salience. This can necessitate further action at a political level to counter what may seem to be misinformation or fearmongering.

Strengthen and further institutionalise adaptive learning, periodic assessment and evaluation

The state of knowledge may change over time, which in turn implies that regulations may have a need for mechanisms for revisions and adjustments.

There is a general understanding that measures based on the precautionary principle are, in principle, "provisional" in nature and thus likely to be subject to changes over time (Tosun, 2013[11]). Therefore, these measures should be reviewed when new evidence becomes available in order to assess whether precautionary action has produced the intended consequences (Garnett, K. and Parsons, D. J., 2017[12]). To that end, risk analysis as a scientific field (also referred to as risk science) should be strengthened and systematically relied upon.

In practice, evidence-based reassessment and periodic review are however not commonplace. As illustrated by the GMO example (see Chapter 3), bans tend to have a negative impact on public perception, thereby consolidating beliefs that a given technology is intolerably dangerous and should be prevented from deploying. To counter this banning-inertia and favour adaptive learning (in line with the 2021 OECD Recommendation for Agile Regulatory Governance to Harness Innovation (OECD, 2021[13]), it would be beneficial to promote the development of carefully monitored regulatory experimentation, testing, and trialling in areas with high potential to help bring about a sustainable energy transition. Examples of this include regulatory sandboxes, testbeds, innovation spaces and laboratories. Such development could learn from the example of initial pilot approvals of drugs with significant therapeutical benefits that are combined with strict supervision and pharmacovigilance systems. This approach helps to source the necessary information to progressively adapt and refine associated guidelines for using those drugs, as well as to restrict their use or ban them altogether further down the line.

While it is very difficult to know for sure whether precautionary measures are effective (Wiener and Rogers, 2002[14]), and counterfactual analysis is often not possible, adaptive learning should be actively promoted (except when global catastrophic or existential risks are at play). Measures to do so notably include carrying out horizontal comparisons across jurisdictions and designing regulatory systems that are conceived to adapt and learn from experimentation. More generally, risk management systems should be geared towards drawing the appropriate lessons from implementation of the PP and enabling informed revision on a systematic basis. This is essential to fight institutional inertia and ensure that organisational efforts and management priorities are driven by likely major hazards.

Hazard analysis should be dealt with at the level of the relevant bodies (e.g. agency) — as opposed to being left to individual inspectors (whose expert input to a wider process should however be encouraged, not least to avoid group think or leader-only-wisdom phenomena). To that end, it may be valuable to explore the potential for refocusing the mandate of those bodies towards outcomes (not simply enforcing the letter of the law), as well as to take account of situations in which hazard analysis may override risk analysis. To do so, it would be beneficial to extract relevant learnings from regulators and government agencies with experience of implementing outcome-based approaches; e.g. US Coast Guard (1996-2008), SEPA (2003-2012) and US EPA (1992-2012) – all the while bearing in mind that idiosyncratic factors may render specific approaches hard to replicate in a straightforward fashion. Relevant mandates should stress the importance of a regular review of hazards at a strategic level – the PP being applicable in cases of new emerging hazards.

Moreover, the independent assessment and review of the hazard and risk landscape in the relevant policy or regulatory area (e.g. environment, human health) should be clearly identified as an organisational duty upheld by their leadership and reflected in management practices and structure. If necessary, organisational requirements may be defined for systematic reviews to determine whether the current approach to risk is relevant and coherent. Evaluation of policy performance over time (with comparisons to both alternative policy designs and the counterfactual scenario (Wiener, 2016[15]) should also be encouraged from a whole-of-government perspective. The same goes for strengthening capacities for anticipatory analysis (e.g. foresight, horizon scanning) and embedding these activities systematically in risk governance frameworks.

A specific case concerns disasters that occur infrequently and for which it may not be possible to “judge whether the regulatory agency has struck the optimal balance in its risk management strategies”. Under these circumstances, it may be useful to explore alternative hypotheses (problems may have other causes than a lack of adequate regulatory oversight), and examine the regulatory mechanisms employed in other similarly situated regulatory environments or time periods (Carrigan and Coglianese, 2012[16]).

Independent assessment and review may usefully draw on peer review processes across government, as well as on the involvement of existing networks. Such a collaboration model has already shown its effectiveness on several occasions. This includes the joint efforts by environment protection, anti-money laundering actors and justice bodies in various environmental crime contexts, e.g. INTERPOL and EUROPOL’s joint initiatives with EPAs, police authorities and prosecutors on the prevention of waste and pollution crimes, as well as wildlife trafficking.

While politically sensitive, systematic assessment and review may also be capitalised upon to assess whether precautionary approaches and measures in place need to be modified. Such a process could consider new information or knowledge that may, for example, reduce the degree of scientific uncertainty. It may also facilitate the identification of opportunities to simplify how risks are operationally managed.

Quality guidance is also necessary to that end; all the more since it has been pointed out that there is often little or no guidance as to what conditions justify a re-examination of the potential risk, and who would be responsible for producing the evidence required for risk assessment (Garnett, K. and Parsons, D. J., 2017[12]).

Adaptive learning will effectively hinge on the existence of appropriate and well-structured approaches to (risk-related) data monitoring and knowledge management. If appropriate, it may be useful to set internal organisational requirements to gather, hold, review and use relevant data and information. These requirements may be coupled with staff selection, training and incentives, and adequate reskilling/talent management measures. Repositories of both public and neutral sources of data and information may also be particularly instrumental in that respect.

The case for reconsidering common characterisation of precaution: balancing harms with potential benefits, ensuring proportionality

Based on the analysis and examples presented in this report, there is a case for reconsidering some of the commonly accepted characterisations of precaution and precautionary measures. In a context of complex decision-making systems ridden with uncertainty, political economy struggles and multiple trade-offs across risk and policy objectives, the "default setting" matters hugely. Given major impending challenges related to climate change and sustainability more generally, regulatory choices that lock in the status quo may not be precautionary at all. In a similar vein, it is known that regulatory bans tend to render subsequent authorisation difficult due to their effect on risk perception. This warrants the consideration of alternative, non-binary options that allow for more agile and adaptable regulatory governance, at least for those risks that do not warrant a regulatory ban.

Moreover, to be prudent, regulatory decisions must not only consider the harms (e.g. potential magnitude and level of certainty), but also the potential benefits stemming from the deployment of a given technology or innovation. In other words, decision-makers need to be mindful of the (evolving) balance of risks between acting and *not* acting, allowing and *not* allowing. This holistic view may also be useful to inform differential regulatory treatment. For example, bans may be the right precautionary approach for technologies with significant downside risks, but no major expected benefits; however, the approach to managing trade-offs is likely to be more problematic for those technologies that can also bring major benefits.

Finally, a default setting of banning the development of potentially beneficial innovations also incurs the opportunity cost of not being able to gather evidence and enable an improved understanding of that technology's real-life behaviour and impact. Controlled testing, piloting and experimentation thus appear as useful regulatory tools which — when combined with appropriate oversight and robust data strategies — can contribute to delivering superior outcomes. One such outcome is a sustainable energy transition.

Report structure

- **Chapter 2** of the report provides an overview of the core elements of the PP as well as its evolution over time (including the surrounding public controversies). In addition to a general overview, the chapter includes specific examples of the PP as it relates to energy, including cases where precaution was *not* applied, and the lessons learned from these.
- **Chapter 3** focuses on the various interpretations of the PP as a regulatory approach, especially regarding the articulation between risk, uncertainty and precaution, as well as the methods and criteria developed to help determine whether application of the PP is warranted. It also delves into the role of public perception, human psychology, and incentive structures in the use of the PP, as well as their implications for public trust. Energy examples are specifically discussed, as public

perceptions and trust issues are particularly salient in several major cases, with strong divergence between scientific risk-assessment and the generally perceived threat and harm.

- **Chapter 4** elaborates on the articulation between precautionary approaches and innovation by outlining key arguments in this long-standing debate. It showcases examples of frameworks aimed at reconciling both objectives to the extent possible.
- **Annex A** presents selected examples of PP integration into national and international law.
- **Annex B** presents selected cases involving the adoption of precautionary approaches.

Selected assessments and estimates in the context of precaution and risk-based regulation are provided in Chapters 2 and 3, and Annex B.

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Note

[1] For the sake of clarity and consistency, the term precautionary principle is used in this report, though it is understood that there is no unitary definition, and precautionary approach or approaches are also commonly used terms.

2 The precautionary principle

This chapter looks into several formulations of the precautionary principle, its origins and evolution and early applications into national law. It also provides background on the polarised debate around the precautionary principle.

Key messages

- There is no universally accepted definition of the PP. Several formulations of it include the following elements:
    - the need for (environmental or health) protection;
    - the presence of a threat or risk of serious damage;
    - the understanding that a lack of scientific certainty should not be used to avoid taking action to prevent that damage, and — in the case of stronger formulations — an obligation to act in the face of uncertainty, and
    - the need to provide evidence of safety ("reverse burden of proof").
- The PP is a useful background principle in the development of new rules and regulations, including standards, monitoring measures or licensing arrangements, and to the application of existing legislation and definition of associated legal requirements.
- Several countries incorporated the PP into national law and strategic policy documents since its inception some 40 years ago. Others are in the process of doing so. International and EU-level instruments started referring to the PP in the 1990s. This includes the Rio Declaration on Environment and Development (1992), the Wingspread Statement (1998), the Maastricht Treaty (1992) and Treaty on the Functioning of the European Union (Article 191), and the European's Commission's Communication on the PP (2000).
- Proponents of the PP highlight its usefulness in preventing potentially severe, even irreversible harms stemming from hazard sources for which there is insufficient scientific evidence.
- Critics of the PP tend to point at the numerous interpretations of the principle and the resulting inconsistent applications (including risks of "casually" invoking it). They also note that applying the PP can stifle innovation.

Definition and key concepts

The precautionary principle (sometimes referred to as "precautionary approach") came to prominence several decades ago. It was first formulated as an attempt to confer legal status to the notion of precaution, in order to protect the environment from potentially severe or irreversible damage in those situations of scientific uncertainty where a full risk or cost-benefit analysis was not practical (or possible). It needs to be distinguished from the notion of prevention (see Box 2.1). It has been subsequently applied to a range of other areas including public health and consumer safety.

A range of formulations, from very weak to very strong, exist for the PP. Its core elements include the need for (environmental) protection; the presence of threat or risk of serious damage; and the understanding that a lack of scientific certainty[1] or inconclusive findings should not be used to avoid taking action to prevent that damage (Pinto-Bazurco, 2020[1]) (Sands, P. & Peel, J. (Eds), 2012[2]). Authors such as Wiener & Rogers propose a more constraining approach by also referring to the resulting obligation to take action in the face of uncertainty and the need to provide evidence of safety ("reverse burden of proof") (Wiener and Rogers, 2002[3]). The PP may be applied in a variety of contexts, notably related to the development of new laws and regulations, including standards; monitoring measures or licensing arrangements; and to the application of existing legislation and definition of associated legal requirements. It should be noted that outside the environmental policy area, the application of the PP is contested – but, *de facto*, a number of countries either apply it, or at times take policy decisions premised on a "cautious" approach, to which these findings and recommendations can apply.

Box 2.1. Precaution and prevention; hazard and risk

According to Gollier and Treich, the notion of ***prevention*** aims at managing risk whereas ***precaution*** is about managing the wait for better scientific information (Gollier C., and Triech, N., 2003[4]) (Nerhagen, Forsstedt and Edvardsson, 2018[5]). In addition:

> *[…] the precautionary principle is seen as more complex and dynamic than the principle of prevention, which addresses better-understood risks to the environment. In reality, it is difficult to draw a sharp line between 'precaution' and 'prevention', given that science always entails elements of doubt and uncertainty. (European Commission, 2017[6])*

A similarly useful distinction is between *hazard* and *risk*. According to the International Risk Governance Council (IRGC), it is crucial to distinguish between hazard and risk. Hazard is defined a source of potential harm, whereas risk refers to the degree of likelihood that the harm will be caused and its magnitude (International Risk Governance Council, 2006[7]). The consequence of this distinction is that identification (establishing a cause-effect link) and estimation (determining the strength of the cause-effect link) need to be performed for hazards and risks separately; i.e. ensuring that hazard analysis precedes risk analysis is particularly important in the context of the PP.

The estimation of risk depends on an exposure and/or vulnerability assessment. *Exposure* refers to the contact of the hazardous agent with the target (individuals, ecosystems, buildings, etc.). *Vulnerability*, in turn, describes the various degrees by which the target can experience harm or damage as a result of the exposure (for example: immune system of target population, vulnerable groups, structural deficiencies in buildings, etc.).

To date, there is no universally accepted definition of the PP. According to Wiener, there is no single authoritative statement of the PP but rather several different precautionary principles (Wiener and Rogers, 2002[3]) (Wiener, 2016[8]). In a similar vein, academic work has identified at least 19 definitions of the PP (Sandin, 2004[9]).

Despite the absence of a single definition of the PP and the various formulations available, a number of key elements common to many of them have been outlined by the World Commission on the Ethics of Scientific Knowledge and Technology (UNESCO, World Commission on the Ethics of Scientific Knowledge and Technology, 2005[10]).[2]

- The PP applies when considerable inconclusive scientific findings about causality, magnitude, probability, and nature of harm exist. It can also apply when there is a lack of agreement as to the nature or scale of the likely adverse effects of a given activity or substance.
- The PP is not intended to apply to hypothetical effects or imaginary risk, and it should be based on a scientific examination. In addition, it will not apply to situations in which the desired level of protection is defined, and the risk of harm can be quantified. These situations can be dealt with using traditional risk management tools such as prevention.
- In a precautionary approach, interventions are required before possible harm occurs, or before certainty about such harm can be achieved. As such (and in general terms), a wait-and-see-strategy is excluded, although active wait-and-see approaches coupled with ongoing monitoring and assessment can be part of precautionary interventions. Any interventions should be proportional to the chosen level of protection and the magnitude of possible harm (to the extent that the latter can be assessed).

- In case of action, a wide range of initiatives may be available; e.g. measures that constrain the possibility of the harm, or measures that limit the scope of the harm and increase the controllability of the harm, should it occur.
- There is a need for ongoing systematic empirical search for more evidence and better understanding (long-term monitoring and learning) of potential harms.

It should be noted that, given the lack of an agreed definition, a number of existing interpretations are much narrower in scope and do not encompass many of the elements presented above.

Origins and evolution

From the onset, the advent of new technologies has given rise to critical, opposing voices that herald their potential for major, possibly irreversible damage. These worries about potential harm were originally more focused on social (cultural, political) consequences, as was seen with the invention of the printing press in the 15th century and the increasingly rapid diffusion of varied, hard-to-control printed material:

> *Ironically, the uniformity of the copies of Gutenberg's Bible led many superstitious people of the time to equate printing with Satan because it seemed to be magical. Printers' apprentices became known as the "printer's devil". In Paris, Fust [a typographer] was charged as a witch. Although he escaped the Inquisition, other printers did not. (Waite, 2001[11])*

Early technical changes leading to increased use of mined coal instead of charcoal may have lacked visibility (even though they proved, in retrospect, to have far-reaching consequences). However, the application of several combined innovations (hard coal, steam machine, cast iron production), which notably led to the introduction of steam-powered locomotives and railroad expansion in the early 19th century,[3] encountered quite severe reactions warning of an impending disastrous impact on health and safety. For example, preliminary surveys for railroad construction conducted in England at the time were reported to face "strong opposition, which did not always stop at legal action and verbal attack, but in some instances led to the display of force" (Robert H. Thurston, A. M., C. E., 1878[12]).

It would be tempting to wave away the example above as being "obviously" wrong in hindsight. While critics' predictions were indeed proven entirely misplaced in their specifics, they were arguably far less wrong in their warning that such a completely novel, radically transformative technology, which brought human civilisation to a completely new era, could have unpredictable, extremely far-reaching and potentially disastrous consequences. Indeed, this was true not only in cultural, social and political terms, but also in environmental and safety ones. Assessing the balance of positive and negative effects of the transformation is immensely difficult, and ultimately cannot be done without a value of judgment, prioritising certain outcomes over others. Railroads enabled massive improvements in agricultural productivity and food supply, with immediate positive impacts in terms of life expectancy and average wealth. However, they also contributed to a growing gap in development between different parts of the world, thereby facilitating increased imperialism, which went on to destroy millions of lives. The energy and transportation revolution (further continued with oil and the internal combustion engine) transformed human life in many ways and brought immense benefits (making humans, at least those above the poverty level, safe from death from cold and hunger, and bringing uncounted comforts to their lives). However, it has also led to environmental destruction on an unprecedented scale, to the point that runaway global warming is now a real threat (Goldblatt and Watson, 2012[13]).

This early example, even though it pre-dates the use of the "precaution" terminology, matters in many ways; the early industrial, energy and transport revolutions were criticised from many corners, and while a hundred years later these critics appeared to have been largely proven wrong, this is all far less obvious two hundred years on. This illustrates the difficulty in predicting the longer-term, large-scale impact of profoundly disruptive, transformative innovations.

Interestingly, and importantly for our research, the concerns about the health and social impacts of the industrial revolution provide another example. Many critics at the time raised the alarm about the unacceptable health and safety harms, environmental destruction, and extreme exploitation of workers (including juveniles). This was sometimes combined with a romantic view generally hostile to "unnatural" innovations (a trend also present in many of the precaution discussions today).

The gradual improvement of conditions of industrial workers and towns over more than a century provides several insights:

- Regulation can play a role in addressing some of the harms, as exemplified by the emergence of health and safety regulation in the 19th century, and later by environmental regulation (Blanc, 2018[14]).
- Policy changes proved indispensable to addressing the major abuses driven by extremely unequal bargaining power. Various measures included regulatory interventions and income redistribution. (UK Parliament, 2022[15]) (Moselle, 1995[16]).
- While "in the longer term" the transformations worked largely to the benefit of most of the populations in industrialised countries, this does not mean that risks and harms could not have been managed better or addressed more effectively today. Nor, indeed, does it mean that the catastrophic longer-term, initially unpredictable consequences, are to be ignored. Many cities that relied on soft coal or fuel suffered through decades of dense air pollution (Stradling and Thorsheim, 1999[17]) and, in 2016, outdoor air pollution was estimated to cause 4.2 million premature deaths worldwide each year (World Health Organization, 2021[18]).

This example of the industrial and transport revolution illustrates that, whilst contemporary calls for "precaution" were not always justified, they did point to the fact that — in the longer run — major innovations have far more complex, far-reaching and sometimes disastrous consequences than initially predicted by their proponents. Historically closer to us, recurring environmental and health scandals have impacted public trust in new technologies and in the reassurances of "official" voices, be they scientific or governmental. These notably include the harm caused by DDT and related chemicals, the Thalidomide scandal, and the Love Canal disaster in the US (Blanc, F., Ottimofiore, G. and Macrae, D., 2015[19]) (OECD, 2010[20]).

What distinguishes the PP from both appeals to "precaution" in general, and public reactions to earlier health and environmental scandals, is its definition of a *legal principle* which aims to avoid disasters or lasting harm by a proactive application of precaution in a mandatory way.

Early applications of the PP into national law

Notable examples of the PP can be found in Swedish and German law. The 1969 Swedish Environmental Protection Act (Sand, 1999) stated that authorities do not have to demonstrate that a certain impact will occur, and that mere risk (if not too remote) is deemed enough to warrant protective measures or a ban on the activity. West Germany's 1970 Clean Air Act upheld the "Vorsorgeprinzip" to help "prevent the development of harmful effects" (Wey, 1993). The PP has subsequently been recognised by some countries in their national legislation (sometimes with Constitutional status) — e.g. Belgium, France and Brazil. Regarding the energy sector, a relevant example can be found in the Netherlands. The country is currently developing a set of policy principles for safety and health in the energy transition. The current version of these principles, which are to undergo a national consultation, refers to precaution specifically, with the PP being applicable mainly to long-term health risks in contexts of relatively high uncertainty (Government of The Netherlands, Unpublished[21]). While a number of countries have included the PP in their national laws, countries across the world have taken a variety of approaches in the application of the

PP, including deliberately not incorporating it into their legislation. As indicated in this report's introduction, the findings and recommendations can be valid and useful regardless of this specific context.

In addition to being incorporated into national law by some countries, the PP was increasingly used in international and EU-level instruments from the 1990s onwards. Key milestones in this respect include the 1992 Rio Declaration on Environment and Development, representing the multilateral recognition of the PP, and the 1998 Wingspread Statement, i.e. an academic definition of the PP.[4] These illustrate the variety of PP formulations: the Rio Declaration is stated in the negative (uncertainty should not preclude preventive action), whereas the Wingspread Statement imposes an affirmative obligation to act notwithstanding uncertainty (Mossman, K.L. and Marchant, G.E., 2002[22]).

At the EU level, the PP was enshrined in the Maastricht Treaty in 1992 and it is now included in Article 191 of the Treaty on the Functioning of the European Union. However, the PP is not *defined* in the either treaty. It states: "Union policy on the environment shall aim at a high level of protection considering the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay." Hence, through the Maastricht Treaty, the PP acquired constitutional status. It was formally articulated by the European Commission's Communication on the Precautionary Principle (see Box 2.2), which was subsequently endorsed by the Council of Ministers (Nice Resolution). The Communication states that: "The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU."[5]

For more details, Löfstedt provides an analysis of the evolution of policymakers' use of the PP over time (Lofstedt, 2003[23]), and authors including Klinke and Renn provide an overview of risk reduction activities derived from the PP's application (Klinke and Renn, 2002[24]).

Interpretation of the PP has continued to evolve in recent decades. In the EU, the PP is argued to have evolved from being associated with a "better safe than sorry" perspective, to being identified with "reversed burden of proof" (Lofstedt, 2004[25]). In 2004, Lofstedt concluded that, at EU level, the "pendulum" may have been swinging back from precaution and harm prevention towards approaches based on risk assessment (Lofstedt, 2004[25]) (Wiener and Rogers, 2002[3]). However, there have been examples of precautionary approaches in recent years suggesting that this trend is not so clear-cut (Lofstedt, 2011[26]) (Lofstedt et al., 2011[27]) (Lofstedt and Bouder, 2017[28]).

Annex A presents selected examples of the integration of the PP into national and international law. Annex B showcases international examples and experience regarding the application of the PP and risk-based regulation, including in the energy sector.

Box 2.2. The European Commission's Communication on the Precautionary Principle (2000)

The PP was formally articulated by the European Commission's Communication on the Precautionary Principle. Since then, the PP has been introduced into EU legislation (Regulations and Directives), and has been recognised by the Court of Justice of the EU as a general principle of law. The Communication provides a general framework for use of the PP in EU policy. It describes the use of the principle in a range of policy areas and suggests that the PP must be considered in the overall framework of risk analysis.

According to the Communication, the PP pre-supposes the identification of potentially adverse effects resulting from a phenomenon, product or process, in addition to a scientific evaluation of the risk (which, because of the insufficiency of the data, or their inconclusive or imprecise nature, makes it impossible to determine with sufficient certainty the level of the risk in question). In some cases, the right response may be to do nothing, or at least not to introduce any legally binding measure. If action is deemed necessary, there are a wide range of initiatives available, from legally binding measures, to recommendations for extra controls, or the launch of a research project.

The Communication states that the PP should be informed by three specific principles: a) implementation should be based on the fullest possible scientific evaluation; b) any decision to act or not to act must be preceded by a risk evaluation and an evaluation of the potential consequences of inaction; c) all interested parties must be given the opportunity to study the various options available, whilst ensuring the greatest possible transparency. Based on these principles, the Communication provides three prerequisites for invoking the PP: the existence of scientific uncertainty; the identification of possible negative effects, and the performance of a scientific evaluation. While not legally binding, the Communication sets out that measures must be:

- Proportional to the chosen level of protection and must not aim at zero risk.
- Non-discriminatory in their application.
- Consistent with similar measures already taken.
- Be based on an examination of the potential benefits and costs of action or inaction.
- Be subject to review, in light of scientific data (i.e. the measures shall be maintained as long as the scientific data remain incomplete, imprecise or inconclusive; scientific research should be continued with a view to obtaining more complete data).
- Indicate responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment (i.e. assign the burden of proof).

Academic literature has often been critical of the Communication.[1] Critics argue that the Communication does not provide a definition of the PP and it remains unclear how and by whom the PP should be applied. The Communication has also been criticised for leaving controversial aspects unanswered, in particular what would be the minimum scientific information needed to trigger exercise of the PP, the acceptable level of risk, or the sequence of actions to be taken (EPRS, 2015[29]). It has also been claimed that, contrary to its declared goals, the Communication does not place meaningful and effective constraints on the application of the precautionary principle, nor does it provide a means to determine which hazards should be prioritised over others when applying the PP. Additionally, although the Communication favours cost-benefit analysis, it argues that it should not only consider the costs to the EU but also several non-economic considerations such as public acceptability, leaving too much room for interpretation. Finally, the Communication does not address the problematic issue of risk-risk trade-offs, and it ignores the issue of technical stigma by assuming that decisions based on the precautionary principle can easily be reversed when new scientific findings become available.

1. For instance, see (Vos and De Smedt, 2020[30]), RECIPES, WP1 Report: Taking stock as a basis for the effect of the precautionary principle since 2000; (Löfstedt, 2014[31]), The precautionary principle in the EU: Why a formal review is long overdue'. Risk Management 16(3), p. 143-145; (Graham and Hsia, 2002[32]), Europe's precautionary principle: promise and pitfalls', Journal of Risk Research 5(4); (Majone, 2002[33]), What price safety? The precautionary principle and its policy implications, Journal of Common Market Studies 40(1), p. 89–109; (Zander, 2010[34]), The Application of the Precautionary Principle in Practice: Comparative Dimensions, Cambridge, p. 348; (Mcnelis, 2000[35]), EU Communications on the precautionary principle, in Journal of International Economic Law, 3(3), p. 545-551.

Source: (European Commission, 2000[36]).

The PP: a polarised debate

As reminded by Wiener, the PP remains controversial. The author quotes Marchant & Mossman (2004):

> *The precautionary principle may well be the most innovative, pervasive, and significant new concept in environmental policy over the past quarter century. It may also be the most reckless, arbitrary, and ill-advised. (Wiener, 2018[37]) (Wiener, 2018, citation of Marchant & Mossman,2004).*

While it is beyond the scope of this paper to describe the full range of arguments for and against the precautionary principle, a summary of the main ones is presented below. Subsequent sections of this report elaborate further upon a number of these arguments.

Arguments in favour of the PP (selected examples)

Proponents of the PP highlight its usefulness in preventing potentially severe (and sometimes irreversible) harms stemming from hazard sources for which there is insufficient scientific evidence:

- Precautionary measures (early and anticipatory) can help address the risks of latent impacts, i.e. those that do not occur until long after their causes (climate change being a prime example) (Wiener, 2018[37]).
- The PP can encourage more open discussion of the value judgements underpinning methods of risk assessment and cost-benefit analysis (Stirling, 2016[38]).
- It may help to avoid situations in which standard risk analysis otherwise creates a bias in favour of taking chances on poorly understood risks (Grant & Quiggin, 2013, quoted in (European Commission, 2017[6]).
- PP can be used as a decision-making rationale that incorporates concerns for distributional effects (equity), which can complement appraisal methodologies that quantify the benefits and costs of a proposed, activity, such as cost-benefit analysis (Sadeleer, 2012[39]). Related to this are various examples of outcomes that the PP may potentially help avoid (see Box 2.3).

Box 2.3. Examples of outcomes the PP may help to prevent

(Patterson and Gray, 2012[40]) describe the initially failed attempt of the UK Government's to adopt a precautionary approach to bovine spongiform encephalopathy (BSE) in British cattle. A major policy mistake consisted in misinterpreting "no evidence of harm" as "evidence of no harm".

Historical case studies have led some to conclude that a more precautionary response was needed to manage human exposure to substances such as asbestos and dichlorodiphenyltrichloroethane (DDT). In the case of asbestos, it is not clear the extent to which resulting harm resulted, respectively, from uncertainty about its potential negative effects on health, and conscious decisions to use the material despite the existence of evidence of such negative effects.

Prior to the growing solidification of scientific evidence concerning climate change in recent years, it had been suggested that using the precautionary principle in climate-change-related legal cases could increase the chances of success (of legal cases going forward) by overcoming problems of scientific uncertainty that are otherwise exploited by defendants. The high degree of confidence in IPPC 6th Assessment Report suggests that such uncertainty is no longer arguable (if it ever was).

Source: (Patterson and Gray, 2012[40]) (European Environment Agency, 2011[41]) (European Commission, 2017[6]).

Criticism of the PP (selected examples)

Critics of the PP as a tool for decision-making tend to point at the existence of multiple interpretations, leading to inconsistent application (including risks of the PP being invoked "casually"), and its potentially deterring effect on innovation:

- Since it is not well-defined, the PP can undermine legal certainty. In addition, it is subject to a number of psychological biases.
- Consistently applied, evidence-driven risk-based regulation already foresees ways to deal with uncertain risks, potential major hazards with low or uncertain probability, in a proportionate way (IRGC, 2017[42]) (OECD, 2021[43])
- It can stifle innovation, particularly if applied rigidly (see Chapter 3, "The PP and innovation: How well do they mix?") – and thus clash with other key policy principles and priorities (OECD, 2021[44]).
- It could negatively affect world trade and international regulatory co-operation (Bailey, 1999[45]) (Hannesson, 2014[46]). Moreover, unwarranted recourse to the PP may be a disguised form of protectionism.
- There is insufficient guidance on the level of precaution to adopt in practice, or the level of scientific information needed to trigger the exercise of the PP.
- Gemmell and Scott argue that, while the PP was deployed "as a justification both for greater care and for the operator to prove the harm would be managed", there has been too casual and unsubstantiated reliance on it, as well as an overly prescriptive approach to activity and process detail rather than on outcomes. This, they argue, has been a real weakness (Gemmell, J. Campbell; Scott, E. Marian, 2013[47]) and often led to a political backlash against "excessive burden". Given the importance of this aspect, this report seeks to provide recommendations on how the original spirit and intent of the PP can be effectively "reactivated", moving away from overly rigid "all-or-nothing" or "no-by-default" approaches.
- It is not applied consistently, thus leading to "unprincipled" decision-making; e.g. Wiener's EU-US comparative analysis concludes that both jurisdictions were selective in the use of the precautionary principle, with neither consistently more precautionary than the other (Wiener and Rogers, 2002[3]); Garnett and Parsons' case studies (EU and case law) conclude that:

> *The decision whether or not to apply the precautionary principle appears to be poorly defined, with ambiguities inherent in determining what level of uncertainty and significance of hazard justifies invoking it (Garnett, K. and Parsons, D. J., 2017[48]).*

Chapter 3 discusses and elaborates on some of the notions and key arguments outlined so far. It draws on select, relevant applications of the PP, their associated challenges, and how the PP is articulated between notions of uncertainty, hazard, risk and precaution.

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Notes

[1] Lack of scientific certainty is understood as any kind of instance in which if the scientific findings are inconclusive, have large errors, or come with unacceptable uncertainties to policymaking.

[2] For an overview of academic discussion around the scientific foundations and justification of the PP, the reader may notably refer to (Aven, 2006[49]) and (Klinke and Renn, 2002[24]).

[3] Experiments combining use of the steam locomotive and a permanent travel way of metal rails culminated in the Stockton & Darlington Railway, opened in 1825; the Liverpool and Manchester Railway, which opened in 1830, constituted the first fully timetabled railway service with scheduled freight and passenger traffic relying entirely on the steam locomotive for traction (Buchanan, R. A. et al, 2022[50]).

[4] The Wingspread Consensus Statement on the Precautionary Principle was made following a three-day academic conference involving lawyers, policymakers and environmentalists.

[5] Lofstedt reports that in the period 1994 to 1999, the term “precautionary principle” was referred to in 27 European Parliament resolutions (Lofstedt, 2004[25]).

3 The PP as a regulatory approach: risk, uncertainty and precaution

This chapter describes the precautionary principle as a regulatory approach, including in the context of energy-related decision-making. It analyses precaution as a "continuous variable", illustrating the importance of taking into account the (implicit) trade-offs when prioritising certain risks. Finally, it discusses the interplay between precautionary approaches with public perception and the wider socio-political context.

Key messages

- The PP is a potentially useful tool in high stakes situations of uncertain environmental or human health hazard. It is not a prescribed formula. The PP should be understood as a flexible principle which can help decision makers to:
    - ensure they are not ignoring problems of scientific uncertainty; and
    - avoid unintended disastrous impacts that can arise when actors may be inclined to reckless risk-taking behaviour.
- Pinpointing "obvious" precautionary decisions is challenging from a regulatory standpoint. This challenge is ubiquitous in the energy transition context. Not deploying certain technologies may also entail important potential — even major — negative long-term effects.
- In the face of uncertainty, taking precautionary decisions is shaped by social-political and psychological elements as well as the political economy. These factors are equally as important as scientific evidence, which was the traditional emphasis of academic research and debate on the PP. Empirical evidence suggests that the PP is applied with a high degree of discretion – in often heavily politicised decision-making.
- Governments do not follow "national styles" when it comes to applying the PP. Even within single countries, patterns of systematic application are difficult to detect. Variations in application are due to specific risks and concerns. They are not a result of general differences.
- Precautionary measures should aim at optimising trade-offs across interconnected risks as much as possible. Moreover, application of the PP should rely on robust and iterative assessment in order to reduce incrementally any uncertainty surrounding potential outcomes and their probabilities.
- In the energy transition context, the critical question (and challenge) relates to identifying the truly precautionary regulatory choices in a context of impending catastrophic risks linked to climate change. The main question is not whether to apply the PP or not but rather *what the actual precautionary choice would be.* Furthermore, the question is whether there is a demonstrated or sufficiently credible claim that the technology can make a real positive contribution to fighting climate change and its impact. Not the "classical" PP question of whether a given technology is sufficiently risky as to warrant a ban or other severely restrictive action.
- If a technology can credibly make a positive contribution to fighting climate change, the relevant regulatory choice should be between "normal" risk-based regulation *and* — if justified by its potential harm — restrictions, strict monitoring and gradual implementation.
- The fact that some risks, related to the use of hydrogen, are unknown or insufficiently quantified does not justify the use of the PP in hydrogen risk regulation. Certain applications of hydrogen might warrant more precaution due to higher uncertainty and potential harm. However, this decision is not a yes-or-no question, it must rely on stepwise, scalable and experimental approaches.
- Socio-political and psychological elements play an important role in shaping precautionary decision-making in the face of uncertainty.

The PP in the context of energy-related decision-making

When considering the "big picture" of energy sources, vectors and applications, the application of the PP is both very relevant in principle, and highly challenging in practice. As discussed, it may bring about important benefits in terms of determining rules that protect from severe harm (environment, safety etc). It can, however, bring about negative consequences such as unduly stifle the use of new technologies.

In the context of the 2020s, "precaution" is a highly problematic and conflictual issue in the energy field. Arguably, the *lack* of precaution when it could have made a difference has led us to the current climate crisis: the roll-out of fossil fuels on a massive scale was seen by some as a potential source of global warming early on (Thompson, 2019[1]), and solid scientific findings of CO2-induced warming date back at least to the 1970s (NASA, 2022[2]).[1] Even though the research produced internally by Exxon was suppressed for profit motives, warming became increasingly understood and noticeable over the 1980s and 1990s. However, it did not become a prevailing concern until several years later, and a vast number of energy-related decisions continued to be made without taking it into account.

Moreover, the core question for energy technologies is not only about "applying the PP or not", but rather *what the actual precautionary choice would be.*

Hydropower initially looked like an environmentally friendly source of electricity, adding the benefit of flood control for valleys that had often suffered from disastrous flooding (with, of course, the major safety risk of dam failure to control for). However, longer-term, negative impacts on many fish species, marshlands and coastal deltas (which are no longer reinforced by alluvions), have become a major concern. This is illustrated by the evolution over time of guidance on implementation of the Water Framework Directive and associated regulations in several jurisdictions with regard to the impact on good ecological status ratings of heavily modified waters, engineering works etc. – e.g. Scotland (Scottish Environment Protection Agency, 2022[3]). This realisation has led to a sharp decrease in large new dam construction projects as well as to the removal of a number of existing dams. Investment in wind and solar energy now far outpaces investment in hydropower (Leslie, 2018[4]), with associated challenges in variability of supply, as only hydropower can be considered a stable baseload source.

After an initial enthusiastic global rollout of civilian nuclear energy from the 1950s onwards, major incidents (Three-Mile-Island, Chernobyl and Fukushima) led to an increasingly strong backlash (Kiyar, D. & Wittneben, B., 2012[5]) (Beale, 2016[6]), which has resulted in a particularly safety-focused regulatory framework (NEA, 2022[7]), and sometimes in particularly strong precautionary postures. A 2016 article quoting data from the World Nuclear Association's Reactor Database noted that, in the 32 years before Chernobyl, 409 reactors were opened, but only 194 had been connected in the three decades since (Beale, 2016[6]). However, other dimensions of precaution (e.g. energy independence) were actually one of the motives why some countries strongly developed nuclear electricity production (e.g. France in the 1970s) (Le Gros, G. (, 2020[8]). Security of supply has been again highlighted as a key issue due to the invasion of Ukraine, and this tends to show that a more holistic vision of precaution should also consider reliability in all sense.

More deeply, however, the safety and environmental dimension of precaution in the case of nuclear energy is far less easy to judge in light of the global climate emergency. The early 1990s anti-nuclear, PP-based narrative fundamentally contested the use of an energy source carrying significant safety risks and unknowable longer-term risks around high-level nuclear waste (Weber, 1991[9]). This latter point, in particular, made the discussion more about precaution than only about risk management. However, opponents of nuclear energy were also arguing that the downside risks of an accident were so high that no benefits could justify them — i.e. that no risk-benefit balance could properly be found in this case. Considering what is known from data on effective harms and risks of nuclear energy compared to other energy sources (particularly baseload energy sources) and, *most importantly,* given what we now know about the climate crisis (a risk that dwarfs by its magnitude and potential impact all the safety concerns from any individual installation), it seems legitimate to ask whether the genuine PP-driven choice would still be to avoid or abandon nuclear energy — or rather the opposite.

If we take energy sources and vectors with less "longer-term, hard-to-predict" impact, such as hydrogen, there is even a stronger case to be made that the PP may not lead to *avoiding the use* of the new technology (which has safety risks, but not of the "unknown and unpredictable" kind), but rather to advocating its use (given the open-ended catastrophic risk of climate change). This discussion is further developed in subsequent sections (see Box 3.9).

Applying the PP in practice

If the PP is to be understood as more than a pure declaration of intent, there are two ways in which it can function as a regulatory approach.

The first relates to the implementation stage: i.e. an approach that operators (and regulators) should follow to maximise meaningful prevention and management of risks in conditions of uncertainty (Gemmell, J. Campbell; Scott, E. Marian, 2013[10]). In this respect, the PP is probably always relevant, as well as — unfortunately — insufficiently understood and implemented (too often being substituted by formalistic, process-focused "make believe" steps that have little real preventive effect). In this perspective, the PP is about the "how", rather than the "what" or "whether": it should guide operators (and, along with them, regulators) in caring about each potential risk driver and uncertainty in the processes or products they use. This includes paying attention to potentialities, early signs of unforeseen problems, etc.

The second way the PP can function is more problematic and relates to the rule-making stage. If the PP is to have practical consequences in legislative and rule-making activity, it needs to be a principle that can: a) actually help decision-making, b) serve as a useful heuristics instrument for decision-making, and c) give an indication of which direction the default decision should take in a context of high uncertainty and significant potential (but not quantified or confirmed) harm. The purpose of such a tool is to avoid unintended disastrous impact in situations where some actors may be too inclined to reckless risk-taking behaviour because rewards are concentrated and short-term, whereas harms are typically distant in time, uncertain and diffuse. The problem is that it is unclear how often "obvious" precautionary decisions exist, and this seems to be particularly rare in the energy transition context. This is because *not using* certain technologies also conveys important, even major, downside risks and harms – again, not fully certain, or quantifiable, but no less important than the risks of using them.

The PP has attracted the attention of policymakers, regulators, industry, and academics. It has been recognised as a potentially useful tool in situations where environmental or human health hazard is uncertain and the stakes are high (European Parliamentary Research Service, 2015[11]). This applies to decisions about products or activities that could be seriously harmful to public health or the environment (Vos and De Smedt, 2020[12]).

While the PP has certainly been contested, it has received renewed interest in recent years, driven by emerging threats and ongoing crises. This suggests that it can be useful to analyse its articulation around notions of risk and uncertainty. It is also crucially important to evaluate whether the application of the precautionary principle is subject to changes, and to assess the drivers of those changes (Tosun, 2013[13]).

As discussed in the previous chapter, the PP has been incorporated into national as well as international law (indeed, the European Commission's 2000 Communication endorsed it as a guiding policy of the European Union in areas such as environmental, consumer and health protection). However, the application of the PP presents many challenges, especially regarding the articulation between uncertainty, hazard, risk and precaution. Empirical evidence suggests that differences in application owe to "the particular question of which risks to worry about and regulate most", rather than to the general application of the PP as such (Wiener and Rogers, 2002[14]). Overall, governments do not seem to follow "national styles" when it comes to applying the PP. For instance, while it has been argued that — across the board — Europe is more precautionary (i.e., erring on the side of safety at the cost of opportunity) than the US, "no evidence is found to support this argument" (Shapiro and Glicksman, 2003[15]); (Tosun, 2013[13]); (Vogel, 2012[16]); (Wiener et al., 2011[17]). Moreover, "even within single countries such as the UK or the US, scholars find it difficult to trace patterns of the systematic application of the precautionary principle" ((Hood, Rothstein and Baldwin, 2001[18]); (Majone, 2016[19])cited in (van der Heijden, 2019[20]). Box 3.1 presents additional examples of comparative country analysis of the PP's application.

Box 3.1. Comparative country analysis of the PP's application

Wiener's EU-US comparative analysis of the use of precaution recommends further comparative analysis of regulation and a shift from simple principles of precaution toward a more holistic concept of "prudent precaution".

Wiener finds that the degree of precaution often depends on the legal system and the context of the regulation (e.g. technology, location, politics, public perception…), rather than on some overarching national regulatory position. He notes that regulators face multiple risks and need to optimise the trade-offs across "interconnected risks" (Wiener and Rogers, 2002[14]). In a similar vein, Li's comparative analysis of the US and China and the relative stringency of respective federal/central regulatory approaches to environmental risks concludes there is a more complex pattern of risk-specific policy selection in each country. The study emphasises that estimates used in regulatory production are dependent on a range of societal and environmental issues in each country. Li finds that factors such as crisis, international pressure and trade competition can lead to more stringent regulation.

Comparative analysis by Lofstedt on chemicals regulation in Europe concludes that "there is no clear consensus as to when risk or hazard considerations should be the basis for regulatory decision-making, with wide discrepancies between Member States (e.g. the UK is overall more risk based than Sweden) and between regulatory agencies within Member States" (Lofstedt, 2011[21]).

Vogel has attempted to explain why the U.S. and Europe have often regulated differently a wide range of similar risks. He observes that, between 1960 and 1990, American health, safety and environmental regulations were "more stringent, risk averse, comprehensive, and innovative than those adopted in Europe". One key explanatory factor according to the author is that "concerns over such risks — and pressure on political leaders to do something about them — have risen among the European public but declined among Americans". Vogel also notes that "policymakers in Europe have grown supportive of more stringent regulations while those in the United States have become sharply polarised along partisan lines"[…]; he adds "as European policymakers have grown more willing to regulate risks on precautionary grounds, increasingly sceptical American policymakers have called for higher levels of scientific certainty before imposing additional regulatory controls on business" (Vogel, 2012[16]). Of importance to this trend was: 1) the embedding of risk/cost/benefit analysis in the US legal process from the late 1970s onwards; and 2) a need for the European Commission to secure stakeholder acceptance of the Single Market (NGOs in particular).

Farrow and Hayakawa, in an analytical review of the PP, identify that a "real options approach" has in some cases been adopted for regulatory decisions that involve uncertain safety impacts, social costs, and differences in perception among the public. The "real options approach" entails an economic analysis that determines if it is optimal to invest in safety, even if the estimated costs significantly exceed the estimated benefits. This approach — in order to develop a quantitative appraisal of precaution — aims to calculate the uncertainty and the size of the potential irreversible costs should the risk materialise. If the result of this calculation is zero, then there is no uncertainty and thus no justification for applying the PP. The authors argue that the ‘real options approach’ provides an analytical and quantitatively feasible approach to the “descriptively conceivable but analytically weak PP”.

Source: (Wiener and Rogers, 2002[14]) (Farrow and Hayakawa, 2002[22]) (Li, Xu and Wiener, 2021[23]).

Since understanding the range of interpretations and applications of the PP requires linking it with notions of uncertainty and risk (and risk governance in particular), the next section begins by outlining these aspects succinctly. It then discusses several applications of the PP, as well as some of their determining factors.

The PP and risk governance

The PP matters from a risk governance perspective in that the latter must often confront uncertainty, and decision makers are expected to answer public policy questions that science is not in a sufficiently advanced state to answer

Von Schomberg stresses that scientific uncertainty is key to understanding how and why the PP applies. He distinguishes between situations that can be dealt with by using “normal” risk management tools, and those that may justify precautionary approaches. Typically, precaution would apply when an activity or substance poses a plausible threat of harm, but there is insufficient scientific evidence or lack of agreement as to the nature or scale of the likely adverse effects; or, when the potential harms are known but the particular cause-effect relationships cannot be scientifically established (Von Schomberg, R., 2012[24]). Risk governance can be defined as the “the totality of actors, rules, conventions, processes and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken” (International Risk Governance Council, 2006[25]).[2]

According to the European Parliamentary Research Service (EPRS), most risk governance models encompass three main components: risk assessment, risk management and risk communication (including stakeholder engagement). Execution and evaluation are, however, also essential components that are sometimes overlooked in this context. Other, alternative risk governance models do exist; e.g. Stirling’s five-phase model (screening, appraisal, evaluation, management and communication), and the IRGC’s Framework (see Box 3.5 later in this section) (EPRS, 2015[26]) (Renn, O. (editor) et al, 2008[27]). The Standard ISO 31000 represents an additional characterisation of risk governance: its principles (ISO, 2021[28]), provide a framework and process for managing risk, and is among the most commonly adopted models worldwide (outside the areas of food safety and environmental protection).

There is a variety of viewpoints regarding the role of the PP within risk governance. A number of authors (Belvèze, 2003[29]) and key policy documents contend that the PP should be integrated into risk management frameworks, and that it is relevant for the decision-making stages of risk governance (European Risk Forum, 2011[30]) (International Risk Governance Council, 2006[25]). The European Commission’s Communication states that “application of the precautionary principle is part of risk management, where scientific uncertainty precludes a full assessment of the risk and when decision makers consider that the chosen level of environmental protection of human, animal and plant health may be in jeopardy” (European Commission, 2000[31]). Moreover, there have been attempts to devise a policy framework for the application of the PP; the PrecauPri project,[3] for instance, did so in order to provide guidance to policymakers with respect to European and international risk governance (Renn, O. et al. (coord.), 2003[32]).

In contrast, (Taleb, N. N. et al, 2014[33]) – who notably limit application of the PP to cases of potential ruin — point out, that the PP should not be conflated with risk management:

> *Risk management involves various strategies to make decisions based upon accounting for the effects of positive and negative outcomes and their probabilities, as well as seeking means to mitigate harm and offset losses. Risk management strategies are important for decision-making when ruin is not at stake. However, the only risk management strategy of importance in the case of the PP is ensuring that actions which can result in ruin are not taken, or equivalently, modifying potential choices of action so that ruin is not one of the possible outcomes (Taleb, N. N. et al, 2014[33]).*

The regime model of risk governance posits that, in theory, any viable control system must contain three basic components: a goal setting component; an information gathering component to check that the goal is being reached; and a behaviour modification component to bring activities into line with the goal (Hood, Rothstein and Baldwin, 2001[18]). The PP may arguably be applicable for both goal setting (e.g. permit, ban or control a given substance that may or may not pose some kind of harm), and behaviour modification (e.g. whether child protection officers should leave a child in, or remove a child from, a family setting that may or may not be abusive).

From a risk regulation perspective, the PP also has implications in terms of its legal philosophy and its repercussions for international regulatory co-operation. These have been discussed by Van Calster among other authors (see Box 3.2).

Box 3.2. The PP and conflicts law perspectives

According to the Van Calster, there is need for supra- and transnational law to set up structures of accountability. This will allow risk-averse and risk-tolerant societies to work out their differences in a space that is legally defined through meta-rules acceptable to both (inasmuch as the risk-averse state claims to regulate on grounds of protection against danger).

In addition, the condition imposed by the PP for some minimally objective, empirical scientific support is a requirement for consistency that will be acceptable to a risk-averse state. It is also one that the law can verify. Moreover, it gives the regulating state “freedom to evaluate if the less corroborated empirical evidence creates sufficient concern to warrant regulatory action based on the nature of the suspected hazard.”

Conflicts law perspectives argue that European and transnational law derive legitimacy from their ability to set up legal structures that require the inclusion of the other in the assessment of conflict constellations. The PP respects the prescriptive premises of conflict law: that states take seriously the extraterritorial effects that they produce and reconsider them in light of the concern of the affected jurisdictions, but it tolerates diversity and limits judicial review to a marginal role.

Source: (Geert Van Calster, ed., 2014[34]).

The Precautionary Principle and uncertainty

As the precautionary principle is intended to enable more prudent decision-making under conditions of scientific uncertainty, a major point of contention relates to the level of uncertainty associated with a given phenomenon (Vos and De Smedt, 2020[12]). As stated by the European Parliamentary Research Service (EPRS):

> *A key variable of the different understandings of the precautionary principle is the degree of scientific uncertainty likely to lead to action from the authorities. However, other variables also feature prominently in the different interpretations of the precautionary principle, including the severity of the risks involved, the magnitude of the stakes and the potential costs of action or inaction. (EPRS, 2015[26])*

It has been argued that a realistic analysis involves explicit consideration of the entire "spectrum of uncertainties", including both irreducible uncertainties (due to intrinsically random and uncontrollable phenomena), and reducible or epistemic uncertainties (due to lack of knowledge) (Patelli, E. and Broggi, M., 2015[35]). Scientific uncertainty can have a variety of causes; e.g. it may stem from a lack of data or inadequate models of risk assessment, or it might exist in the form of indeterminacy, when not all the factors influencing the causal chains are known (European Commission, 2017[36]). Furthermore, scientific uncertainty might arise when there is ambiguity, contradicting data or in situations of ignorance, where certain risks are still unknown (European Commission, 2017[36]).

Available evidence suggests the potential existence of gaps and/or biases in the way uncertainty is often characterised — with social and cultural factors tending to receive little attention.

A 2000 meta-study from the European Environment Agency (EEA) discussed the relationship between modelling and scenario-building on the one hand (i.e. an approach that seeks to characterise uncertainty and "explore the different outcomes associated with 'what-if' questions"), with the strategic and cultural approaches to regulation and precaution, on the other. The study noted that the socio-cultural domain had not been explored in satisfying depth by any of the models. Indeed, when it came to analysis of issues related to sustainability, "the indicators chosen to represent this domain are still largely demographic or economic and only marginally correlated to the underlying issues" (EEA, 2000[37]).

The Intergovernmental Panel on Climate Change (IPCC) has produced a guidance note for the treatment of uncertainty. It attempts to provide a common approach and calibrated language which can be used broadly for developing expert judgments, and for evaluating and communicating the degree of certainty of findings from any assessment process. Although specifically intended for the authors of the IPCC's 5th Assessment Report, the note contains background information and suggestions that can be useful more broadly (see Box 3.3).

Box 3.3. IPCC Guidance Notes for Lead Authors of the IPCC Fifth Assessment Report on Consistent Treatment of Uncertainties and The concept of risk in the IPCC Sixth Assessment Report (summary of cross Working Group discussions)

The guidance note uses confidence levels to characterise uncertainty as expressed by expert judgments on the correctness of a model, analysis or statement. This confidence scale serves to express the numerical chance of an assessed finding being correct, where confidence levels are categorised as very high confidence, high confidence, medium confidence, low confidence and very low confidence). It synthesises the author teams' judgments about the validity of findings as determined through evaluation of evidence and agreement.

The IPCC also relies on two metrics for communicating the degree of certainty in key findings:

- Confidence in the validity of a finding. This is based on the type, amount, quality, consistency of evidence (e.g. mechanistic understanding, theory, data, models, expert judgment), and degree of agreement.
- Quantified measures of uncertainty in a finding as expressed probabilistically (based either on statistical analysis of observations / model results, or expert judgment).

Risk management relies on an ability by decision-makers to weigh up alternative courses of action, and to balance a range of potentially adverse consequences, since no action is entirely free of the potential for adverse consequences. Such balancing inevitably relies on individual or collective value judgements, including whether risks are viewed as manageable, intolerable or existential. A critical contribution from IPCC assessments to inform decision-making lies in a careful and transparent characterisation of risks, considering both the adverse consequence and its potential:

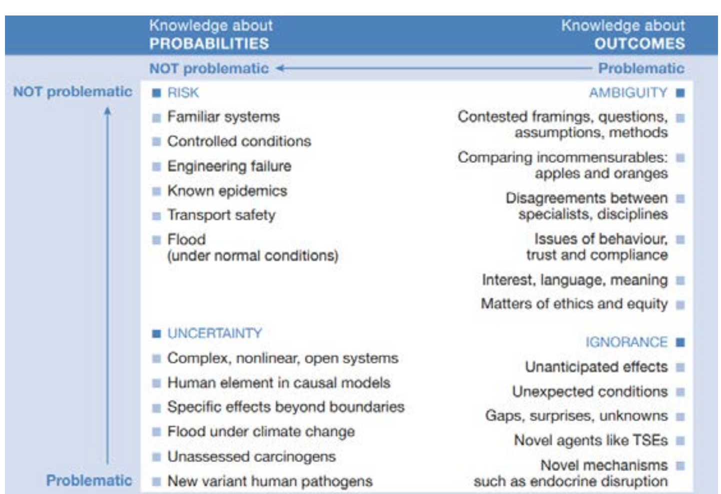
- What is the magnitude, reversibility, distributional effects, etc. of the adverse consequence?
- How confident are we in our understanding of those aspects?
- How much do those consequences depend on socio-economic trends or other assumptions?
- How well do we understand the potential for such events/outcomes to occur, and how much does this potential depend on climate change, policy design or socio-economic variables?
- Can we quantify the probability of occurrence? If not, can we characterise the potential in some other way that helps stakeholders decide whether to take this potential seriously, and how it compares with potential adverse consequences from alternative courses of action?

These considerations apply not just to risks related to climate change impacts but equally to risks related to responses to climate change, including adaptation and mitigation technologies, investments, practices and behaviours, and policies.

Source: (IPCC, 2010[38]) (IPCC, 2020[39])

Furthermore, the EPRS describes three possible ways of interpreting the PP in situations of scientific uncertainty (European Parliamentary Research Service, 2015[11]).[4] The first consists of classifying uncertain situations according to the *sources of uncertainty, complexity, ambiguity and ignorance* (see Figure 3.1). As also highlighted in the 2000 Communication, the PP is not intended to apply to hypothetical effects or imaginary risk and should be based on a scientific examination of the issue at hand. Nor will it apply when the desired level of protection is defined and the risk of harm can be quantified; where risks are established with certainty, the *prevention* principle as enshrined in the Treaty on the Functioning of the European Union is applicable instead (European Commission, 2000[31]).

Figure 3.1. Classification of uncertain situations according to the sources of uncertainty, complexity, ambiguity and ignorance



Source: (Stirling, 2007[40]).

The second approach discussed in the EPRS report is based on three schematic interpretations that depend on the *degree of uncertainty, obligation and stringency*:

- *First/minimal interpretation*: uncertainty does not justify inaction and warrants legislation despite the absence of complete scientific evidence concerning a particular hazard.
- *Second/median interpretation*: uncertainty justifies action and warrants legislation even if the link between cause and effect has not been fully established.
- *Third/maximal interpretation*: uncertainty necessitates legislation until the absence of hazard has been proven.

This approach disregards certain variables, such as the severity of the risks involved and the stakes at hand. These variables may, however, prove decisive when uncertainty is substantial.

A third approach relies on a *procedural interpretation* that encompasses four elements: a) potential hazards are characterised by their serious, irreversible and uncertain consequences; b) dynamic decision-making processes should be both iterative and informative to allow learning over time; c) the burden of proof is shared between the regulator and the proponent; and d) no decision is prescribed *a priori*.

Precaution as a "continuous variable"

The following section analyses precaution as a continuous variable, including its interplay with different levels of uncertainty, when applied as a regulatory approach. It starts by attempting to dispel the notion that precaution is a matter of binary choices, illustrating the importance of taking into account the (implicit) trade-offs that exist when prioritising certain risks at the expense of others. This section continues by briefly discussing the following: tools to support decision-making in the presence of trade-offs, when and how to apply the PP; frameworks and tools to determine the appropriateness of precautionary measures; iterative approaches for enhanced adaptability, as well as regulatory design for scientific uncertainty.

Regulatory choices and trade-offs

A frequent shortcoming of precautionary measures has been the narrow focus on a single target risk.

Instead, precautionary measures should select which risks are top priority and consider the potential to address affect multiple risks at the same time (Wiener, 2018[41]). Graham and Wiener call for "stepping out of the single-risk mind-set"; instead, they see a real world of multiple, interconnected risks, with regulators needing to optimise the trade-offs between them:

> *We should neither ignore uncertain risks, nor overreact; but rather seek 'risk-superior' ways of reducing those risks without worsening countervailing risks (Graham, J. and Wiener, J., 1995[42]).*

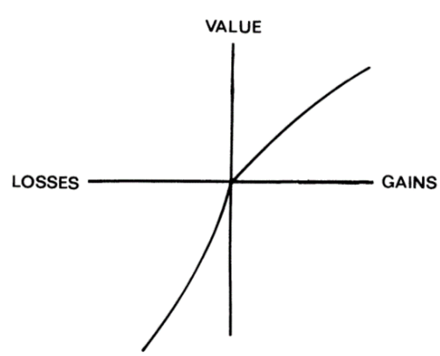
The problem of trade-offs between different risks and choices (in situations where none of the choices is zero-risk or even low-risk), is particularly central to the energy transition context. Many of the energy-related choices currently facing public opinion, policymakers and regulators in the 2020s are risk-heavy, regardless of whether the decision is "ban" or "allow", "do not use" or "use".

Typically for such scenarios, one side of the alternative has more "tangible", immediate or somewhat measurable risk (primarily safety risk, secondarily environmental risk), e.g. when considering if the use of nuclear power, large-scale wind farms, hydrogen as hydrocarbon substitute etc. is allowed (rather than remaining with existing, carbon-intensive but well-known sources). By contrast, the alternative option (i.e. *not* to use these technologies), has lower immediate and tangible risks, but makes it even more difficult to address the climate emergency. Indeed, *not* using these low-carbon technologies significantly increases the probability of catastrophic harm from climate disaster.

It is worth, here, unpacking the relative uncertainties on these two sides of the energy-source choice. Even though there is *some* uncertainty as to both the temperature and climate pathway that will eventually result from different energy choices, and the eventual harm that they will cause (IPCC, 2022[43]). In particular, each atmospheric CO2 concentration leads to probabilistic scenarios in terms of temperature increase, and, in turn, these lead to again probabilistic scenarios in terms of climate systems transformation – including a certain probability of "vicious cycle" leading to "runaway climate change", which can best be summarised as absolute, life-extinguishing disaster. Even though this particular pathway has overall a low probability, its potential impact dwarves in magnitude most (if not all) harmful impacts considered in risk-based regulation or precautionary decisions. What this means in our case is that handling the uncertainty on low-carbon energy sources negative impacts (e.g. long-term risk from nuclear energy or shorter-term risk from large-scale hydrogen use) should not be considered against a zero-risk baseline, but against the practical certainty of massive harm from climate change on every time horizon – including a non-zero probability of total disaster. Seen in this perspective, *well-understood precaution* would, in most cases, be to accept (and, of course, seek to properly manage) the risks from low-carbon energy sources in order to reduce catastrophic climate risk.

The additional difficulty, in this situation, is that the arbitrage between the two choices is not just an issue of difficult quantification – but one of perceptions and the psychological mechanisms of decision-making. There tends to be a range of additional decision-making biases at play whereby, once something has been banned, it is assumed even more strongly to be harmful (e.g. GMOs). Prospect theory, which contains the notion of loss aversion, can be useful to understand this process better. The hypothetical value function developed under prospect theory is defined by deviations from a reference point and is "normally concave for gains, commonly convex for losses, and is generally steeper for losses than for gains" (see Figure 3.2). In other words, losses generally seem larger than gains. In addition, decision-making being subject to a reference point (in this case, the ban) arguably excludes the notion of purely "neutral" decisions. Another implication is that people tend to overestimate small risks and underestimate large risks, and have difficulties properly estimating probabilities (tending to "over-weight" low probabilities in their decision-making) (Kahneman, D. and Tversky. A., 1979[44]).

Figure 3.2. Hypothetical value function under prospect theory



Source: (Kahneman, D. and Tversky. A., 1979[44]).

In addition to loss aversion, related biases that potentially affect decision-making in this context include the status quo bias/sunk cost fallacy (which may help perpetuate initial bans), confirmation bias (involving a selective, one-sided treatment of available evidence), and a biased preference for avoiding scrutiny (by not changing the initial regulatory stance).

From this perspective, the central problem is that prevailing human heuristics bias can lead decision-making to privilege a "tangible", immediate, risk of harm over the distant, incomprehensible, and unimaginable risk of catastrophic climate change — something never before encountered in our experience. In such a context, there is a pattern of the PP being misunderstood and misapplied to push towards default decisions that refuse the use of low-carbon technologies perceived as “high risk”, even when proper consideration of the two sides of the alternative may mean that the *really precautionary* decision would be “use, with appropriate caution and safeguards”. This report will later explore what such “appropriate caution and safeguards” could look like, and how more “agile” regulation could combine regulatory design and delivery to implement precaution in a more flexible, graded and regularly revised way, rather than as a definitive “yes or no”.

Wiener and others argue that precaution should not be understood as a formal binary classification but as general posture: a continuum of precaution defined by varying degrees of earliness and stringency (Wiener, 2016[45]). Here, a regulation is more precautionary the earlier it takes effect and the more stringently it restricts the suspected source of the risk. As such, every regulatory choice involves uncertain future risks and hence a trade-off between two kinds of errors (commonly referred to as Type I and Type II errors respectively):

- *False positives (Type I error)*: an initial finding of (unacceptable) harm later turns out to have been incorrect. In this case, adopting precautionary regulations can incur the cost of false positives; e.g. economic and financial losses, restricted freedoms, and any foregone health and environmental benefits of restricted technologies (Wiener and Rogers, 2002[14]).
- *False negatives (Type II error)*: an initial finding of no harm (or acceptable harm) later turns out to have been incorrect. Insufficient *ex ante* regulation can incur the harm of neglecting false negatives; e.g. health and environmental damage.

As anecdotal evidence, the Hansen and Tickner study of 88 cases identified as potential false positives (i.e. where the authorities take precautions which later prove unnecessary), concluded that only four of those cases had led to “unnecessary measures”, and that the risk of false positives was, therefore, low (Hansen and Tickner, 2013[46]).

Lemons et al argue that scientists are more interested in avoiding false positives than false negatives (Lemons, J. et al., 1997[47]). Similarly, Underwood argues that “most ecological and environmental work is designed to keep the possibility of Type I error small”, whereas the PP “dictates that Type II errors are a serious problem for environmental management, much more so than Type I errors. Thus, not detecting impacts (Type II) is not precautionary” (Underwood, 1997[48]). This distinction between Type I and Type II may, however, be less of a clear-cut case in a climate emergency context where it is not so much a question of *avoiding* health and environmental damage as of estimating the *balance* of such damage between two pathways (using, or not using, the technology under consideration).

On a related note, and in the context of assessing technological impacts, Shrader-Frechette refers to Type I and Type II errors as “industry risk” and “public risk” respectively. She outlines several factors that could explain the prevailing preference for minimising industry risk, i.e. the risk of not developing or using a technology that is actually acceptable and safe. These factors include the following: the preference “appears more consistent with scientific practice”; consistency with the standards of proof required in criminal cases which stem from the State to protect its moral legitimacy (the “need to be sure beyond a reasonable doubt that the defendant is guilty before deciding against him”); the fact that “many risk assessments and impact analyses are done by those who are closely associated with the technology being evaluated and who are therefore sympathetic to it and to those who implement it” (thus underestimating risk probabilities); and the prevalent use of Bayesian decision rules[5] based on expected utility and subjective probabilities, rather than the maximin principle (Rawls, 1971[49]). Again, this distinction and assessment may become less clear-cut in the energy transition context. First, because we have in fact “public risk” on both sides. Second, because the relative frequency of cases of “excessive” precaution or “insufficient” precaution may be less important than their impact, as a few technological choices one way or another may have massive importance to large-scale events.

Shrader-Frechette argues that there are grounds for minimising public rather than industry risk, as "neither science nor criminal law provides arguments for minimising industry, over public, risk". She evokes two sets of different arguments in favour of contending that an assessor's *prima facie* duty is to minimise the chance that an unsafe technology is implemented. The first set stresses that the dangers faced by the public "represent the kind of risk most deserving of reduction"; the second set focuses on "the public as the locus of decision-making regarding societal hazards, since laypeople typically argue for reducing public risk" (Shrader-Frechette, K. S., 1991[50]).

When considering the trade-offs at hand, Wiener stresses that reducing a *target risk* can by the same token increase a *countervailing risk*. In their seminal work, "Risk vs. Risk", Graham and Wiener acknowledged "challenges in comparing risks with diverse attributes on which people may have different perspectives (and perceptions), including probability, severity, population, uncertainty, type of impact, timing, and distributional equity", and called for full impact analysis methodologies including both countervailing harms and co-benefits (Graham, J. and Wiener, J., 1995[42]) (Wiener, 2020[51]). This warrants transparent and clear presentation of trade-offs, possible options, uncertainty, and what is (not) known — including the limitations of scientific evidence and advice in assessing risks and costs/benefits (Blanc, F. et al., 2015[52]).

As suggested by several of the authors referenced in this sub-section, the human factor remains therefore a critical one when it comes to apprehending uncertainty, risk and precaution. Decision-maker knowledge, experience and approach to risk (including appetite for it), all impact upon how the notion of precaution may be applied to the system, subject or question at hand.

Some will understand better than others the system, science, uncertainties, state of knowledge, emerging trends, nature of causation and availability, and the effectiveness of different solutions. Others may, in turn, be inclined to accept risk if doing so appears profitable, or if the costs and other negative impacts fall upon others. In a similar vein, the power structures of organisations, agencies, departments and governments etc. play an important role in shaping attitudes towards risk and precaution, as well as the associated regulatory decisions themselves. Later in this chapter, the section on Precaution, the human factor and the socio-political context provides additional insights into these and related aspects.

Tools to support decision-making in the presence of trade-offs across policy objectives

Decision-makers have several tools at their disposal when it comes to dealing with the trade-offs that are inherent to regulatory choices.

Multi-criteria analysis (MCA) methods appraise or evaluate a given course of action by taking into account the various dimensions of interest and the interplay between multiple, often contrasting, objectives, and different decision criteria and metrics (Dean, 2022[53]). MCA can be effectively applied to the "areas and sectors where single criterion–based methodologies are found ineffective, and important social and environmental impacts cannot be expressed in terms of monetary values" (Nautiyal and Goel, 2021[54]). MCA assesses one or more regulatory/policy options against a number of different objectives for which criteria have been identified. The performances of an option against the various objectives and criteria (which can be assigned different weights), are identified by scores.

A multi-criteria method is formally defined by the set of rules establishing the nature of options, objectives, criteria, scores and weights. This includes how those objectives, criteria, scores and weights are used to assess, compare, screen in/out or rank options. (See Box 3.4 for an overview of MCA's key elements).

Box 3.4. Key elements of multi-criteria analysis (MCA)

Multi-criteria analysis comprises various classes of methods, techniques and tools, with different degrees of complexity. MCA is also known as multiple-criteria decision-making (MCDM), multiple-criteria decision analysis (MCDA), multi-objective decision analysis (MODA), multiple-attribute decision-making (MADM), and multi-dimensional decision-making (MDDM).

A 1983 review identified more than 100 different MCA approaches. Despite this diversity, many of these methods share a number of common elements and exhibit a similar decision-support framework which includes the following key elements:

Option: an alternative course of action proposed to address a perceived problem and achieve an overarching end result.

Objective: an intended and specific aim against which any proposed option is being assessed. Objectives are usually clustered around different overarching appraisal and evaluation dimensions (e.g. sustainability policy problems generally include the economic, environmental and social dimensions). They can also be grouped according to their geographical scope (e.g. local, regional, national, supra-national objectives), temporal dimension, or the social groups for whom they are relevant.

Criterion: a specific measurable indicator of the performance of an option in relation to an objective that allows measuring the extent to which an option meets that objective.

Performance Score: a pure number (with no physical meaning), belonging to a given scale (e.g. a 0 to 1 scale, a 1 to 100 scale or a -5 to +5 scale) that identifies the performance of an option against a specific objective/criterion. High-performing options are ascribed high scores, whilst low-performing options score lower on the scale. Critical objectives and criteria may also be assigned some constraints in the form of specific threshold values. These place some restrictions concerning the worst acceptable performance of an option against specified criteria that can include policy targets and legal instruments, ethical standards, or scientific criteria that identifies limits to natural processes and systems.

Criterion Weight: a coefficient representing the level of importance of an objective and corresponding criterion relative to the other objectives and criteria under consideration (i.e. high-importance objectives and criteria are identified with high weights). The actual meaning of weights can change substantially according to the different MCA method employed.

Source: (Dean, 2022[53]).

The Analytic Hierarchical Process (AHP) is one example of a frequently used MCA method. A key advantage is that it reduces multi-criteria decision-making problems to "a series of smaller, self-contained analyses based on the observation that the human mind is incapable of considering simultaneously too many factors when taking a decision" (Dean, 2022[53]) (see Figure 3.3 for an example).

Figure 3.3. Example of pairwise comparisons between criteria with the AHP method

'Greenhouse Gas Reduction' is more important than 'Economic Growth'

'Greenhouse Gas Reduction' is slightly more important than 'Equity'

'Greenhouse Gas Reduction' is strongly more important than 'Strategic Fit'

Criteria	Greenhouse Gas Reduction	Economic Benefits	Equity	Strategic Fit	Geometric mean*	Normalised Weights
Greenhouse Gas Reduction	1	4	3	7	3.03	3.03/5.54 = 0.55
Economic Growth	1/4	1	1/3	3	0.71	0.71/5.54 = 0.13
Equity	1/3	3	1	5	1.50	1.50/5.54 = 0.27
Strategic Fit	1/7	1/3	1/5	1	0.31	0.31/5.54 = 0.06
				Total	5.54	1

*Geometric mean = $\sqrt[n]{x_1 x_2 \cdots x_n}$

Source: (Dean, 2022[53]).

When (and how) to apply the PP: there is no silver bullet

The PP should not be understood as a prescribed formula but rather a "flexible principle that ensures that decision makers are not ignoring problems of scientific uncertainty" and have the means to address complex and uncertain problems in an ongoing and flexible fashion (Fisher, 2007[55]). According to Persson:

> *Extra precaution may be justified when dealing with important values (such as health and environmental protection), although these are systematically downplayed by more traditional decision methods; or when we suspect that the decision might lead to irreversible and severe consequences, and where the values at stake are also irreplaceable; or when it is more important to avoid false negatives than false positives. (Persson, 2016[56]) (European Commission, 2017[36])*

The PP does not prescribe specific policy responses (Tosun, 2013[13]) or prejudge of the type of measures (e.g. bans) to be adopted, or the associated substantive requirements. Instead, the constraints it imposes aim at "identifying, characterising, and evaluating outcomes" (Kaebnick,G. E. et al, 2016[57]). Although it is generally agreed that precautions should be proportionate to the expected risk (Wiener and Rogers, 2002[14]) (European Commission, 2000[31]), the practical application of this premise is not straightforward. Garnett and Parsons formulate this precaution-uncertainty continuum as follows:

> *There is [thus] a range of uncertainty, between the lower bound of evidence required before the precautionary principle should be considered and the upper bound where the evidence reduces the uncertainty to the level where risk assessment is feasible and appropriate. Unfortunately, the positions of these bounds are unclear, and subject to variations in interpretation in practice (Garnett, K. and Parsons, D. J., 2017[58]).*

A 2016 independent review of underground coal gasification (UGC) in Scotland illustrates the relationship between precautionary measures and expected risks. In this case, a few serious incidents — especially where there were clear management failures, serious environmental impacts and an attempt to cover up or avoid monitoring / assessing those impacts — had serious consequences in terms of the approach taken to the sought permissive policy environment, thus making precaution even more likely:

> *[…] while the industry could be allowed to develop, it would be wise to consider an approach to this issue based upon a precautionary presumption whereby operation of UCG might be considered only were a series of tests applied and passed. These tests would be in relation to the practicality and safety of the full UCG life-cycle - the end-to-end planning, licensing, extraction, processing, use, closure and abandonment regime including provision for long term management, reinstatement and monitoring (Scottish Government, 2016[59]).*

In a similar vein, authors have referred to an "epistemic threshold" or minimum level of necessary evidence to invoke the PP (Crawford-Brown D. and Crawford-Brown S., 2011[60]), thereby excluding wildly hypothetical theories where there is no scientifically conceivable link between the technology and the alleged potential harm. Such cases, like unfounded theories about vaccination harm, belong more to the realm of conspiracy theories than of the precautionary principle. It has been argued that extending the application of the precautionary principle from prevention of environmental damage to protection of human health and consumer safety has changed the nature of the hazards considered and the types of evidence available. In that sense, the cases reviewed by Garnett and Parsons revealed "a trend toward requiring less evidence of harm where there was a severe threat to human health" (Garnett, K. and Parsons, D. J., 2017[58]).

A common misconception is that the PP provides an "obvious" answer to difficult policy questions. As already suggested earlier in this report, this is seldom the case in practice. The fundamental guidance for the application of the PP is the consideration of the severity of potential harm. However, different cases have seen different standards of proof being used (see for example Table 3.3).

The specific issue in the climate change context is that the severity of potential harm due to climate disruption is "off the charts". In this sense, it should be considered a game-changer in the application of the PP since, even in best-case scenarios, harm due to climate change will be of a much greater order of magnitude than the harm due to the use of most technologies under consideration. To be more specific, even in best-case scenarios, the intensity of climate-driven harm is extremely high and the scope of the impact is global. By contrast, all the interventions considered under the energy transition (apart from geoengineering technologies)[6] can generate — at worst — far more limited and localised harm. In the worst-case scenarios, runaway global warming could create feedback loops that lead to massive temperature increases, with a "Venus-type" climate trajectory being a remote-but-not-excludable possibility. If, at some point, there were serious indications that this was becoming a somewhat higher-likelihood scenario, it would automatically trump all potential harm from known and foreseeable energy and mitigation technologies. This is because — put simply — that level of global warming would mean total extinction of life on Earth.

In this context, the question that arises when considering the use of a given technology with serious potential to reduce CO2 emissions or concentration has changed. It is no longer — as in a more "classical" PP context — whether the potential harm from a technology is sufficiently severe and has sufficient credibility to warrant a ban or other severely restrictive action. Rather, the first question that should be asked is whether there is a demonstrated or sufficiently credible claim that the technology can make a real and positive contribution to decreasing or limiting the growth of carbon levels in the atmosphere, and/or if it can mitigate the harmful impacts of climate change.

If the answer is positive, then the incommensurability of climate change harm means that the next question cannot be (as it would be with "normal" risk-based regulation): "Is the harm from this new technology sufficiently severe to warrant a ban or severe restriction?" Instead, it can only be: "Is the harm sufficiently severe and well-demonstrated to justify restrictions, strict monitoring *and gradual implementation*?"

Therefore, some form of precaution could still be warranted for a technology demonstrating exceptionally high-potential harm, serious proof of this potential harm, and still little-known behaviour. However, given climate change considerations, this precaution would generally not be a total or even partial ban. Instead, it could take the form of allowing only an initial implementation, for instance through a "sandbox" regulatory approach, where the results of a pilot with limited geographical space and duration are used to inform a more permanent regulatory framework. As a result of the pilot, this framework would factor in more knowledge about the technology's behaviour in practice, as well as the effectiveness of different mitigation measures. Indeed, the 2021 OECD Recommendation for Agile Regulatory Governance to Harness Innovation (OECD, 2021[61]) seeks to help governments and regulators realise the full potential of innovation in high-uncertainty contexts, thereby enhancing its benefits for societies while addressing any risks. One important pathway to developing more agile regulatory frameworks consists of facilitating regulatory experimentation by means such as regulatory sandboxes, trials, testbeds, innovation spaces and laboratories.

Table 3.1 presents a selection of technologies with high potential in terms of CO2 reduction/abatement and/or direct climate impact (geoengineering). It examines their respective levels of potential harm, unknown factors at play and potentially applicable regulatory approaches. Information presented in the table does not prejudge the technologies' actual effectiveness, reliability, feasibility, etc. Instead, it constitutes an attempt to classify them based on their "profile" and the characteristics put forward by their proponents. The "regulatory response" column indicates the most logical approach from a PP/risk perspective, given existing knowledge and claims.

Table 3.1. Illustration of possible assessed risk profiles and regulatory responses for selected technologies with potential to enable the energy transition

Note: this table does not in any way represent an OECD recommendation on the actual classification of technologies in different risk categories, or the correct regulatory response, because there is a vast number of factors to consider, many of which may be country-specific, and considerable research work that would have to be considered. This is, based on the research done as part of preparing this report, an *illustration* of how such a classification *can* work, and what regulatory response could be appropriate for a given risk and maturity profile.

Assess maturity of technology (illustrative)	Possible examples (illustrative)	Level of potential harm[1] (illustrative)	Unknown factors/behaviour (illustrative)	Suggested regulatory response based on assessed parameters
Existing technologies	• Large-scale wind • Large-scale solar	Low to serious	Limited to moderate	Risk-based regulation
Existing technologies, new/larger-scale applications, early-stage commercialisation	• Hydrogen as energy vector in transportation etc. • New nuclear reactors, SMRs[2] • Simple / small scale CCS • Nuclear spent fuel storage	Moderate to serious	Moderate to serious	Risk-based regulation
Partly novel technologies (existing technology but substantially novel methods or use) / disputed technologies	• Hydrogen as heating/cooking gas • Reprocessing for nuclear fuel and MOX fuel • Direct Geological Repository for nuclear materials	Moderate to serious	Significant to high	Sandbox, pilot, learn lessons (and/or "reversible approach" for spent nuclear fuel, which is the current approach in FR for instance)
Novel / unproven / potentially very hazardous technologies	• Many forms of CCS,[3] particularly large-scale ones • Geoengineering[4]	High to extremely high	High to extremely high	PP applies: start with limited or tightly controlled pilots for the

Assess maturity of technology (illustrative)	Possible examples (illustrative)	Level of potential harm[1] (illustrative)	Unknown factors/behaviour (illustrative)	Suggested regulatory response based on assessed parameters
				technologies that lend themselves to it (CCS); initial bans for those that have unpredictable chain-reaction effects (geoengineering). Regular review warranted because of importance as “last defense” against runaway global warming.

1. Potential harm includes any kind of environmental, health, safety, or other harm to humans and the environment.
2. Technological development has rather moved ahead of regulatory frameworks in the case of SMRs, which emphasizes the need for a risk-based rethink of such regulations to help address climate change (NEA, 2023[62])
3. Major concerns with CCS include the risk of CO2 leakage from the reservoirs into the surrounding air or water. Furthermore, increased seismic risk could result from the built-up pressure underground.
4. Geoengineering refers to the release of particles (such as sulphur) into the atmosphere which, by reflecting solar radiation, intervene in the Earth’s climate and potentially lead to a cooling of the planet. The workings of this technology however are not fully understood and are surrounded by high levels of uncertainty and potential danger, thus making the case for the use of the precautionary principle.
Source: Authors’ own elaboration.

A last point to note is that PP-based decisions should, to the extent possible, avoid total or quasi-total bans — at least when the technologies under consideration have demonstrated major or potential beneficial impact in terms of, for instance, CO2 reduction or climate resilience.

Indeed, bans have a major negative impact on public perceptions in that they tend to consolidate and spread the belief that the technology in question is dangerous, unreliable, and must be avoided. Heuristics and decision-making bias (including issues with inertia, procrastination, mental taxation and exhaustion, and cognitive dissonance) mean that, after a number of years of a technology being banned, it is less likely that it will ever be authorised. This can be the outcome even when scientific research and the experience of other countries can demonstrate that the “potential harm” that led to the initial PP-based decision has not materialised and the technology is substantially safe. This is largely what has happened with bans (total or partial) on genetically modified organisms (GMOs), despite accumulating evidence that early worries about edited genes “crossing species” more easily, or other potential unpredictable environmental and health harms, have not been confirmed by experience. For example, a 2012 review of the previous ten years of genetically engineered (GE) crop safety research concluded that no significant hazards had been detected that were directly connected with the use of GE crops (Nicolia et al., 2013[63]). As GMOs constitute one of the important technologies for climate-change mitigation (in particular for farming), the negative impact of such a ban is bound to increase over time.

To avoid such a pitfall in the future, it seems preferable to use more targeted, scaled measures – and to communicate more cautiously and regularly about how a PP-driven regulatory framework does not prejudge the eventual conclusion regarding the technology but, on the contrary, seeks to provide a space to experiment with as few downside risks as possible, and learn lessons from such experimentation to, eventually, take a more informed regulatory decision.

Selected frameworks and tools to determine the appropriateness of precautionary measures

The EPRS has discussed a number of methods that, subject to sufficient available evidence, can be used to help determine whether it is appropriate to take precautionary measures (none of which is without shortcomings) (European Parliamentary Research Service, 2015[11]):

- *Cost-benefit analysis (CBA) incorporating Bayesian risk assessment* (although critics deem CBA inappropriate if there is uncertainty about the hazards/costs). On a related note, Gollier and Triech have proposed an interpretation of the precautionary principle within the standard Bayesian framework. In this context, they conclude that "more scientific uncertainty as to the distribution of a future risk—that is, a larger variability of beliefs—should induce society to take stronger prevention measures today" (Gollier C., and Triech, N., 2003[64]).
- *Risk trade-off analysis*, sometimes used in administrative law in the United States (and criticised for overestimating the negative effects of regulation).
- *Cost-effectiveness analysis* (to help pre-define an acceptable level of risk at the lowest cost).
- *Assessing the pros and cons of action/inaction*, including non-quantifiable (e.g. ethical) aspect.

As pointed out by the EEA, "the costs of preventive actions are usually tangible, clearly allocated and often short term, whereas the costs of failing to act are less tangible, less clearly distributed and usually longer term, posing particular problems of governance" (European Environment Agency, 2011[65]). OECD analysis suggests that the costs of inaction for society are sometimes substantial and can impact economies negatively (OECD, 2008[66]) – this is particularly true in the energy transition and climate crisis context. The OECD has thus, for instance, emphasised the importance of "regulatory agility" rather than a rigid "yes/no" approach to technological innovation (OECD, 2021[61]).

In a similar vein, the World Health Organization (WHO) has identified two patterns regarding the appraisal of potential impacts in the context of precaution and risk-based regulation. First, the *Bayesian-utilitarian* approach, entails choosing the course of action with the most favourable outcome for all involved. The outcome of an action is measured using a utility function. This approach tends to favour the option that maximises the average utility and may therefore overlook distributional issues. Second, the *Maximin* approach is based on a rule according to which, in decision-making, attention should be paid to the worst outcome that could possibly occur. The Maximin approach has also been criticised, e.g. by arguing that it would lead to "absurd decisions" and "force us to discriminate against the legitimate human needs of all individuals enjoying good fortune in any way" (Harsanyi, 1975[67]).

The WHO state that, regardless of the chosen approach, the precautionary framework should include potential or suspected hazards (uncertainty concerns not only the magnitude of the risk, but also its very existence). Despite uncertainty, all efforts must be made to maximise the use of the available scientific information. Lastly, if the risk at hand can lead to involuntary exposures and can be viewed as inequitable, then the precautionary approach and preservation of public health must be prioritised – which is linked to the essential issue of *environmental justice.* In this perspective, again, harm created by climate change is known to be particularly inequitable, affecting the poor far more than the rich (IPCC, 2022[43]), and should logically be considered in priority.

The WHO note that examination of available evidence on the exposure, hazard, or risk must be done in an interdisciplinary manner. For instance, it must look at direct, indirect, cumulative, and interactive effects. They argue that a comprehensive risk assessment must examine the gaps and uncertainty in information and find ways to reduce these where appropriate. Moreover, the determination of an appropriate course of action must be based on the scientific evidence but also on an assessment of alternative approaches and public input (Martuzzi, 2004[68]).

The IRGC's Framework for Risk Governance provides guidance for early identification and handling of risks, involving multiple stakeholders. It recommends an inclusive approach to frame, assess, evaluate, manage, and communicate important risk issues often marked by complexity, uncertainty, and ambiguity. The framework notably includes the notion of *concern assessment*, which "takes into account the values and socio-emotional issues that may be associated with the risks" and "explicitly recognises that people's decisions about how to handle risks are influenced by their past experience, their perception as well as their perhaps more emotional and value-based concerns" (IRGC, 2017[69]). Further details on this framework are provided in Box 3.5.

Box 3.5. The IRGC's Framework for Risk Governance

The IRGC's Framework encompasses the following four interlinked elements, as well as three cross-cutting aspects:

1. Pre-assessment – Identification and framing

- Leads to framing the risk, early warning, and preparations for handling it.
- Involves relevant actors and stakeholder groups, so as to capture the various perspectives on the risk, its associated opportunities, and potential strategies for addressing it.

2. Appraisal – Assessing both the technical and perceived causes and consequences of the risk

- Develops and synthesises the knowledge base for the decision on whether or not a risk should be taken and/or managed.
- If so, identifies and selects what options may be available for preventing, mitigating, adapting to, or sharing the risk.

3. Characterisation and evaluation – Making a judgment about the risk and the need to manage it. This comprises:

- Process of comparing the outcome of risk appraisal (risk and concern assessment) with specific criteria.
- Determines the significance and acceptability of the risk.
- Prepares decisions.

4. Management – Deciding on and implementing risk management options

- Designs and implements the actions and remedies required to avoid, reduce (prevent, adapt, mitigate), transfer or retain the risks.

Cross-cutting aspects: Communicating, engaging with stakeholders, considering the context

- Crucial role of open, transparent, and inclusive communication.
- Importance of engaging stakeholders to both assess and manage risks.
- The need to deal with risk in a way that fully accounts for the societal context of both the risk and the decision that will be taken.

Source: (IRGC, n.d.[70]).

Iterative approaches to risk and regulation for enhanced adaptability

It should be borne in mind that, to be truly meaningful, any risk/regulatory analysis in the context of precaution will need to be conducted *iteratively*; e.g. discussion by Gollier and Treich (2003), Farrow (2004), and Hansson (2016) around the dynamic aspects of decision-making and the fact that learning improves scientific knowledge over time (Centre for Transport Studies, 2018[71]). Indeed, robust and iterative assessment can incrementally reduce uncertainty surrounding potential outcomes and their probabilities (Kaebnick,G. E. et al, 2016[57]).

An iterative process flow is all the more useful since the relation between the scientific level of knowledge and the possible hazards is of central importance (Martuzzi, 2004[68]). Situations with low probability or uncertainty of the potential dangers should be treated differently in the analysis from situations where there is adequate scientific evidence (Centre for Transport Studies, 2018[71]). As stated in the European Commission's communication on the PP, precautionary measures may have to be modified or abolished by a particular deadline, considering new evidence. However, this is not always linked to the time factor, but to the development of scientific knowledge (European Commission, 2000[31]). This iterative, evolving approach requires knowledge sharing as well as institutional development to improve transparency, apply new scientific tools and assess alternatives (Martuzzi, 2004[68]). It can also encourage more dynamic, reflective and critical relationships between policymakers, scientific advisers and wider stakeholders (Stirling, 2003).

The relevance of iterative approaches can be illustrated through the proposal for creating shared data repositories for the regulatory governance of robotics innovation (see Box 3.6). This proposal also raises the question of the potential role of AI-based and data mining solutions in reducing uncertainty. They may for example serve to refine assessments of hazard and risk, as well as to review and revise regulatory standards and practices accordingly. While promising, such approaches need to be assessed and applied carefully, the nature of underlying data and the applicable frameworks being essential parameters in that context.

Box 3.6. Regulatory governance model for robot technology innovation

Fosch-Villaronga and Heldeweg propose a future regulatory governance model for robot technology innovation.

This model builds upon a process that commences with technological advancement, that is later passed through a precautionary and legal/ethical assessment and ends with a go/no go decision (depending on the assessment). Then, the process moves to considering the possibility of modifying existing regulations and considering regulatory impacts upon future developments in robot technology. According to the authors, impact assessments in the legal domain are currently used merely as a way to show a roboticist is compliant with the legal framework, and the law is not updated with new advancements in technology.

Therefore, the authors propose the creation of Shared Data Repositories (SDRs): databases of robot impact assessments and related legislation collected over time and across projects of robot development. They argue that this mechanism of data collection for regulatory purposes can inform regulatory strategies and help "match" emerging technologies to regulation and vice versa.

Source: (Fosch-Villaronga, E. and Heldeweg, M., 2018[72]).

Regulatory design for scientific uncertainty

Jones examines a variety of regulatory design approaches to scientific uncertainty by looking at various regulatory design tools. She concludes that these approaches are often incorporated into legislation in various combinations, rather than occurring in isolation. The seven approaches identified are: 1) acknowledgement of scientific uncertainty; 2) burden shifting approach; 3) "sound science" approach; 4) consequences approach; 5) consensus approach; 6) estimation approach, and 7) adaptive management approach (Jones, 2007[73]).

Jones suggests that the development of a single approach to address regulatory scientific uncertainty is unrealistic, which is why the PP ends up being understood and applied in a number of different ways. Due to the complexity of regulatory conditions and societal factors that environmental regulation seeks to address, a diverse range of approaches for managing scientific uncertainty in a regulatory context is needed instead. Rather than portraying precaution as a regulatory design solution for addressing scientific uncertainty, the author argues that precaution merely plays a role alongside a range of regulatory approaches or tools. Table 3.2 presents the advantages and disadvantages of each the seven approaches identified by Jones' work, as well as the various circumstances that favour the adoption of a particular regulatory approach.

Table 3.2. Seven regulatory-design strategies for scientific uncertainty

Regulatory strategy	Advantages	Disadvantages	Suggested circumstances when useful
Acknowledgement of uncertainty	Invites reflection on unknowns.	Acknowledgement without any action maintains status quo thereby permitting the continuation of any currently harmful activity.	All contexts where scientific information is required for decisions.
Burden shifting	Protective action without delay.	Potentially costly errors if protective action is subsequently found to be unnecessary.	Potentially serious and especially irreversible harms.
Sound science	High levels of scientific information available for decision maker.	Slow and expensive. Potential for interminable argument over what is "rigorous" science risking paralysis of decision-making.	Big budget available for research. Long timeframe permits research.
Consequences	If sensitive to perceptions of catastrophic harm, may provide "early warning".	If action limited to the emergence of a "crisis" situation, then such action may be too late.	Useful where severe environmental consequences considered likely.
Consensus	Potentially more likely to be voluntarily adopted and complied with by industry.	If a compromise is made, then may not provide the most scientifically rigorous method.	High levels of disagreement about the choice of alternative scientific methodologies.
Estimation and avoidance	Potentially rapid, inexpensive, and broadly applicable. Low administrative burden.	Not sensitive to locality and specific circumstances. May inadvertently authorise negative impacts on localities.	Useful when many entities are to be regulated. Probably only feasible if consequences not predicted to be severe and/or there are low levels of scientific uncertainty.
Adaptive management	Logical appeal permitting incremental progress. Potentially an efficient use of research resources.	Risk of impact from "experimental" approval. Administrative costs of on-going regulatory oversight.	Useful for the trial of novel activities provided low environmental harm is likely. Research resources also need to be available.

Source: (Jones, 2007[73]).

Analysis and categorisation of selected PP applications

Several authors have set out to examine the variety of interpretations adopted in the application of the PP in regulatory decisions and court judgements. This section presents a number of examples focusing primarily on the EU context and illustrates the difficulties that relevant institutions often face in applying the PP consistently.

A central criterion used in existing literature refers to the *strength* of application of the PP. Garnett and Parsons, for instance, establish three main strength levels (weak, moderate and strong) based on the following attributes: severity of potential harm prompting precautionary action; degree of epistemic uncertainty/quality of evidence prompting precautionary action; and nature of measures taken and provisions for review (Garnett, K. and Parsons, D. J., 2017[58]). The spectrum of weak to strong refers to the standard of scientific proof required to invoke the principle: weak requiring a higher standard than moderate, with strong requiring the lowest standard of proof.

According to the Court of Justice of the EU, "the precautionary principle can be defined as a general principle of Community law requiring the competent authorities to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests."[7] According to the findings of the EU project *REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders* (RECIPES) (Vos and De Smedt, 2020[12]), the criteria to perform a proper risk assessment or cost-benefit analysis are not consequently checked by the Court (see examples in Box 3.7). However, it is highlighted that the Court is not bound by the guidance laid down in the Commission's Communication on the precautionary principle.

Box 3.7. ECJ cases analysed in the RECIPES project

One of the most complex ECJ cases involving the use of the PP was the **Pfizer case**[1] (and the linked **Alpharma case**[2]).

The case arose from a 1999 EU regulation banning antibiotic additives in animal feed, on the basis that bacterial resistance to antibiotics could be transferred to humans. This antibiotic "transfer link" was challenged by Pfizer Animal Health and Alpharma, who stated that the ban was based on a zero-risk approach, instead of a thorough risk assessment. In its conclusion, the Court upheld an interpretation of the PP that can be inconsistent with the Communication's evidence-based approach. It invoked a strict reverse burden of proof in its ruling, stating that the company was unable to prove conclusively that there was no link between the use of an antibiotic as an additive in animal feed and the development of antibiotic resistance in humans. The application of the PP in this case proved useful in preventing irreversible harm on a significant scale.

In the **Afton case**,[3] the Commission did not conduct a risk assessment to determine the negative impact of methylcyclopentadienyl manganese tricarbonyl (MMT) on pollution abatement techniques. However, the Court considered the proportionate character of restrictions demonstrating that the Commission had struck a careful balance between the interests of the consumer and those of traders.[4]

In the **Bayer CropScience case**,[5] the Court accepted expert consultations as sufficient as a risk assessment and it decided the restriction on the uses of clothiandin, imidacloprid and thiamethoxam.[6]

In the **Paraquat[7] and Gowan[8] cases,** the Court has supported the use of the PP to ban substances in the absence of full scientific evidence.

1. Case T-13/99, Pfizer Animal Health v. Council of the European Union, (2002).
2. Case T-70/99, Alpharma inv.v Council of the European Union (2002).

3. Case C-343/09 Afton Chemical Limited v Secretary of State for Transport (2010).
4. Vos E. and Smedt K., RECIPES, WP1 Report: Taking stock as a basis for the effect of the precautionary principle since 2000 (2020).
5. Case T-429/13 and T-451/13 Bayer CropScience AG and Others v European Commission.
6. Vos E. and Smedt K., RECIPES, WP1 Report: Taking stock as a basis for the effect of the precautionary principle since 2000 (2020).
7. Case T-229/04, Sweden v Commission (2007).
8. Case C-79/09, Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute (2010).

Source: (Vos and De Smedt, 2020[12]).

Garnett and Parsons (Garnett, K. and Parsons, D. J., 2017[58]) have also investigated how the PP has been applied in EU regulatory decisions and court judgments. In most cases, their review pointed to a "weak" application of the PP, where a high standard of scientific proof needed to be established before invoking the principle. More precisely, in cases regarding food safety and public health, the Court required a high standard of proof for invoking the PP by setting out requirements for strong scientific evidence, a cost-benefit analysis, and some consideration of the effectiveness of the measures. The authors notably highlight the examples below:

- In the case Commission v. Kingdom of Netherlands,[8] the Commission challenged the interpretation of the precautionary principle and suggested that a high standard of proof was needed to impose restrictions on the sale of the vitamin-fortified products. The Commission suggested that such restrictions constituted unjustified obstacles to intra-Community trade and required credible evidence of the threat of serious harm. The Court ruled against the Dutch government, requiring high standards of proof.
- In the case United Kingdom v. Commission,[9] the Court proceeded to a moderate-to-strong application of the PP. The Commission had imposed stringent precautionary measures by banning the movement of animals, meat and derived products that had possibly been exposed to bovine spongiform encephalopathy (BSE). Despite the lack of definitive evidence, it was argued that the potential impact on human health warranted a high level of protection; protecting public health and the maintaining public trust in European beef were set as a priority over the effect on trade and U.K. agriculture.

This last case is insightful on several accounts (Blanc, F., Ottimofiore, G. and Macrae, D., 2015[74]): a) the initial decision could be described as a "generally sound" application of the PP (potential risk was very severe even though there was uncertainty on whether it would materialise at its full potential); b) the intervention has contributed to a very risk-averse regulatory regime in relation to animal health that *may be* appropriate but *may also not be* completely proportionate, and c) there has been insufficient subsequent review and *ex post* evaluation of the situation and, as a result, no actual reassessment. (This, despite the fact that eventual harm from bovine spongiform encephalopathy (BSE) was relatively limited: slightly above 200 cases worldwide reported as of 2014). Such a situation impedes adaptive learning and somehow departs from the notion that PP application is a *precautionary measure* that *should be reviewed regularly* – and not an irrevocable final decision.

In addition to the court cases above, the authors refer to European Commission Decision 1999/832/EC[10] as an example of a weak-to-moderate application of the PP. This decision approved a proposal by the Dutch government to establish more restrictive regulations on the use of creosote. The Netherlands' proposal was based on new scientific evidence and so the Commission approved the national provisions because a potential health risk was substantiated by credible evidence of harm.

Table 3.3 below displays the authors' conclusions regarding the strength of application of the PP in selected EU Regulatory Decisions and Court Judgments.

Table 3.3. Strength of Application of the Precautionary Principle: Examples of EU Regulatory Decisions and Court Judgments

Case	Subject(s) of protection	Severity of potential harm	Conditions for precautionary action: standard of proof	Nature of regulatory action	Strength of application
United Kingdom v. Commission: C-180/96 (BSE)	Human health	Severe	Relatively low-to-moderate	Product ban upheld; hazard considered "sufficiently severe" despite uncertainty about the casual link	Moderate-to-strong
Commission Decision 1999/832/EC (Netherlands, creosote)	Environment/human health	Severe-to-moderate	High	Product ban upheld; "credible evidence" of a threat of harm where local circumstances warrant precautionary action	Weak-to-moderate
Commission Decision 2003/653/EC (Austria, GMOs)	Environment/human health	Moderate-to-low	High	Product ban rejected; insufficient evidence around a "local or geographic-specific" risk of potentially "dangerous effects"	Weak
Council Decision 2009/121/EC (antimicrobials)	Human health/environment	Low	High	Product ban rejected; lack of sufficient evidence around "likelihood of occurrence and severity of consequences"	Weak
Commission v. Denmark: C-192/01 (fruit juice)	Human health	Low	High	Product ban rejected; insufficient scientific data to substantiate "real" threat to public health	Weak
Germany v. Commission: C-512/99 (mineral wool)	Human health/consumer safety	Low	High	Reclassification of carcinogenic potential of product rejected; lack of definitive scientific position on potential for harm	Weak
Commission v. Kingdom of the Netherlands C-41/02 (breakfast cereal)	Human health	Low	High	Product ban rejected; insufficient scientific data to substantiate "real" threat to public health	Weak

Source: (Garnett, K. and Parsons, D. J., 2017[58]).

In contrast with the predominantly "weak" interpretations of the PP inventoried by Garnett and Parsons, in those judgments concerning the transfer of resistance to antibiotics from animals to humans and the authorisation of medicines for human use,[11] the Court found that the competent public authorities could be obliged to actively adopt precautionary measures.

In a similar vein, the Court has often applied a broad interpretation of the PP to nature conservation. It considered, for example, that a project "may be granted authorisation only on the condition that the competent national authorities are convinced that it will not adversely affect the integrity of the site concerned".[12] Moreover, in a judgment concerning wastewater treatment,[13] the Court considered that a degree of probable causality was sufficient to require Member States to adopt protection measures. More recently in 2021, in Case C-499/18 P Bayer CropScience AG and Others v European Commission, the Court restated that there is a "low bar" on the initiation of a review, and a "high bar" on challenging restrictive measures taken as a result of such a review regarding the PP.

Although the PP is not explicitly mentioned in the agreements of the World Trade Organization (WTO), its Appellate Body, which handles disputes between the WTO's Member States, has on several occasions reached decisions that could be construed as admitting recourse to that principle. In a case concerning EU measures prohibiting the import of meat treated with growth hormones,[14] the Appellate Body pointed out that the PP did indeed find reflection in a specific provision of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, and that Members had the right "to establish their own appropriate level of sanitary protection, which may be higher than that implied in existing international standards, guidelines and recommendations". In a case concerning US measures prohibiting the import of shrimp caught in nets that do not allow sea turtles to escape,[15] the Appellate Body defined sea turtles as an "exhaustible natural resource" that warranted restrictive measures. In a dispute concerning a French ban on asbestos and products containing asbestos,[16] the Appellate Body confirmed that a country may take measures to protect human health from serious risks on the basis of a divergent opinion coming from qualified and respected sources.

Precaution, the human factor and the socio-political context

Precautionary approaches have sometimes been characterised as part of public authorities' quest for legitimacy and credibility (Lofstedt, 2004[75]). Many authors have expressed concerns that superfluous precautionary measures could be taken on the basis of unfounded public fears (European Parliamentary Research Service, 2015[11]), and some sociologists view the PP as a reaction to fears driven by situations of risk and uncertainty (G. Bronner and E. Géhin, 2010[76]). In addition, precautionary action may sometimes be the result of knee-jerk reactions in the wake of calamities. Conversely, misperceptions may cause decision makers to neglect risks associated with rare catastrophic events. In the context of precautionary approaches to technology and innovation (which is further discussed in the next chapter), it has been argued that, while "risk panics" might explain some precautionary policy positions ("grounded on emotion or fear of the unknown rather than reason"), the opposite emotional response to new technologies (an "innovation thrill") should also be counteracted (Kaebnick,G. E. et al, 2016[57]).

More generally, while academic research and debate have traditionally emphasised the importance of scientific evidence for an appropriate application of the PP, the political economy and a number of, socio-political and psychological elements arguably play an equally important role in shaping precautionary decision-making in the face of uncertainty. A traditional political science assumption is that politicians are risk averse in the face of electoral pressures. However, regulators may swing back and forth between risk taking and risk aversion dependent on contingent events and the outcomes of past decisions. Moreover, the degree of risk aversion may depend on the distributional politics of particular issues across the population, as well as the mobilisation and organisation of professional, public and private interest groups. Referring to the EU law context, Heyvaert has defined the PP's main function as providing "a rationale and justification for administrative discretion". According to the author, as a legal principle, it has not played a significant role in compelling decision-making by relevant EU institutions (Heyvaert, 2006[77]).

Indeed, academic research presented in the previous chapter, including by both Wiener and Li, seems to suggest that the PP is applied with a high degree of discretion. It has been pointed out that, in practice, the application of precautionary regulatory measures may be driven by interests and circumstantial issues rather than objectives that maximise social wellbeing (A. Dembe, Raffensperger, C., & Tickner, J., 2004[78]). Similarly, the decision-making context around the PP is often heavily politicised and not necessarily based on a careful assessment of the pros and cons of applying the principle:

> *Discussions on the precautionary principle quickly turn toxic. Critics argue that it gives policymakers and regulators a motive for far-reaching and intrusive regulatory interventions, in which the costs of regulation outweigh its benefits (Majone, 2016). Advocates argue that it is the most sensible approach to regulating possible harm in the absence of sound knowledge of the possible occurrence or impact of the risk (Taylor, 2018) (van der Heijden, 2019[20]).*

The role of public perception and cognitive bias

Governments are created and run by humans, who can experience the same behavioural biases and barriers as individuals in society. A 2021 OECD research paper (Drummond, Shephard and Trnka, 2021[79]) maps the ways in which barriers and biases can affect the institutions, processes and tools of regulatory governance. The paper focuses on regulatory oversight bodies and regulatory management tools and provides a number of recommendations to better account for those factors in decision-making.

In the area of risk regulation specifically, Trappenburg has argued that, "in modern Western societies the societal emphasis on risk and the minimisation of it frequently leads to a call for increasing risk regulation". She refers to this mechanism as "the vicious circle of risk regulation", with overregulation and breaches of individual privacy as potential negative effects (Trappenburg and Schiffelers, 2012[80]). In a similar vein, Trappenbrug and authors including Van Tol and Blanc et al have referred to the notion of "risk regulation reflex" to characterise situations in which decisions may be adopted too fast, with little to no analysis or regard for alternatives, and underpinned by unrealistic expectations. Under such circumstances, excessive demands for absolute safety and protection may result in regulations that go beyond the needed and reasonable (Blanc, F., Ottimofiore, G. and Macrae, D., 2015[74]), with increased risk aversion potentially leading to regulatory inflation.

The Dutch Risk and Responsibility programme has extensively investigated the risk regulation reflex. It has notably studied the attitudes of citizens towards safety risks. One important conclusion from their work is that:

> *When analysing citizens' perceptions of risk it is more important to question whether a risk is morally acceptable rather than focusing on the exact size of the risk. Technocratic argumentation only strengthens the moral need to reduce risks, as it disconnects risks from the moral reasons why we perhaps ought to take them. And, only the latter contains the key to achieve risk acceptance by the public (Van Tol, 2016[81]).*

To prevent the risk regulation reflex from resulting in suboptimal policy decisions, there is, according to the authors, a strong case for combining precaution and proportionality[17] when dealing with uncertainty. It is also important to bear in mind that a track record of discounting risks when uncertainty is significant, and subsequent significant harm occurs, can lead to credibility and legitimacy loss, and thus build ground for support for risk regulation reflex-based decisions further down the line ("snowball effect").

Such issues have been observed in the context of vaccine regulation, including during the COVID-19 pandemic. Namely, some authors pointed to a potential "misapplication" of the PP because of blood clot fears associated with the use of COVID vaccines. More precisely, it was argued that, rather than avoiding risk, the PP had instead moved countries away from one risk (blood clots) towards another (lower vaccine coverage) of which the negative impact could be much larger:

> *Plans for COVID-19 vaccine safety monitoring until now have been based around rigorous scientific evaluation of safety signals, careful communications to ensure vaccine hesitancy is not increased, and ensuring that signals are investigated to examine if any risk requires regulatory action. Because potential safety signals arise often in vaccine and drug safety, with many being false signals, the precautionary principle doesn't fit with such plans (Cox, 2021[82]).*

Similar arguments or concerns have applied for other vaccines. For instance, claims of side effects have led to the suspension or delay in the introduction of the human papillomavirus (HPV) vaccine. As an example, due to reported side effects, Japan suspended the active recommendations of the HPV vaccine in June 2013. The active recommendation of the vaccine has been resumed since April 2022 (Haruyama, R. et al., 2022[83]), based on emerging scientific estimates that suspension would likely result in almost 11,000 deaths from cervical cancer over the next 50 years, if not reversed (Reuters, 2020[84]).

In a similar vein, Coglianese and Carrigan identify psychological impulses and political pressures as factors that lead politicians to "rush to judgment" and neglect the multiple trade-offs that are inherent in regulatory decisions (Carrigan and Coglianese, 2012[85]). According to the authors, the complete elimination of all harms, including from low-probability catastrophic events, is not possible without stopping altogether the very activities that give rise to these harmful events. Thus, the very choice to regulate, instead of banning, a certain economic activity implicitly rejects the goal of eliminating a risk. For instance, authorities regulate restaurants to prevent them from operating in an unsanitary manner but do not shut them down. Likewise, authorities regulate to ensure that potentially high risk industries follow safety protocols, but normally do not seek to shut down all of them. Hence, when laws allow activities to go forward that have a probability of catastrophic harmoccurring, it is difficult to decide how unpredictable the catastrophic event is. For instance, when an oil spill occurs, it may not be possible to ascertain whether it is due to the failure of the relevant regulator to oversee sufficiently or, conversely, an inevitable consequence of trying to balance oil exploration with environmental concerns (Coglianese, C. (Ed.), 2012[86]).

Moreover, the authors argue that decisions may be driven by cognitive biases rather than well-grounded evidence. For example, the "availability heuristic" tends to focus attention on the worst-case outcomes and may make them appear to be more frequent or more likely than they actually are. Factors including media treatment of potential calamities may increase the pressure on politicians to act fast: "politicians decide on quick legislative action to respond to calamities as voters tend to focus less on the impact of the law than on the enactment of the law itself." (Coglianese, C. (Ed.), 2012[86]) Consequently, solutions that are either unrelated to the cause of the disaster or highly inefficient/ineffective can end up being adopted.

The authors contend that regulation adopted by invoking the PP often originates from rushed judgements and a lack of complete trade-off analysis, and they conclude that "rigorous academic research needs to play a larger role in decision-making to avoid hasty reactions under political pressure." The 2010 BP oil spill is presented as an example. This catastrophe led to changes in the underlying regulatory systems, including the creation of new agencies and the adoption of new laws in the US. The US Department of the Interior imposed a temporary moratorium on offshore drilling, closed its Minerals Management Service and transferred regulatory authority to a new Bureau of Ocean Energy Management, Regulation, and Enforcement. However, the authors find that, "although the sweeping reforms were predictable, they were neither necessary nor comprehensive, as they lacked better empirical grounding."

Sunstein has developed extensive analytical work on the role of cognitive biases in the application of the PP. He argues that people are far more willing to tolerate familiar risks than unfamiliar ones, even if they are statistically equivalent. In this context, he adds the PP often seems helpful because decision makers often focus on the "target" risk, and not on the systemic, risk-related effects of precautionary approaches or the risk-related consequences of risk reduction. Box 3.8 provides further detail including examples.

Box 3.8. Behavioural insights into the application of the PP: the role of cognitive biases

Sunstein argues that a problem with the PP is that "it often offers little to no guidance on its application" even though the regulations that apply the PP for its risk assessment often define very specific benchmarks.

For instance, in the United States in 1993, the government was unsure which benchmark to use in arsenic regulation. The government proposed a limit of 50 parts per billion litres. This would cost around 200 million USD annually and prevent up to six of the hundred lives lost each year. The proposed limit was introduced by invoking the PP; however, the PP did not provide any actual guidance as to what limit of arsenic would be the most effective.

Another example provided by Sunstein regards global warming. He claims that even though "scientists have not reached a uniform accord on the dangers of global warming", the Kyoto Protocol adopted in 1997 did require most industrialised nations to reduce greenhouse gas emissions to 92%-94% of 1990 levels.[1] Furthermore, the very high risk perception of risks around nuclear energy, far higher than scientifically assessed risks (Slovic, 1987[87]) (Slovic and Peters, 2006[88]) often results in regulations making its use impossible or extremely difficult. However, according to the Intergovernmental Panel on Climate Change (IPCC) and International Energy Agency (IEA), if a nation does not rely on nuclear power, it is likely to rely instead on fossil fuels such as coal-fired power plants. The impact of this shift is not accounted for in some of the assessments of measures claiming to apply the PP.

In a similar vein, according to the author, a highly precautionary approach to pharmaceutical regulation regarding the introduction of new medicine onto the market, can cause a “drug lag”. While precaution may help protect people from any harms associated with new inadequately tested drugs, it may also prevent people from enjoying the potential benefits of those drugs. Accordingly, Sunstein concludes that “more stringent regulation may not always imply the most precautionary approach.” In line with this, Sunstein argues that those who invoked the PP to seek regulation against human cloning neglect the possibility that, without therapeutic cloning, many people may die. He also finds that banning the genetic modification of food might result in numerous deaths, as genetic modification holds the promise of producing food that is both cheaper and healthier.

Based on these examples, Sunstein also argues that regulating more stringently is not always the most precautionary approach.[2]

1. Sunstein made this argument in 2002. Its validity has arguably diminished since.
2. It is important to note that further research on the debate on the genetic modification of food has developed; therefore, this argument is also not as applicable today.

Source: (Sunstein, 2002[89]).

(Bellaby, P. and Clark, A., 2016[90]) acknowledge that the circumstances, beliefs, geopolitical situation, and attitude of a population determine its awareness and acceptance of potential hazards. In their article on the role of public perception on risk management and the PP, they outline some of the uncertainties about the hazards of hydrogen as energy carrier and examine qualitative evidence from deliberative Citizens' Panels in England and Wales (see Box 3.9 for further details).

Box 3.9. Ambiguity, complexity and uncertainty surrounding the hazards of low-carbon hydrogen and public views of emergent risks

PP application to the use of low-carbon hydrogen energy

Increasing attention is being paid to the possibility of using green hydrogen energy as a partial replacement for fossil fuels. In the literature on the risks associated with hydrogen, certain authors assert that the risks of hydrogen use are well known, whereas others emphasise that the properties of hydrogen pose special and partly (at this point) unpredictable risks in terms of certain specific safety aspects. Risks, hazards, and time horizons of hydrogen production may be additional elements of consideration. In terms of the International Risk Governance Council (IRGC) framework on risk governance, hydrogen energy is simultaneously an emergent and uncertain risk.

Based on available evidence on hydrogen's behaviour, it could however be argued that most use cases would not warrant the application of the PP and may be allowed to be developed in a conventional risk-based regulatory environment. Indeed, there is no uncertainty on large-scale, longer-term environmental impacts of hydrogen, for instance – but only specific, limited uncertainty on the probability of certain safety outcomes in particular situations and scenarios of use. This does not mean that the PP is applicable, but rather that these specific situations and scenarios need to be addressed through appropriate risk-management measures, and additional knowledge gradually grown through piloting, so that the regulatory framework can be adjusted and improved over time (OECD, 2021[61]).

The fact that some of the risks associated with the use of hydrogen energy are not perfectly known or quantified yet is not, indeed, sufficient to justify the use the PP – no risks are ever perfectly known or quantified. As the industry, research, and regulation develop, there will be opportunities to for further refining the regulatory framework as more evidence becomes available. To be sure, a number of specific applications of hydrogen energy (e.g. in the home) do warrant more precaution due to higher uncertainty and potential harm. However, even in these cases, precaution should not revolve around a yes-or-no question but rather rely on stepwise, scalable experimental approaches.

Stakeholder perception of risks associated with hydrogen and the importance of public deliberation

The IRGC model suggests the use of the PP in risk assessment and management. However, in terms of alternative scenarios on the possible development of hydrogen applications, there is also uncertainty reflecting different stakeholder interests and values, and about which regulatory regimes are appropriate. Hence, the IRGC model recommends deliberative methods and participatory discourse to address some of these issues. In line with the notion of concern assessment, the framework includes consultation, participation, and public engagement, which is deemed necessary to build more transparent and inclusive systems of risk governance. Indeed, without undertaking such public engagement to improve public knowledge and awareness about hydrogen technologies, there is a risk of projects not getting social licence.

As part of a wider series of case-studies about hydrogen in England and Wales, the authors carried out two all-day meetings with citizens' panels in Teesside (Middlesbrough, in Northeast England) and Wales (Llanelli, South Wales) during 2008–2009. These two areas were selected as they already had some hydrogen production plants, as well as demonstration projects for hydrogen energy technologies. During the two meetings, members of the public were provided with basic information about hydrogen, including alternative scenarios created by a wider use of hydrogen. The authors identified several knowledge gaps about the nature and properties of hydrogen as an energy carrier, and about the required regulatory codes and standards to deal with anticipated risks. The authors found that "though the final deliberations by this panel suggested some positive interest in hydrogen use as energy carrier, this was conditional upon people receiving more detailed information and reassurance about measures to regulate safety in the entire system of production, storage, and distribution." This experience illustrates that public perception of risks associated with hydrogen can depend on the knowledge and information made available.

The evidence outlined in the article shows the importance of public deliberation about the possible hazards and risk governance of future applications of hydrogen. While the authors acknowledge that conducting deliberative citizens' panels does not solve the problem of achieving public acceptance of emergent risks, the IRGC framework differentiates important dimensions of risks, which may benefit from wider citizen involvement and debate. For instance, citizen involvement can help ensure more transparent and inclusive risk governance, which is recommended in situations where there is a high degree of uncertainty about framing the risk problem.

Source: Authors' analysis, (Bellaby, P. and Clark, A., 2016[90]) (Robert Flynn, Miriam Ricci & Paul Bellaby, 2012[91]).

Available evidence points to the importance of inclusion and transparency in risk management and communication. Unconditional pro-transparency approaches may however prove counter-productive by undermining trust and leading to risk-regulation-reflex situations. For instance, Bouder and Löfstedt have highlighted the "ambivalent" relationship between transparency and risk communication; they distinguish between "fishbowl" transparency (full disclosure of information without explanation or contextualisation), and reasoned or managed transparency, which "is about keeping sight of the impact of openness and disclosure on the wider audience" (Löfstedt, R. and Bouder, F., 2014[92]). They advocate the latter, which implies taking the science of risk communication into account. In a similar vein, O'Neill has argued that current "enthusiasm for ever more complete openness and transparency has done little to build or restore public trust", as "the very technologies that spread information so easily and efficiently are every bit as good at spreading misinformation and disinformation" (O'Neill, 2002[93]).

Complementary insights regarding the role of perception and sociological phenomena can be found in Wiener's *The Tragedy of the Uncommons* (Wiener, 2016[94]) (Wiener, 2021[95]). This piece of research explores the factors that can help society to learn through experience and collective mobilisation. The *tragedy* stems from the mismanagement and misperception of rare catastrophic events. The author identifies this to be caused by psychological unavailability, mass numbering (the larger the number of fatalities, the fewer people will care about the lost lives), and under-deterrence (owing to weak legal mechanisms). It concludes that expert assessment is needed to overcome the public neglect of uncommon risks. While risk assessments often use policy learning from experience and experimentation, rare one-time occurrences do not offer such opportunities for learning. According to the author, foresight, anticipation and precaution are thus particularly important under such circumstances, as is the careful analysis of potential risk-risk trade-offs (preventing one catastrophe might "invite" another).

In the specific context of climate change and the energy transition, there are a number of examples of debatable PP-driven regulatory decisions that have arguably failed to consider the above-mentioned risk-risk trade-offs. As discussed earlier in this chapter (see When (and how) to apply the PP: there is no silver bullet), nuclear energy and GMOs have strong potential, respectively, for limiting/reducing CO2 emissions/concentrations and enabling climate change adaptation in agriculture. Both these technologies have, however, been subject to particularly stringent regulatory approaches invoking the PP. These include outright abandonment in the case of nuclear energy, and a de facto EU moratorium on new GM crops from 1999 to 2004 that "steered the development of an extremely strict and expensive regulatory framework concerning the import and cultivation of GM crops" (Blancke et al., 2015[96]).

While there are a number of factors at play, perception and cognitive biases have arguably played an important role in the process leading up to such regulatory decisions. They have also contributed to preventing subsequent reassessment of the decisions based on newly available evidence and increased awareness of the countervailing risks (e.g. from a climate perspective). A 2015 study, for instance, explains the apparent discrepancy between public opinion and scientific evidence in terms of particular intuitions and emotions that make the mind highly susceptible to negative representations of GMOs. Psychological essentialism, an example of this, has been argued to play a role in public attitudes towards GMOs. Because of it, people are typically more opposed to GM applications that involve the transfer of DNA between two different species ("transgenic") than within the same species ("cisgenic") (Blancke et al., 2015[96]).

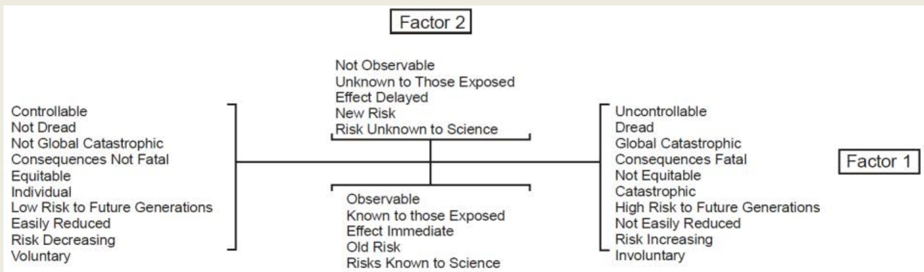
Regarding nuclear energy, a 2021 study examines the role of public perception as a constraint to the deployment of energy technologies. This study attempts to "disentangle public opposition due to the dread of nuclear power from opposition stemming from its actuarial risk". Its results suggest that dread about nuclear power leads respondents to choose 40% less nuclear generation in 2050 than they would have chosen in the absence of this dread. Moreover, the authors indicate that "these methods could apply to other technologies, such as carbon storage, where there may be gaps between actuarial and perceived risks" (Abdulla et al., 2019[97]). This gap in risk perceptions has been evidenced many times by social scientists and affects not only nuclear energy – but is particularly salient in this case (Slovic, 1986[98]) (Slovic, 1987[87]) (Slovic and Peters, 2006[88]) (see Box 3.10).

Box 3.10. Quantitative representations of risk attitudes and perceptions

A commonly used approach by social studies to study perceived risk has been the psychometric paradigm, which aims to capture quantitative judgements about current and desired riskiness, and corresponding desire for regulation. Results of psychometric studies have pointed to several conclusions. First, the concept of risk differs for experts and laypeople. Overall, expert judgement tends to correlate with the actual number of fatalities that the hazard presents, while non-experts base their judgements also on other characteristics (e.g. catastrophic potential threat to future generations).

One of the most important factors of perception of risk for laypeople is the so-called "dread risk", which is associated with characteristics such as uncontrollable, catastrophic, involuntary, presenting a high risk for future generations, etc (see Figure 3.4). Nuclear weapons and nuclear power score highest on the elements that constitute this factor. The higher a hazard's score on the "dread" factor, the higher the perceived risk, and the greater a desire for risk reduction and regulation. In contrast, experts tend to assess risk as expected annual mortality. As a result, different assessments of the magnitude of the riskiness of a given action or technology, and related acceptability of risk may emerge.

Figure 3.4. "Dread risk" (factor 1) and "unknown risk" (factor 2)



Source: (Slovic, 1987[87]) (Slovic and Weber, 2002[99]).

The political economy of precaution

Given this section's earlier discussion on the importance of motivations and the political economy surrounding decision-making, it may be useful to explore how the application of the PP can be affected by incentive structures and level of alignment between the interests of the different actors involved.

A 2008 report by the UK's Risk and Regulation Advisory Council articulates a number of valuable concepts pertaining to the socio-political or political economy context surrounding risk and precaution:

- *Risk landscape*: constituted by "risk actors" and the interactions between them. These actors are groups involved with public risk, "including Ministers, civil servants, parliamentarians, the judiciary, the insurance sector, the media, subject-matter experts, single issue lobby groups, standards setters, compliance officers and risk managers". The risk landscape "influences individuals or organisations responsible for a public risk – usually business, public bodies or the public – to respond in a particular way".
- *Riskmongers*: "people or groups who conjure up or exaggerate risks inappropriately. Sometimes this will be in order to create some kind of advantage for themselves, such as financial gain, attention, power or even job security. Often it will be well intentioned but misguided."
- *Risk alarms*: "external influences that can produce a response on the part of a particular risk actor […] These risk alarms can prompt a response from a particular risk actor which, in turn, may influence the actions or perceptions of others." Examples provided include: events that raise or expose risks (e.g. 9/11, the banking crisis, publication of WHO report highlighting health risks); emerging risk issues (e.g. security of energy supply, pandemic flu, domestic security); newsworthy stories that highlight risk (e.g. flooding, bird flu, child abduction); individuals or groups who stand to gain from highlighting concerns or raising anxiety (e.g. conservation groups, NIMBY campaigners); and issues of broad concern to the public (e.g. environmental, health, education, safety issues) (Risk and Regulation Advisory Council, 2008[100]).

Crucially, the interests and incentives of the various risk actors may be out of alignment, thus leading to undesirable outcomes. Gollier and Triech, for example, note that politicians with strong career concerns may prefer to select the risk policy that "the public" believes is good, and conclude that this kind of political inefficiency may cause the regulator to depart from social welfare maximisation (European Commission, 2017[36]) (Gollier C., and Triech, N., 2003[64]). In addition, institutional constraints may impact incentive structures and alignment. This includes the scope of regulatory mandates, the legal and financial liabilities of decision-makers, and regulatory regime architectures. An example is how fragmented architectures provide scope for inconsistent or incoherent practices to emerge across regimes.

On a related note, Hausken has used principal-agent problem analysis to describe how the PP is usually applied at a societal level. Principals represent society and are usually government departments or agencies which hire agents that may be publicly employed or recruited on the private market:

> *Principals and agents as players make decisions and play the game with each other. As Shapiro (2016) points out, agents may exercise discretion through self-interest at the expense of their principals, and principals may exercise discretion through choosing agents, taking advantage of agent expertise, and responding to uncertain contingent events. Both agents and principals may exploit each other, and an agent may accumulate knowledge and take over the role of the principal (Bhimani et al. 2010). Further problems arise because the players' incentives generally don't align. For example, agents may have information that the government as principal needs for making decisions, agents may withhold information or release disinformation, and agents may undermine government initiatives. (Hausken, 2019[101])*

Hausken distinguishes four dimensions related to the PP and analyses the interactions between principals and agents in each of them:

- *Threat*: threats may be beneficial for some agents (safety specialists who may thereby get contracts), but not others. For example, residents who may get their houses destroyed by flooding or wildfires are evidently not benefiting from threats.
- *Uncertainty*: to the extent that principals are not unitary, interactions are possible between the various principals and sub-principals about suitable thresholds. To the extent that principals are not autonomous, games are possible between them and their superiors, stakeholders, pressure groups, audiences, and other actors that can somehow impact how the principals assess uncertainty.
- *Action*: the agents may interact with external actors and each other — especially when their actions cannot be performed independently of each other, or the geographic space is so small that multiple agents cannot perform their actions simultaneously. The agents may also play games with the principals due to different interests; for example, if the agents possess hidden information or knowledge about costs or performance levels that the principals cannot readily access.
- *Command*: the principals interact with each other and with many potential agents with the objective of obtaining a lower number of agents for completing the objective.

On a related note, Espluga has analysed "precautionary local politics" in the context of risks stemming from radiofrequency fields in Spain. The author identifies three main actors in any conflict relating to environmental risks:

- Risk generators (agents): in this case, the cell phone operating companies who are interested in promoting and spreading the technology for company profit.
- People affected: in this case, members of the public who consider themselves harmed by the installation of antennae, whether in economic, environmental or health terms.
- People responsible for guaranteeing safety levels: in this case, public institutions such as national, regional or local government (principals).

Espluga notices that different interests and motives can often be distinguished within these groups. Cell phone operators were concerned by the public alarm and suspicion and the consequences this had on plans for company development. However, when regulations were drawn up, they were concerned about their impact on corporate results — especially as a new generation of telephones was being developed which would likely require the expansion of existing coverage. At the same time, local councils, due to their proximity to the public, were the first government bodies to take precautionary measures — although there was little coordination between them. When the social conflict became more significant, government at a higher level passed specific legislation. However, because this relied on differing criteria, it failed to resolve the confusion. Espluga also points out that, "the media may be considered part of the system of interrelations, through its role in promoting, spreading, or mitigating environmental conflicts. The media make invisible risks visible and provide individuals with information that enables them to link risk factors to certain effects or damages." (Espluga, 2005[102])

The Bovine Spongiform Encephalopathy (BSE) epidemic in the United Kingdom (see the section Analysis and categorisation of selected PP applications for further details), has also been pointed out as an example of the principal-agent problem. A study noted that "acceptable costs of precaution are equal to subsidies to be paid to the agent in order to elicit the higher effort under the most pessimistic assumptions of the principal on the possibility of catastrophic events", and that, while the principal is expected to act based on the worst probability distribution, this was not sufficiently taken into consideration. Rendered products of cow and sheep carcasses were produced and labeled as feed for hogs, chickens and other farm animals and continued to be exported to many countries. In 1996, when it became clear that this meal had been fed to cows and sheep, the UK banned animal protein in feedstock.

The issue (and pitfalls) of perceived neutrality

A problematic issue when it comes to applying risk-based regulation and precautionary approaches relates to the supposed "neutrality" and independence of certain risk actors (to use the terminology presented above). It concerns the real interests motivating these actors, their trustworthiness (or lack thereof), and how these factors help shape public opinion and risk perception. This issue is particularly acute in the case of the energy sector, although present in many other sectors.

For instance, it has been argued that NGOs are increasingly perceived to advance their own agendas,[18] as opposed to being altruistic or impartial actors (Tortajada, 2016[103]). With regard to issues of independence, developments in recent years around links between the Russian authorities and environmental NGOs abroad can be rather telling.

For instance, the then NATO Secretary General Rasmussen levelled accusations at Russia for meddling in Europe's energy crisis, for example by engaging with "so-called non-governmental organisations working against shale gas – to maintain European dependence on imported Russian gas". Allegations of Russian funding to the environmentalist movement in the U.S. (Defence connect, 2022[104]) have been raised by members of Congress, too (Johnson, 2017[105]).

Conversely, even though NGOs advocating for specific energy technology and policy choices are clearly not exempt from major conflicts of interest, it could be argued that the track record of several key industry players in the energy sector has generated such long-lasting suspicion and mistrust that — to the extent that regulatory decisions are strongly influenced by public opinion — it may have hindered the development of certain energies (e.g. nuclear) with potential for enhancing climate change mitigation.

Major reputational damage has resulted from how some energy companies are perceived to have benefited from contributed to global warming – and continue to do so. Indeed, some are accused of wilfully concealing evidence of the phenomenon itself.[19]

While there is no downplaying the importance of the above-mentioned episodes (just as there is no case for criticising environmental organisations across the board), it may be useful to reflect upon the examples presented to question traditional notions of neutrality and independence, as well as their implications for regulatory decision-making and precautionary approaches in the energy sector and beyond.

Building on the review presented in this chapter, the next chapter explores the articulation between precaution and innovation — something that has no small relevance in the context of climate risks and the energy transition. In doing so, the next chapter pays special attention to existing attempts to overcome the apparent tensions between both principles.

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Notes

[1] As early as 1898, Swedish scientist Svante Arrherius put forward the theory of the greenhouse effect and calculated that doubling of carbon dioxide in the atmosphere would increase temperatures by 5°C to 6°C (Sample, 2005[106]).

[2] Additional important aspects that also need to be considered are the execution, supervision, enforcement and evaluation of the measures derived from those decisions.

[3] The project entitled *“Regulatory strategies and Research needs to compose and specify a European policy on the application of the Precautionary Principle” (PrecauPri)*, is financed by the European Commission (STRATA programme) and aims to put forward a general framework for precautionary risk regulation in Europe.

[4] Consideration of scientific uncertainty in the application of PP is key and requires careful consideration when applied in practice. For instance, scientific uncertainty may apply to the calculation of environmental impacts over the long-term. In some cases, the immediate environmental impact of technologies may be determined more-or-less accurately (e.g. coal mining and coal burning for electricity production), whereas very-long-term events are inherently more difficult to predict and therefore, even if scientific knowledge is accumulated, there is always some space for “what if one day” considerations. This creates a potential disbalance in risk management, whereby comparatively *more harmful but more certain* risks get regulated rather more lightly than *probably less harmful but more uncertain* ones. This is where the “refocused”

approach to understanding and applying the precautionary principle we outline is most essential, to ensure proper risk balance and proportionality is retained.

[5] Bayesian decision rules (or Bayesian Decision Theory BDT) is a statistical approach to pattern classification that quantifies the trade-offs between various classification based on probability and costs. The rules define the most reasonable action to take based on the parameters 'prior probability', 'likelihood', "evidence" and "posterior".

[6] Geoengineering refers to the release of particles (such as sulphur) into the atmosphere which, by reflecting solar radiation, intervene in the Earth's climate and potentially lead to a cooling of the planet. The workings of this technology however are not fully understood and are surrounded by high levels of uncertainty and potential danger, thus making the case for the use of the precautionary principle.

[7] Judgment of 26 November 2002 in case T-74/00 (Artegodan & Others v. Commission, paragraph 184).

[8] Judgment of 2 December 2004 in case C41/02 (Commission v. Kingdom of the Netherlands).

[9] Judgment of 5 May 1998 in case C180/96 (United Kingdom of Great Britain and Northern Ireland v. Commission).

[10] C. 1999/832/EC: Commission Decision of 26 October 1999 concerning the national provisions notified by the Kingdom of the Netherlands concerning the limitations of the marketing and use of creosote.

[11] Judgments of 11 September 2002 in case T-13/99 (Pfizer, paragraph 444) and case T-70/99 (Alpharma, paragraph 355).

[12] Judgment of 7 September 2004 in case C-127/02 (Waddenzee, paragraph 45).

[13] Judgment of 23 September 2004 in case C-280/02 (Commission v. France, paragraph 34).

[14] Appellate Body report of 16 January 1998 on Dispute DS26, paragraph 124.

[15] Appellate Body report of 12 October 1998 on Dispute DS58, paragraphs 129.

[16] Appellate Body report of 12 March 2001 on Dispute DS135, paragraphs 167, 168 and 178.

[17] It should be noted that the question of proportionality is a topic of debate in the context of the PP. As noted by (Iverson and Perrings, 2012[108]) proportionality is an "unresolved question" and there is disagreement about how precautionary efforts should be balanced in a way to ensure that policy solutions (and related costs) are proportional to the level of protection attained. From a broader regulatory policy standpoint, however, the OECD has consistently been emphasising the crucial importance of proportionality (OECD, 2010[110]) (OECD, 2021[61]).

[18] An example of potentially conflicting interests can be found with the energy cooperative set up by Greenpeace in Germany in the wake of power markets deregulation in the late 1990s. While Greenpeace was advocating for specific energy policy decisions, and specifically the exit from nuclear power, which led to a strong increase in the reliance on natural gas – it was also, through this cooperative, selling gas-powered electricity to consumers. The German power sector continued to undergo important transformation and has come under public scrutiny regarding its sales of natural gas (Climate & Capital media, 2021[111]).

[19] For example, in June 2020, the state of Minnesota Attorney General sued ExxonMobil, Koch Industries and the American Petroleum Institute (the leading oil and gas industry trade association in the US) for having allegedly mislead the public about the role fossil fuels play in causing the climate crisis. This lawsuit is similar to consumer fraud cases filed in New York and Massachusetts against ExxonMobil (Negin, 2020[107]). Koch Industries, a group that may have a vested interest in delaying climate action, has also come under heavy criticism for directly financing groups that have attacked climate change science and policy solutions. Greenpeace estimate that financing amounted to USD 145 million between 1997 and 2018 (Greenpeace, n.d.[109]).

4 The PP and innovation: how well do they mix?

This chapter discusses the intersection of precaution and innovation, and the tension between these two concepts. It explores an imaginary scenario to outline the trade-offs related to innovation and precaution. The chapter also provides a definition of the innovation principle, as well as a selection of examples illustrating how the tension between the PP and the innovation principle may be overcome – at least to a certain extent.

Key messages

- The PP has been criticised for its potential "paralysing effect" on decision-making. This applies especially if the PP is introduced at high-level decision-making where it tends to be used for "yes or no" decisions as opposed to decision-making on the "how" of implementation. According to its critics, it can also be a source of legal uncertainty and stifle innovation.
- Proponents of the PP maintain that the PP is vital for innovation — especially at the developmental stage of new technologies — because it provides essential procedures and standards to assess, appraise and control risks. Moreover, some argue that the PP provides a framework that helps to achieve a better balance in public policies and mitigate the difficulties associated with scientific demonstration, prior to justifying preventative measures.
- In determining whether precautionary measures against innovations are warranted, the focus needs to be on how, and under which conditions, a given technology should be deployed and applied. The focus should not simply be about whether to allow it or not. In addition, it is important to keep a holistic perspective that encompasses not only the potential hazards associated with an innovation or specific use case, but also considers potential benefits and available alternatives.
- Implementation of "innovation-friendly" approaches to precaution and uncertainty are not straightforward. Several attempts have been made in recent years. This includes responsible research and innovation, Safe(r)-by-Design approaches, and frameworks for applying the PP to emerging technologies.
- Such implementations are hindered by tensions between the regulatory decisions that scientific findings would seem to warrant on the one hand, and those effectively driven by public perception, stakeholder influence and political considerations, on the other.
- Concerning energy technologies, the PP has been invoked in several cases to justify decisions that arguably did not result from evaluative and deliberative processes, but instead were driven by socio-political factors and pre-existing perceptions of risk.
- Risk regulation can be key in preventing innovation-induced disasters. The PP should not be seen as a reason to ban or avoid certain innovations altogether, but rather as a means to manage their introduction and deployment in an agile way. To achieve, policymakers and regulators need to ensure that knowledge generated through experimentation and gradual upscaling is regularly and systematically fed into regulatory development and improvement.

Precautionary approaches to technology and innovation deployment: a thought experiment

With the benefit of hindsight, it is difficult to "decide" whether particular innovations should have been introduced or allowed – and maybe this difficulty can help clarify why an "all or nothing" approach may not be optimal in most situations.

For illustrative purposes, a scenario could be conceived, in which a modern regulator had to approve the first application of the steam engine, either for a railway or textile spinning or weaving. What would have been the correct PP-driven decision, if this regulator had access to modern scientific knowledge? Arguably, this imaginary regulator could very well have considered the immense downside risk of global warming to be unacceptable, regardless of the potential upsides of the technology. In retrospect, the energy revolution of the late 18th and early 19th centuries brought about industrialisation and further technological progress, which not only brought mankind to face the chasm of climate disaster, but also made possible modern warfare, as well as destruction of biodiversity on a greater scale and speed than ever before.

However, this would certainly be a very partial view of the impact of these (then new) technologies. Indeed, the energy revolution also brought about unprecedented economic and social development, and generally immensely improved material welfare, as humanity exited its previous condition of prevailing scarcity. This, in turn, contributed to transformations in political and social systems that brought about, for many countries at least, major improvements in personal freedoms and human rights.[1] Of course, even someone in the early 1800s who was trying to imagine the future systems and scientific knowledge would have had no way to predict the exact scenarios unlocked by use of these new technologies, let alone model their relative probabilities. What would, thus, have been an appropriate PP-informed decision?

Rather than an "all or nothing" decision, the imaginary regulator could have taken a variety of measures, such as authorising the use of the technology while mandating the periodic review of its impacts on health and the environment. Or, the regulator could run a series of small-scale pilots or regulatory experiments to gain a deeper understanding of the harmful effects of the technology and how they could be better managed and mitigated. Crucial elements in this respect would include: a) apprehending the PP and its realm of application in terms of systems and understanding the relevant impacts and interdependencies; b) monitoring closely what is changing/known/unknown; active investigation and testing, especially with long term assessments; c) communicating and reframing as appropriate, including a readiness to modify regulatory approaches when the signals change (for example, those available through pharmacovigilance, environmental change, climate data, etc).

As a matter of fact, risk regulation can be key in preventing innovation-induced disaster. From this perspective, the PP should not be seen as a reason to ban or avoid certain innovations altogether, but rather as a means to manage their introduction and deployment in an agile way. The PP can achieve this by ensuring that the knowledge generated through experimentation and gradual upscaling is regularly and systematically fed into regulatory development and improvement.

A long-standing controversy – or balancing issue?

Balancing precautionary approaches and innovation is challenging. A fundamental question is that of characterising "appropriate use" of the PP as far as its articulation with innovation is concerned. Indeed, in recent years, the debate around the PP has intensified concomitantly with the articulation of the innovation principle. Difficult questions have been raised: is the precautionary principle an obstacle to progress and innovation? How can the PP and the innovation principle reinforce each other?

For some, the PP is a source of legal uncertainty and may also undermine progress and innovation by not factoring in the opportunity costs of forgone progress (Orset, 2014[1]) (Institut économique Molinari, 2013[2]). Sunstein has referred to the potential "paralysing effect" of measures underpinned by the precautionary principle (Sunstein, 2002[3]), which can be argued to have implications for risk-taking and innovation. Similarly, the UK Institute of Economic Affairs (IEA) has voiced "concerns that badly designed and targeted regulation holds back innovation, due in part to excessive restrictions brought about by misapplication of the precautionary principle". The IEA has called for a more proportionate application of the PP "that gives due weight to the benefits to (amongst other things) the environment, human health and wellbeing that innovation and economic growth can bring" (Hewson, 2021[4]). Moreover, the European Risk Forum (ERF) argues that regulation focused solely on avoiding risk and removing scientific uncertainty stifles technological innovation; it suggests the consideration another principle, the *innovation principle* to ensure the systematic consideration of policy and regulation's impact on innovation.

Conversely, others such as the European Political Strategy Centre (EPSC) maintain that the PP is vital to innovation, especially at the developmental stage of new technologies. This is because it provides essential procedures and standards to assess, appraise and control risks; an approach in stark contrast to the "move fast and break things" philosophy advocated by some industry players. In addition, it has been argued that the framework of the PP supports a better balance in public policies [public policy debate?] and helps to mitigate difficulties associated with scientific demonstration prior to justifying preventative measures (European Parliamentary Research Service, 2015[5]). In a similar vein, according to the European Environment Agency (EEA), appropriate use of the PP can promote a wide range of technologies and activities (e.g. regarding the development of agroecology solutions).

Box 4.1. What is the innovation principle?

The innovation principle was first proposed for adoption in risk management and regulatory practice in 2013 by the ERF in an open letter to the then three Presidents of the EU institutions: "Whenever policy or regulatory decisions are under consideration the impact on innovation as a driver for jobs and growth should be assessed and addressed". In contrast to the precautionary principle, the innovation "principle" has no legal anchoring. Instead, at EU level, the innovation principle is considered a regulatory approach that contributes to achieving EU policy objectives (e.g. jobs and growth, the green and digital transformations, competitiveness and overall value creation) by ensuring that regulation creates the best possible ecosystem for (beneficial) innovation.

According to a 2017 paper, despite its lack of legal anchoring, the innovation principle has been gaining ground and is being referred to in many policy documents. The RECIPES study has identified several initiatives that give the innovation principle a role in law. At EU-level, this includes the European Commission's (DG R&I) definition of the innovation principle as a "tool to help achieve EU policy objectives by ensuring that legislation is designed in a way that creates the best possible conditions for innovation to flourish".

The OECD Recommendation of the Council for Agile Regulatory Governance to Harness Innovation also acknowledges regulation's role in helping to ensure that innovation serves to promote sustainable and inclusive economic development and address global challenges. It provides a conceptual framework and guidance to help governments realise the full potential of innovation in high-uncertainty contexts by enhancing its benefits for societies while addressing its risks. Similarly, the OECD Declaration of Public Sector Innovation – which has been adhered to by 43 countries since 2019 recognise the benefits that can come from enabling experimentation in core systems (such as the use of digital technologies, budgeting, risk management and reporting) and explore whether and how they can be achieved.

Source: (European Risk Forum, 2015[6]); (Vos and De Smedt, 2020[7]); (OECD, 2021[8]); (European Commission, DG R&I, 2022[9])

Going forward, acknowledgement that both the precaution and innovation principles are not "self-evident" when it comes to their application will be key. Both principles can provide guidance and draw attention to aspects and issues that may otherwise be undervalued or overlooked. However, there will always be trade-offs between risks, as well as the nature and distribution of benefits — all of which must be assessed and prioritised. There is also a need to find more agile solutions that go beyond the "ban or allow" dichotomy.

Attempts to develop more "innovation-friendly" approaches to precaution and uncertainty

According to Garnett, Van Calster and Reins, a possible future challenge for the EU is how the innovation principle — if it becomes more established — can be linked to and interrelate with the PP. They conclude that a qualified innovation principle would be perfectly compatible with both the EU's Better Regulation objectives and the PP, as well as with the EU's circular economy goals and commitment to responsible research and innovation. Such a qualified innovation principle would need to recognise the need to act responsibly, while encouraging reasonable risk-taking in a competitive global market (Garnett, K., Van Calster, G. and Reins, L., 2018[10]).

The European Political Strategy Centre (EPSC) highlights that "the precautionary principle is of particular importance for innovation because, especially at an early stage of a new technique or approach, the possibility of a risk often cannot be ruled out. It provides procedures and criteria to assess, appraise and manage risks. An integral part of risk management, as envisaged by the PP, is the examination of the potential benefits and costs of action, or lack of action" (European Political Strategy Centre, 2016[11]).

It has been argued that the PP and innovation principle may at some point "collide" should the latter be incorporated into EU law (Garnett, K., Van Calster, G. and Reins, L., 2018[10]). However, it is also argued that there are ways to reconcile the innovation principle and the PP. One of these is to consider the former as a complement to the latter. According to this view, regulatory assessment processes should try to reconcile the two principles and achieve a more balanced use of the PP. However, this view does not answer the question of what exactly should be balanced with the PP, and how this balancing could be carried out in practice. A second way to reconcile the two involves weighting systematically precautionary measures against the societal benefits of innovations. This approach seeks to develop a science-based appraisal process in line with the agendas of Better Regulation and responsible research and innovation (Vos and De Smedt, 2020[7]).

Responsible research and innovation (RRI)

The dimensions of anticipation and inclusion are central to the responsible innovation concept. Responsible research and innovation (RRI) has been strongly promoted by European Commission as an innovative governance concept, notably in its 2014-2020 research and the Horizon 2020 innovation programme. RRI seeks to reconcile innovation with sufficient safeguard levels. Four elements characterise the approach, which is included in the proposed guidance on the application of the PP as developed under the EU RECIPES project (RECIPES, 2021[12]), which includes four elements:

- *Anticipation*: "Involves systematic thinking aimed at increasing resilience, while revealing new opportunities for innovation and the shaping of agendas for socially-robust risk research."
- *Reflexivity*: "At the level of institutional practice, means holding a mirror up to one's own activities, commitments and assumptions, being aware of the limits of knowledge and being mindful that a particular framing of an issue may not be universally held".
- *Inclusion*: taking the time to involve different stakeholders in order to expose and explore the impacts of a new technology can have on different communities.
- *Responsiveness*: "Responsible innovation requires a capacity to change shape or direction in response to stakeholder and public values and changing circumstances" (Stilgoe et al., 2013[13]).

The EU's research and innovation framework programme highlights the necessity to foster social and environmental responsibility and ethics in the governance of science and technology. This is realised by developing activities that: 1) respond to significant societal needs and challenges; 2) involve a range of stakeholders for the purpose of mutual learning, and 3) anticipate potential problems, identify alternatives and study the underlying values.

A sub-section later in this chapter is dedicated to Safer by design and regulatory preparedness and provides further insights into a specific elaboration of RRI.

Precaution and sustainable development in the EU's Environment Action Programme

The European Environment Agency (EEA) also supports the coexistence of the two principles by stating that "precautionary actions can be seen to stimulate rather than hinder innovation". At the same time, it observes that the speed and scale of today's technological innovations can inhibit timely action because, by the time clear evidence of harm has been established, the technology has been modified, thereby allowing claims of safety to be subsequently re-asserted.

According to the EEA, these features of current technological innovation strengthen the case for taking early warning signals more seriously and acting on lower strengths of evidence than those normally used to conclude to "scientific causality". The EEA states that most of the historical case studies show that by the time such strong evidence of causality becomes available, "the harm to people and ecosystems has become more diverse and widespread than when first identified, and may even have been caused by much lower exposures than those initially considered dangerous" (European Environment Agency, 2013[14]).

The EU's 7th Environment Action Programme (EAP), in turn, stresses that — with new technologies — comes the need to better understand, assess and manage the potential environmental and human health risks that they bring. It suggests that major technological innovations should be accompanied by public dialogue and participatory processes, with need for a broad debate about the possible trade-offs that are deemed acceptable considering the sometimes incomplete or uncertain information about emerging risks. (Official Journal of the European Union, 2013[15])

On a related note, a report by the UK Interdepartmental Liaison Group on Risk Assessment (UK-ILGRA) suggests that the precautionary position adopted "should reflect the commitment to sustainable development that gives full weight to economic, social and environmental factors." It adds that the principle should not obstruct innovation and that, applied properly, it is a positive policy tool "to encourage technological innovation and sustainable development by helping to engender stakeholder confidence that appropriate risk control measures are in place" (Interdepartmental Liaison Group on Risk Assessment, 2002[16]).

Application of the PP to emerging technologies

The following section discusses the application of the PP to emerging technologies. It explores in further detail the concept of 'safer by design' and regulatory preparedness, as well as the EU Commission's approach to regulating artificial intelligence. The section also looks into a series of case studies related to the RECIPE project (REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders), which analyse the application of the precautionary principle across different thematic areas.

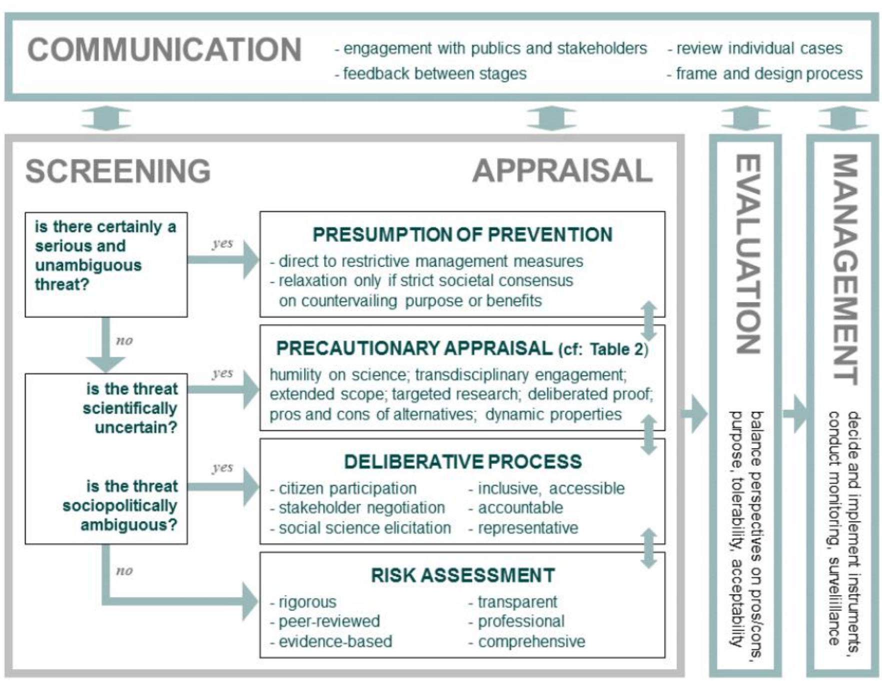
In a 2016 article, several leading authors contended that precaution can be consistent with support of science and innovation. The article noted that "the charge that precaution means giving up on technology depends both on the triggers and the precautionary recommendations". Quoting a report on gene drive research by the US National Academies of Science, Engineering, and Medicine (NASEM), it called for "targeted but meaningful measures" to "encourage a broader range of perspectives on — and questions about — the technology". The article also advocated for a "robust and iterative assessment that can incrementally reduce uncertainty surrounding its outcomes and probabilities" and "ensure that risks are acceptable to the relevant publics and are reduced to the greatest extent possible" (Kaebnick,G. E. et al, 2016[17]).

Regulatory approaches (including precautionary) related to innovation and emerging technologies have also been analysed by Stirling, who claims that "Precaution is about steering innovation, not blocking it" (Stirling, 2016[18]). The author proposes a framework for applying the PP to emerging technologies. Figure 4.1 provides an overview of this framework.

The general framework shown above encompasses 17 key considerations: *what needs to be demonstrated in a precautionary technology appraisal*, with appraisal criteria that includes independence from vested interests, and the examination of uncertainties, sensitivities and possible scenarios. An initial screening process for targeted precautionary appraisal (including socio-political factors) is also foreseen as an aid to determining when a precautionary appraisal, stakeholder deliberation or risk assessment are needed. The various stages of the framework are conceived as interlinked elements, all of which "feed into the communication, evaluation and management of identified threats" (European Commission, 2017[19]) (Stirling, 2016[18]).

As always, the challenge lies in the implementation of this approach. There can be material tensions between the regulatory decisions that scientific findings would seem to warrant on the one hand, and those effectively driven by public perception, stakeholder influence, and political considerations, on the other. As far as energy technologies are concerned, the PP has arguably been invoked in a number of cases to justify decisions that did *not* seem to result from the kind of evaluative and deliberative processes put forward by Stirling among others. As discussed earlier in this report, it is not unusual for policy and regulatory decisions to be driven by factors other than scientific knowledge and evidence, such as socio-political factors and perceptions of risk.

Figure 4.1. General framework for applying the precautionary principle



Source: (Stirling, 2016[18]).

Decisions around the EU taxonomy of environmentally sustainable activities illustrate well the complexity of such decision-making processes. After nuclear energy was initially excluded, in 2020, the European Commission launched in-depth work to assess whether to include nuclear energy in in this taxonomy and entrusted its Joint Research Centre (JRC) with drafting a technical report on the "do no significant harm" aspects of nuclear energy. This report's findings notably indicate that "nuclear energy-based electricity generation can be considered as an activity significantly contributing to the climate change mitigation objective", and that "all potentially harmful impacts of the various nuclear energy lifecycle phases on human health and the environment can be duly prevented or avoided" (European Commission Joint Research Centre, 2021[20]). To best support the discussion, the JRC brought together several group of experts[2]. Nonetheless, policy discussions around nuclear energy continue to often focus on potential consequences of an extreme accident, rather than on the aggregate average risk. This may reflect both other policy preferences and deep divergences in how we *perceive* risk, which often do not match quantitative risk assessments (Slovic, 1987[21]) (Slovic and Peters, 2006[22]). Such discussions and decisions may end up focusing on one aspect (consequences of a possible tail-risk accident), at the expense of a more holistic consideration of the risks and benefits (including climate, biodiversity, etc.) of different options, where any decision is about risk trade-offs rather than the total avoidance of risk, which is impossible in the climate and energy context. In practice, *not using* any low-carbon energy source often means using a higher-carbon alternative, which is itself not without other safety and environmental risks, and thus this report emphasizes the importance to understand precaution as a careful consideration of this balance of aggregate risks and benefits, with due importance being given to the climate consequences given the existing emergency.

Safer by design and regulatory preparedness

Authors such as Kletz (Wolke, 1985[23]) and Van Gelder et al. have made substantive research contributions to the analysis of Safe(r)-by-Design approaches (SbD, also named Safe-by-Design or Safety-by-Design). Van Gelder et al. present SdB as a tool that can help shape governance arrangements for accommodating and incentivising safety, while fully acknowledging uncertainty by organising for responsibility through monitoring practices and facilitating adaptive change (van Gelder et al., 2021[24]).

After assessing SbD's application in various engineering disciplines (including construction engineering, chemical engineering, aerospace engineering, urban engineering, software engineering, bioengineering, nano-engineering, and cyber space engineering), the authors conclude that:

> *Safe-by-Design is best considered as a specific elaboration of Responsible Research and Innovation, with an explicit focus on safety in relation to other important values in engineering such as well-being, sustainability, equity, and affordability. Safe-by-Design provides for an intellectual venue where social science and the humanities (SSH) collaborate on technological developments and innovation by helping to proactively incorporate safety considerations into engineering practices, while navigating between the extremes of technological optimism and disproportionate precaution (van Gelder et al., 2021[24]).*

The authors also identify the need for further research and analysis, and go on to formulate qualitative principles for inherently safer design (e.g. green chemistry). In their conclusions, they highlight the importance of having a context-specific understanding of "disciplinary and regulatory histories". This supports the alignment of safety practices with other values "at the heart of societal challenges, from climate mitigation to building resilient societies capable of dealing with the pressures of a global pandemic".

They also conclude that it would be valuable for developers and regulators to "work together to develop, test, and assess how different safety-oriented design approaches and dedicated governance arrangements for warranting safety and security fare in different contexts and to investigate how best to adapt such approaches in response to both lessons learned and evolved circumstances" (van Gelder et al., 2021[24]).

The OECD has also developed conceptual and analytical work on this topic. Its report "Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products" proposes a combination of Safe(r)-by-Design and *regulatory preparedness*. This combined process can raise awareness and improve decision-making effectiveness, leading to a Safe(r) Innovation Approach for nanomaterials and nano-enabled products (OECD, 2020[25]).

According to the report, SbD refers to identifying the risks and uncertainties that concern humans and the environment at an early phase of the innovation process. This is with the goal of minimising uncertainties, potential hazard(s) and/or exposure. The SbD approach addresses the safety of the material/product and associated processes through its whole life cycle: from the research and development phase to production, use, recycling and disposal. Regulatory preparedness, in turn, refers to the capacity of regulators (including policymakers), to anticipate the regulatory challenges posed by emerging technologies such as nanotechnology — particularly those relating to human and environmental safety. This requires that regulators become aware of, and understand, innovations sufficiently early in the process to take appropriate action, and that appropriate regulatory tools are modified or developed as needed. Regulatory preparedness helps to ensure that innovative materials and products undergo a suitable (and if appropriate, adapted) safety assessment before entering the market. Regulatory preparedness requires dialogue and knowledge-sharing among regulators, and between regulators and innovators, industry actors and other stakeholders.

The SbD approach has very relevant applications in facilitating the management of risks, including imperfectly quantifiable risks, to support the energy transition. This is the case for instance with electrolysers for the production of hydrogen. The SbD approach can be applied to the construction and operation of hydrogen electrolysers. Electrolyser manufacturers should design their products in accordance with applicable standards. For example, ISO 22734:2019 is an International standard that defines the construction, safety, and performance requirements of hydrogen electrolysers and can be used for certification purposes. This standard applies for industrial and commercial use. One point to consider, though, is that the rapid growth of hydrogen technologies and the decarbonisation goals that countries have set demand large-scale installations, where the operating experience is limited. Hence, the need to develop safety best practices and guidelines for large-scale electrolysis plants is emerged.

For a more elaborate discussion on regulatory preparedness, the reader may usefully refer to the report summarising the presentations and discussions at the first NanoReg2 Workshop on Regulatory Preparedness for Innovation in Nanotechnology (Publications Office of the European Union, 2018[26]).

The role of good communication in SbD and regulatory preparedness

Related work that notably builds on concrete project experience includes the development of a methodological SbD approach. One of its important conclusions is that a continuous and proactive combination of interconnected activities is required for ensuring regulatory preparedness. As a result, anticipation (e.g. horizon scanning), was seen as particularly important, as was communication between regulators, innovators (industry) and other stakeholders.

Regulators need to become aware of innovative products under development to ensure that the legislation and methods for safety assessment are available and adequate. Similarly, innovators must be aware of regulatory requirements and their likely evolution. This mutual awareness helps to develop safe products and to avoid delays or other problems in obtaining market approval.

Awareness can be achieved through communication and this requires trust. A format for achieving this includes the promotion of "trusted environments" for confidential inquiries and information sharing. Such trusted environments are physical or virtual spaces in which industry actors, innovators, governmental institutions and other stakeholders can share and exchange knowledge, information, and views on new technologies. Furthermore, regulators need early access to the existing information and data relevant to the safety assessment of innovative products. This enables them to provide timely guidance and advice to industry, as well as develop their own strategies for dealing with uncertainty (e.g. by applying the PP).

For the PP to be applied in a proactive and time-efficient way, regulators need to acquire early any information about a new technology — while it is still being developed. With early knowledge of a technology’s characteristics and potential safety concerns, the necessary regulatory tools — such as adapted legislation and appropriate safety assessment methodologies — can already be in place by the time industry is ready to seek any necessary market approval.

The participation of a variety of stakeholders has also been found to be crucial in implementing regulatory preparedness. This can help regulators to anticipate the need for new or modified regulatory tools, whilst reducing for innovators and industry those uncertainties associated with future safety legislation and the regulation applicable to emerging technologies.

Challenges of the SbD approach

There are several issues that can be obstacles to the implementation of the SbD approach:

- **Cost and resource constraints** (additional costs for technical and human resources; extra time in implementation of SbD). A number of incentives have been proposed to resolve this: allocate resources with particular focus on the benefits of SbD; develop structures to help design products and support usages at a reduced price; provide tax reduction of nanomaterial SbD; specific funding to support regulators in making transition to this approach.
- **Lack of knowledge/data gaps** (in identification of potential issues/problems; lack of specific knowledge at early stages; lack of structure for training; education and information). Incentives proposed to resolve this: publish clear and concise guidance; indicate area and cases where SbD is supported; offer training and access to infrastructures; greater involvement of SMEs.
- **Cultural change** (innovator/manufacturer have poor understanding of their responsibilities in SbD). Incentives proposed to resolve this: establish an international agreement on the SbD concept with support of national governments; create international certificates or rewards for applying SbD; create governmental platforms to provide technical support on SbD to SMEs; educate the public on the benefits brought by SbD (for example by promoting success stories).
- **Lack of frameworks, guidance and tools** (gaps between what is needed and what is available, lack of predictive tools in risk assessment, life cycle analysis and socio-economic analysis). Incentives proposed to resolve this: need of a supportive regulatory environment; development of normative activities; creation of certifications; introduction of SbD to the curricula of techno scientific studies.
- **Inadequate regulation** (lack of regulatory process to support SbD for nanomaterials (including legal instruments and liabilities), lack of a discussion platform between regulators and innovators). Incentives proposed to resolve this: develop regulatory requirements and corresponding measures for fulfilment of the essential social and environmental aspects of SbD.
- **Insufficient communication, collaboration and open-mindedness** (competitive industrial environment may make communication difficult between industry actors and regulators/policymakers). Incentives proposed to resolve this: develop an International Consensus on SbD at a high level; improve communication between innovators and regulators (e.g. by establishing open channels or platforms of communication and interaction between them); greater promotion in public and across the media of SbD and its success stories.

The European Commission's risk-based approach to regulating Artificial Intelligence (AI)

Identifying safety and security risks caused by AI is an essential task for the EU and its Member States as they aim to build safe AI in order to use the full potential of this technology while mitigating its potential negative impacts (van der Linden-Smith, M., Dufour, R., Smits, J., & Koehof, J., 2021[27]). In its 2021 Draft Regulation for Artificial Intelligence, the European Commission proposed to establish a technology-neutral definition of AI systems in EU law and to lay down a classification for AI systems with different requirements and obligations following a risk-based approach. The proposed classification is as follows:

- *Unacceptable-risk AI systems* include: "(1) subliminal, manipulative, or exploitative systems that cause harm, (2) real-time, remote biometric identification systems used in public spaces for law enforcement, and (3) all forms of social scoring, such as AI or technology that evaluates an individual's trustworthiness based on social behaviour or predicted personality traits."
- *High-risk AI systems* include those that evaluate consumer creditworthiness, assist with recruiting or managing employees, or use biometric identification, as well as others that are less relevant to business organisations. Under the proposed regulation, the EU would review and potentially update the list of systems included in this category on an annual basis.
- *Limited- and minimal-risk AI systems* include many of the AI applications currently used throughout the business world, such as AI chatbots and AI-powered inventory management (European Commission, 2021[28]).

AI systems in the unacceptable-risk category are prohibited. As currently proposed, high-risk systems would be subject to the largest set of requirements, including human oversight and checks on transparency, cybersecurity, data quality, monitoring, as well as reporting obligations. Lastly, the limited and minimal risk AI systems merely have an obligation of transparency. To classify the AI, the Commission examines features such as opacity, complexity, dependency on data, autonomous behaviour, which can adversely affect several fundamental rights and users' safety.

The following section summarises the findings of several case studies on the application of the PP to a range of areas involving the use of (disruptive) technology.

Case study analysis (RECIPES project)

The RECIPES project (REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders) was set up in 2019 by the European Commission and is based on the idea that the application of the PP and responsible innovation do not necessarily contradict each other. The project analyses the application of the precautionary principle across different areas and presents a series of thematic case studies. Box 4.2 presents selected summaries of this analysis and puts forward several additional elements.

The information presented in this subsection highlights the difficulties associated with determining whether precautionary measures are warranted in the presence of certain technologies and innovations. Particularly challenging is the fact that pre-existing perceptions are likely to determine the course of action to be pursued. Several of the examples above do show, however, that the relevant question is often about how and under which conditions a given technology should be deployed and applied, rather than simply about allowing it or not. In addition, it is important to keep a holistic perspective that encompasses not only the potential hazard associated with an innovation or specific use case, but also related potential benefits and available alternatives – including any risk-risk trade-offs.

Box 4.2. RECIPES project: Selected case study summaries

Gene drives

This case study investigates the application of the PP to gene drives, an area linked to many benefits including sustained and durable genetic change. There exists, however, a high degree of epistemic uncertainty surrounding the impact of gene drives (the alteration of a population may bring unforeseen and unknowable consequences). The case study illustrates how — despite differences in view about *how* the PP should be implemented — there is a consensus amongst gene drive researchers, policymakers and other stakeholders that the application of the PP is important in the context of gene drives.

GMOs

The case study highlights remaining uncertainty about the consequences of using GMOs as food and food ingredients. It argues that it is not entirely possible to determine the extent and likelihood of possible harms — something which strengthens the scientific uncertainty — and concludes with the need for a precautionary approach. As discussed earlier in this report, there seems to be, however, scant scientific evidence of significant hazards directly connected with the use of GE crops (Nicolia et al., 2013[29]).

Endocrine disruptors (EDCs)

According to this case study, "the precautionary principle is of utmost relevance for the governance of EDCs". There is scientific uncertainty about the effects of EDCs because it is difficult to determine the precise causal chains through which EDCs act on the hormonal system of both humans and wildlife. The growing scientific evidence on the negative effects of EDCs for health and the environment caused debate within the EU about the identification and regulation of EDCs. From 2014 to 2017, there was controversy surrounding the Commission's delay to set out scientific criteria for the determination of endocrine disrupting properties. Despite the subsequent establishment of criteria for the identification of EDCs in several – but not all – EU legislative areas, there remain ongoing concerns about the suitability of the EU's regulatory framework to EDCs.

In stark contrast with GMOs and nuclear energy, the benefits of EDCs —or the cost of parting with them — are limited and suitable alternatives exist (even if they are not without their own risks).

Nanotechnology

According to this case study, nanotechnology and emerging technologies are defined by uncertainties rather than risks. This is due notably to a lack of data and analytical methods, lack of long-term experience, scientific ambiguities, and terminological vagueness, etc. The European Commission produced an "integrated and responsible approach" on nanotechnology in its Nanoscience and Nanotechnology Action Plan of 2005. This was largely based on the PP. Consequently, Member States (e.g. Germany, Austria, and Switzerland) have been implementing regulatory measures such as safety research programmes, standardisation projects or the establishment of evaluation processes and commissions to integrate safety issues into innovation at an early stage.

Glyphosate

The PP effectively shapes the approval procedure and regulation of pesticides in the EU. However, as in the risk assessment of glyphosate at EU level no risk was determined, no precautionary measure in the form of a ban was taken. This reflected the fact that glyphosate was assessed as presenting no clear and demonstrated health risk, while any environmental harm should be cautiously weighed against the fact that available alternatives to glyphosate (extra tilling, other compounds) are not necessarily without negative environmental impacts, some of which are possibly worse than the substance they are meant to replace. The assessment and the decision have been contested by various stakeholders, and some Member States have introduced partial or complete glyphosate bans at national level. This example shows that "precaution" or the PP itself are not "cookie cutter" approaches that automatically deliver a clear and one-sided conclusion, or always lead to a more restrictive outcome. Indeed, in this case, the decision was taken *not* to act (as alternatives appeared rather worse), at least at EU level.

Urban wastewater

This case study deals with the implementation of the EU Urban Wastewater Treatment Directive 91/271/EC (UWWTD). The UWWTD is part of the European Water Framework Directive (WFD). It refers directly to the PP, the control at source principle, and the polluter pays principle (Art. 191(2) of the Treaty on the Functioning of the European Union. This case study investigates the dynamics that occur under an established precautionary principle regulatory regime. The challenges posed by this regime instigate innovative practices and shift risks (e.g. financial risk) to other sectors. The case study shows that if the precautionary principle is taken seriously (in the sense of Responsible Research and Innovation), then the accompanying financial risks can also be brought under control.

Artificial intelligence in healthcare

This case study indicates that the PP may be applicable to the use of clinical decision support systems, but only in specific circumstances. A variety of scientific research suggests that human rights and public health are at issue in some uses of Clinical Decision Support Systems (CDSS). Because of the difficulty in many cases of defining the specific outcome and statistical probability of the risks, the PP is, according to the case study, more suitable than the principle of prevention. From this perspective, the PP may enable appropriate regulatory and technical boundary setting for CDSS — for instance, by limiting the medical procedures in which a CDSS can be used, or the amount of human oversight that is necessary for important decisions in healthcare. Arguably, however, the crucial question in this context would probably be about identifying which decision-making system (be it AI-supported or not) will be less-biased and more evidence-based and, ultimately, more effective.

Microplastics in food products and cosmetics

The European Commission has been working on rules to prohibit microplastics in certain products. This will be done via the REACH regulation, which is based on the precautionary principle, to protect the environment. According to the case study, this prohibition will not include an end date and will not be changed even if new scientific evidence emerges". This is because the intentional release of microplastics into the environment is now seen as unacceptable. Moreover, the use of microplastics carries few to zero benefits, while generating very substantial harm.

Source: RECIPES, D2.4.1 Intra Case Study Analysis (2020).

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Notes

[1] It should, of course, be noted that this process did involve extended periods of deepened labour, health and social inequalities (with significant deteriorations from even basic agrarian conditions). For example, in *The Condition of the Working Class in England* Condition, Engels argued that the Industrial Revolution had made workers worse off in terms of health and living and working conditions; e.g. referring to "excessive mortality, an unbroken series of epidemics, [and] a progressive deterioration in the physique of the working population" (Engels, 1845[30]).

[2] The JRC report was subsequently reviewed by two sets of experts: the Group of Experts on radiation protection and waste management under Article 31 of the Euratom Treaty, and the Scientific Committee on Health, Environmental and Emerging Risks on environmental impacts (European Commission, 2022[31]). These reviews served to qualify a number of these findings.

Annex A. Selected examples of the integration of the PP into national and international law

National law

Switzerland: Section 74, Paragraph 2 of the Federal Constitution: In principle, all the formulations of the concept of precaution in environmental protection are based on the notion that indeterminable risks are to be avoided. Section 1, Paragraph 2 of the Environmental Protection Act (EPA) [*Umweltschutzgesetz,* USG]: "Precaution as defined implies that any effects likely to be harmful or noxious are to be limited early on." This formulation comprises the obligation to limit effects below the threshold of harmfulness and the obligation to limit effects for which no threshold of harmfulness can be ascertained by scientific means. Section 148a of the Agricultural Act [*Landwirtschaftsgesetz*]: revised as part of the 2007 Agricultural Policy, it defines the precautionary principle in accord with those of the EU (WHO, 2003[1]).

Greece: The PP is indirectly integrated in national law. Article 24 of the Greek Constitution: the state government takes "preventive or repressive measures" to ensure and support sustainability and protect the environment. In addition, Article 15 of the Basic Act on Biodiversity Conservation: the state should implement measures to "avoid any risk that threatens the structure of the ecosystems and prevents or reduces any environmental" damage" (Koehler, L., Giovos, I., & Lowther, J., 2022[2]).

Sweden: Chapter 2, Section 3 of the Environmental Code (1998): it adheres to the strong version of the principle and includes two important aspects: the requirement to take measures to prevent harm applies already when there is a scientifically established risk thereof; and, in order to avoid the requirements, the operator must show that there is no risk ((Michanek, 2007[3]); (Michanek, 2012[4]) (Pettersson, 2016[5]).

In some EU countries such as **Belgium** or the **Netherlands**, the courts recognise the precautionary principle provided that it has been included in a normative text. In Belgium, the principle was first introduced in Belgian legislation in a decree of the Flemish Region of 5 April 1995, while on a federal level it was reiterated in the Federal law of 30 January 1999, aimed at protecting the marine environment in the maritime areas under Belgian jurisdiction (Article 4). In the latter, the principle is directly binding on all users of the marine environment, both public and private (Nicolas De Sadeleer, 2000[6]).

Italy: The Environment Code includes many explicit references to the PP. Article 3 enumerates it as one of the general principles of environment law, and Article 301 is called "the conversion of the precautionary principle". The first paragraph stipulates that, in the presence of dangers (potential or confirmed), a high protection level must be guaranteed, even in the absence of scientific certainties on the risk existence. The following paragraphs delimitate the application of the principle (in compliance with the European Commission Communication on 2 February 2000), especially stipulating that the application of the principle refers to the risk that may be identified after a preliminary objective scientific assessment. The principle is also invoked in certain normative technical deeds, such as: the Law no. 36/2001 (about the protection against the exposure to electric, magnetic and electromagnetic fields), the Legislative Decree of the Government no. 224/2003 (on the deliberated dissemination of the genetically modified organisms in the environment), and the Legislative Decree of the Government no. 257/2006 (on the protection of workers from the risks related to exposure to asbestos at work) (Fainisi, Florin; Ilie, Marian; Artene, Diana Anca, 2012[7]).

In other countries such as **Spain**, the principle was not raised to the rank of constitutional principle and the courts based their decisions on the precautionary principle only if the provisions under consideration derived from European legislation. The first domain covered through legislation was environmental protection with Law no. 11/2001 (on the creation of the Spanish Agency for food security), and later Law no. 9/2003 (establishing the legal regime around the limited use and commercialisation of genetically modified organisms; it stipulates that the principles on which the law is based are those existing in the European and international area). The autonomous communities of Spain also have the legal capacity to introduce the principle in their legislation (e.g., the Catalan law on the food security, and the law on public health in the Valencia region) (Fainisi, Florin; Ilie, Marian; Artene, Diana Anca, 2012[7]).

International law

The 1990 **Ministerial Declaration of the Third International Conference on the Protection of the North Sea** stated that the contracting governments "will continue to apply the precautionary principle, that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even where there is no scientific evidence to prove a causal link between emissions and effects".

The PP achieved global recognition in 1992 when it was included in Article 15 of the **Rio Declaration** resulting from the UN Conference on Environment and Development. The provision makes the precautionary approach a guiding principle for the management of forests: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". By this definition, the precautionary principle is the duty of a state and scientific uncertainty should not be used to avoid adopting precautionary measures that could prevent environmental degradation.

At EU level, the PP was enshrined in the Maastricht Treaty in 1992 and it is now included in Article 191 of the Treaty on the Functioning of the European Union. However, the PP is not defined in the Treaty. It states: "Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay." Hence, through the Maastricht Treaty, the precautionary principle has acquired constitutional status. The PP was formally articulated by the European Commission's Communication on the Precautionary Principle (see Box 2.2), which was subsequently endorsed by the Council of Ministers (Nice Resolution). The Communication states that: "The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU".[1]

Another well-known definition of the PP was formulated with the **Wingspread Statement**. In 1998, at the Wingspread Conference on the Precautionary Principle, the PP was defined as follows: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically". This definition also involved a reversal of the burden of proof.

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Note

[1] Lofstedt reports that in the period 1994 to 1999, the term “precautionary principle” was referred to in 27 European Parliament resolutions (Lofstedt, 2004[8]).

Annex B. Selected cases involving precautionary approaches

This annex presents a selection of cases where precautionary approaches have been at play. While it does not intend to be comprehensive, a variety of sectors and interpretations of the PP are included in this selection. Particular attention is paid to energy transition issues, as well as to innovative technology solutions.

Climate change

There is evidence on the causes and effects of climate change, but certain issues (particularly those related to future impacts and the deployment of geoengineering solutions) remain uncertain (Pinto-Bazurco, 2020[1]). Article 3 of the United Nations Framework Convention on Climate Change (UNFCCC) establishes that "parties should take precautionary measures to anticipate, prevent, or minimise the causes of climate change and mitigate its adverse effects", and states that a lack of full scientific certainty should not be used as a reason for postponing measures to prevent serious or irreversible damage.

Nuclear power

Nuclear energy represents an important component in the energy mix of 13 of the 27 EU Member States, accounting for about one-quarter of the electricity produced in the EU. However, it remains controversial, in spite of its strong benefits in terms of carbon and other emissions. Among the reasons for this are catastrophic accidents such as Chernobyl (1986) and Fukushima (2011)[1], as well as intrinsic factors that tend to increase the risk perception level of some types of technologies irrespective of their actual, scientifically assessed level of risk (Slovic, 1987[2]) (Slovic and Peters, 2006[3]) Nuclear energy in the EU is governed to a large extent by the Euratom Treaty. All EU member states are party to it by default. The EU Directive 2009/71/EURATOM, amended through Directive 2014/87/EURATOM[2] provides a community framework for the nuclear safety of nuclear installations. Article 2(b) of the Directive calls for the establishment of uniform safety standards to protect the health of workers, as well as the public. According to the Directive, Member States must ensure that the national framework in place requires license holders to establish and implement management systems which give priority to nuclear safety. These must be regularly verified by the competent regulatory authority.[3] However, the Directive does not provide guidance on specific impact estimates that should be used by the Member States to that end.

In the wake of the 2011 Fukushima Daiichi nuclear disaster, Japanese authorities shut down most of the country's nuclear plants (a number of which have since then reopened). Many lessons were learned from the disaster in terms of improving regulatory and management effectiveness to strengthen safety (Ostendorff, 2013[4]). Critics noted that, as a result of parting with an important source of electricity, Japan had to meet the resulting energy demand by importing fossil fuels, which led to higher energy prices and an increase of greenhouse gas emissions (Pinto-Bazurco, 2020[1]). A similar debate has taken place in Germany, ultimately leading to the country exiting nuclear power. The recent energy crisis following the invasion of Ukraine, as well as the growing urgency of climate change and its consequences, have led to renewed discussions around nuclear power, and its revival in a number of countries, illustrating the need for a more holistic vision of what "precaution" actually means, as suggested in this report – i.e. that all aspects (climate risk, security of supply, etc.) of risk should be taken into account, and not only one category of safety or environmental risk.

The topic of nuclear energy, its risks and their adequate regulation has been the subject of decades of science, analysis, and debate, which would go far beyond the scope of this report to properly consider or summarize. The readers can refer to a number of important works on the topic (Wellock, 2021[5]) (NEA, 2011[6]). From the perspective of this report, what matters is that understanding *what actually constitutes real precaution* in the case of nuclear energy and its use requires a consideration (a) of scientifically assessed risks rather than risk perceptions, (b) of climate, economic, social and other risks that may be increased if other energy sources are used, and not only of narrowly defined safety issues.

Wind power

The PP has found some wind power applications in biodiversity management. According to the European Commission, The Capercaillies (Black Forest) case study on wind-power developments illustrates a "gradated" approach to precaution (European Commission, 2017[7]). Box A B.1 provides further detail.

Box A B.1. Case study: applying the precautionary principle in wind energy spatial planning – Capercaillie in the Black Forest (Germany)

In their study, Braunisch et al. propose a new wildlife-friendly method, based on PP, for determining prohibition zones for wind farms in ecologically important areas. The study focuses on wind farm planning in the Black Forest, Germany — a hotspot for new wind farms. The concern of the study was the lack of knowledge on how wind energy development would impact the population of the Capercaillie Tetrao Urogallus (a species of bird) in the region.

The study identified areas of different functionality and importance regarding reproduction, metapopulation persistence and connectivity. These were combined with population-related thresholds to define area categories with different levels of vulnerability and corresponding implications for wind power development. As a precautionary measure, they recommend wind farms not be placed in or near important habitats. According to their method, turbines should not be placed within a 1 km radius of the most important areas (category 1) as here they are very likely to bring harm to capercaillies. The authors recommend a detailed assessment of the bird population at these sites before deciding whether turbines are acceptable there, or how their impacts could be minimised.

Braunisch et al. concluded that the PP is an important part of policymaking but suggested that public acceptance of this method is strongly dependent on the coherence of arguments regarding "the probability of the threat and the credibility of the proposed measures." According to the authors, their approach makes the best possible use of available evidence and helps to increase public acceptance of the PP by avoiding criticisms that it is unscientific and leads to regulations that are either too restrictive or not prohibitive enough. The study points out that a frequent application of the PP is to work with worst-case scenarios; however, this can lead to the "exaggeration of the real risk" as referred to by the European Commission. Furthermore, since precautionary measures always represent a temporary solution, the authors recognised that it is crucial to make regular revisions based on up-to-date knowledge.

Source: (European Commission, 2021[8]) (Braunisch et al., 2015[9]).

Guidelines from the Dutch Ministry of Infrastructure and Water Management

The Dutch Ministry of Infrastructure and Water Management has issued a series of guidelines[4] on risk, safety and the application of the PP within the Dutch legal order. These guidelines are based on the Communication of the European Commission on the PP and the general risk management principles. They also mention a set of additional precautionary criteria that Dutch courts use, deriving from case law research in the area of health and safety (which can be of interest for the Dutch government in most areas):

- If scientific data indicates that a new technology is harmful to health or safety, both market players and the government must conduct further research to determine whether precautionary measures are necessary.
- The higher the estimated risk to health and safety, the greater the duty of care for both market players and government to prevent damage as far as possible.
- A duty to warn and inform is part of the duty to act.
- This responsibility translates into an ascending scale: first, the government must provide information and require the market to provide information on the dangers, including safety measures. Then a regulatory framework must be put in place. Finally, this framework must be enforced.
- As insights grow, the government must keep a hand on the tap to see whether increasing stringency of regulation is warranted. Scaling down is also allowed, if objective scientific research shows the dangers are less than expected.

These guidelines also highlight a strong correlation between the application of the PP and liability in Dutch practice. Even though the application of precaution is not solely the responsibility of the national government, government ministers are seen as liable and accountable, as they must be able to prove at any time that adequate measures are taken and that other parties also deal with risks in a careful manner.

The Memorandum “Consciously dealing with safety; red threads” of the Dutch Ministry of Infrastructure and the Environment (182014) states that “measures can be taken in the form of further research to reduce uncertainty, information to offer action perspectives and possibly exposure-reducing measures, a provisional ban or (adapted) regulation. Stakeholders should be involved at the earliest possible stage". The government will also have to establish that they monitor and benefit from any new development, and that new risks are being handled responsibly and carefully.

Chemicals

The EU REACH Regulation (EC) No. 1907/20065 on chemicals states that its provisions “are underpinned by the precautionary principle” (Article 1(3). Burden of proof lies with the supplier or manufacturer, requiring companies to demonstrate to the European Chemicals Agency how the substances can be safely used, and to communicate health and safety information to the other users in the supply chain (European Commission, 2017[7]).

A 2011 report on the topic highlighted that the application of the PP in the chemicals sector requires taking decisions on what is considered an "acceptable" level of risk for society, identifying gaps in knowledge that result in uncertainty concerning the nature of a potentially unacceptable risk, and managing that risk in the face of uncertainty (Milieu Ltd, 2011[10]). The report also notes that the PP should only be applied in the event of a potential risk that cannot be fully ascertained or quantified, or its effects cannot be determined because of the insufficiency or inconclusive nature of the scientific data. It stresses that a scientific evaluation of the potential adverse effects (risk assessment) should always be undertaken based on the available data (hazard identification, hazard characterisation, estimation of exposure and risk characterisation). This should lead to a conclusion on the possibility of the occurrence and the severity of a hazard's impact on the environment or the health of a given population (including the extent of possible damage, persistency, reversibility and delayed effect). It should also lead to a description of the remaining uncertainties in order to help decision makers in the risk management phase.

The report provides a framework for determining whether the information available indicates the potential for harmful effects. The seven steps are as follows:

- Has a potential negative effect been identified?
- Has a scientific evaluation of the substance been carried out?
- What are the uncertainties concerning the nature or probability of the possible harm?
- What are the options available for controlling the risk of possible harm?
- Do the options for risk management measures meet the five elements of the precautionary principle?
- What is the process followed for reaching implementation decisions?
- Is there a plan for reviewing the actions taken if new scientific knowledge emerges?

For each step, the report provides specific guidance on the various elements that should be considered. This includes an excerpt from the 2000 Communication, information on developments in smart regulation, and summaries of appropriate ECJ case law.

Antimicrobials as growth promoters

Since the late 1940s, antibiotics have been added to animal feed to accelerate the livestock growth and productivity. Antibiotic resistance in bacteria was observed in the 1950s and the possibility of transferring resistance to other species of bacteria was documented in the 1960s. In 1985, Sweden banned this use of antibiotics because of its uncertain long-term effects. In 1998, the European Union took the precaution of prohibiting the use of four antibiotics for this purpose (European Parliamentary Research Service, 2015[11]).

“Mad cow disease” (BSE)

By November 1986, important amounts of meat from cattle infected with bovine spongiform encephalopathy (BSE) had been consumed in the United Kingdom. As soon as the first cases of BSE had been diagnosed, senior officials realised that BSE posed a possible risk to human health. However, UK policymakers’ chose to avoid taking any regulatory actions and decided to keep information about BSE from the public. By 1988, the British media began devoting more attention to the cattle disease and, for the first time, a small expert advisory committee was set up to provide advice on BSE. This only occurred at the insistence of the Chief Medical Officer at the Department of Health, who was not informed about the new disease until March 1988. Senior officials from the Ministry of Agriculture, Fisheries and Food introduced a slaughter and compensation policy for diseased cattle which, at the time, were being sold for human food. The delay in implementing the regulations also meant there had already been repeated human exposures to BSE (European Environment Agency, 2011[12]).

(Millstone and Van Zwanenberg, 2007[13]) find that the UK government claimed to be sensibly protecting public health, while in practice it “covertly subordinated the protection of public health to the support of agricultural sales, with a view to minimising state intervention and public expenditure.” According to the authors, if the UK government had adopted a “genuinely precautionary approach”, it would have necessitated, firstly, reforming policy institutions to separate responsibilities for regulation from those of sponsorship. Secondly, a precautionary approach would also have required acknowledging how little substantiated scientific information was available and engaging in open and accountable discussions about the possible costs and benefits of a wide range of different possible courses of action. The authors argue that separating the institutions between those who are responsible for providing the scientific advice, risk assessments and research to policymakers, would encourage more open discussion of possible risks. Lastly, the authors find that research conducted by a wide range of interdisciplinary groups, with open access to the evidence and data, would make it harder to conceal uncertainties (Millstone and Van Zwanenberg, 2007[13]).

Halocarbons

These substances include CFCs, HFCs and PFCs. Their use as refrigerants became widespread in the 1930s and subsequently in aerosol sprays. In 1974, scientists suggested that they could destroy the ozone layer. Some countries began to restrict or ban their use in 1977. In 1987, the Montreal Protocol provided for the phase-out of ozone depleting substances (European Environment Agency, 2013[14]).

Vinyl chloride

Following the first indications of risks to human health (skin and bone conditions, liver cancer) in the 1950s and 1960s, and after having denied the risks for some time, the chemical industry financed carcinogenic tests and then significantly lowered the exposure limits. The International Agency for Research on Cancer has recognised vinyl chloride as a “human carcinogen” since 1979 (European Environment Agency, 2013[14]).

Nanotechnology

The EC’s Recommendation on a code of conduct for responsible nanosciences and nanotechnology research (European Commission, 2009[15]) was designed to help foster collaboration and communication between relevant parties, including policymakers, researchers, industry and civil society. On the basis of a precautionary approach, France has introduced a mandatory nanotechnology reporting scheme, which requires companies to file a declaration for each nanomaterial they produce, import or distribute. It is argued (European Environment Agency, 2013[16]) that “political decision-makers have yet to address many of the shortcomings in legislation, research and development, and limitations in risk assessment, management and governance of nanotechnologies and other emerging technologies. If left unresolved, this could hamper society's ability to ensure responsible development of nanotechnologies”.

GMOs

A number of countries have established a moratorium on GMOs purportedly based on the uncertainty concerning their effects on public health and ecosystems. Critics contend that this moratorium could jeopardise food availability, especially in developing countries.

In an example of precautionary approach, under the EU Directive on the Deliberate Release of Genetically Modified Organisms, suppliers of GMOs have to demonstrate the safety of the organism before it is placed on the EU market (see Box A B.2 for an overview of selected examples of burden-of-proof provisions). There has been criticism that the principle is being applied selectively, with organisms that pose similar risks but have not been produced using genetic engineering not being subject to the same precautionary approach (European Commission, 2017[7]).

Box A B.2. Burden of proof and the release of GMOs

In 2001, the EU introduced legislation to reduce the risks related to the deliberate release of GMOs into the environment (**Directive 2001/18/EC**). The objective of the Directive — to protect human health and the environment—claimed support from the precautionary principle. Under the Directive, the burden of proof lies with suppliers of GMOs — i.e. the applicant for a GMO release is required to demonstrate safety, rather than regulatory agencies or third parties having to demonstrate a risk.

The **Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000)** allows countries to limit the use and release of GMOs in situations where there is scientific uncertainty regarding potentially adverse ecological and health effects. In this case, the precautionary principle was used to a lesser extent — as illustrated by the fact that the Protocol allows decision-makers to take protective measures in regard to the import of GMOs even if supporting evidence is lacking (provided those measures are cost-effective).

In the **Norwegian Gene Technology Act of 2 April 1993 No. 38 Relating to the Production and Use of Genetically Modified Organisms, etc. (amended 2005)**, the deliberate release of organisms may only be approved when there is no risk of adverse effects on health or the environment, placing the burden of proof firmly on the prospective producer. Significant weight when deciding whether to grant an application is also given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development. This legislation, therefore, makes strong use of the precautionary principle.

Source: (European Commission, 2017[7]).

The UK's experience with GMO regulation has also been discussed in academic literature in connection with the PP. The country's government initially saw GM crops as a potential new market, as no hazards had been shown by early research. Given spreading concerns, organisations such as the Royal Society for the Protection of Birds and Friends of the Earth called for GM crop development to be stopped. These concerns included whether GM crops, such as plants resistant to insect pests, might escape into wild populations and impact negatively on biodiversity, as well as potential impacts on human health. As a result, the UK Government delayed development of GM food crops until field trials had been completed. The government also formed a Cabinet Committee on Biotechnology and initiated public debate on genetic modification. The scientific review of GM crops found gaps in the knowledge base and it was therefore decided that approval of these products should be assessed on a case-by-case basis (European Environment Agency, 2013[14]).

Mobile phones and brain tumour risk

In 2011 the World Health Organization's International Agency for Research on Cancer (IARC) categorised the radiation fields from mobile phones and other devices that emit similar non-ionizing electromagnetic fields (EMFs) as a "possible" human carcinogen. Nine years earlier, the IARC had given the same classification to the magnetic fields from overhead electric power lines. The decision on mobile phones was principally based on two sets of case-control studies of possible links between mobile phone use and brain tumours: the IARC Interphone study and the Hardell group studies from Sweden. Both provided complementary and generally mutually supportive results.

There are by now several meta-analyses and reviews on mobile phones and brain tumours that describe the methodological limitations of the major studies published so far and the difficulties of interpreting their results. The fact that the mechanism for radiofrequency electromagnetic fields carcinogenesis is unclear seems to have supported the view that descriptive data on brain tumour incidence is of limited value. It is believed that precautionary actions to reduce head exposures would limit the size and seriousness of any brain tumour risk that may exist. Evidence is increasing that workers with heavy long-term use of wireless phones who develop glioma or acoustic neuroma as a result should be compensated. The first case in the world was established in October 2012. The Italian Supreme Court affirmed a previous ruling that the Insurance Body for Work (INAIL) must grant workers' compensation to a businessman who had used wireless phones for 12 years and developed a neuroma in the brain. It is acknowledged that the benefits of mobile telecommunications are many, but such benefits need to be accompanied by consideration of the possibility of widespread harms (European Environment Agency, 2013[14]).

Trade disputes

Asbestos

In a dispute concerning a French ban on asbestos and products containing asbestos, the WTO's Appellate Body confirmed that a country may take measures to protect human health from serious risks on the basis of a divergent opinion coming from qualified and respected sources. See below for further details.

Box A B.3. WTO upholds French and EU ban on asbestos

In 1997, France banned all forms of asbestos fibres and products in order to protect the health of workers and consumers. Existing "white" asbestos products could be exempt on an exceptional, temporary and annually reviewed basis, if no effective substitute materials were available that posed a lower health risk to workers handling them.

Canada objected to this ban at the WTO but the WTO found in favour of France in September 2000. Canada appealed to the Appellate Body of the WTO and the EU cross-appealed to uphold the main findings of the panel and to seek correction of some "errors" of the panel's interpretations and conclusions. The US cross-appealed against the panel's judgement that glass fibres were as carcinogenic as asbestos. The Appellate Body issued a report in early 2001 out of which a number of main points arose (with implications for other hazardous agents):

- All forms of asbestos ("white", "brown" and "blue") are carcinogenic.
- There is no known threshold of safety for this carcinogen.
- The risk from "white" asbestos in products is based on evidence which "tends to show" a risk rather than not.
- Workers handling asbestos products, such as building and brake lining workers, are at risk from asbestos exposure.
- There is no WTO requirement for countries to provide quantitative risk assessment data: qualitative evidence is sufficient.
- Countries can base their health/environment/animal welfare measures on qualified and respected scientific opinions held by only a minority of scientists: "a Member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion". This means that a WTO Panel need not necessarily reach its decision, on

the scientific evidence, based on a “preponderant weight of the evidence”, but on a lower level of proof.

- The efficiency of the “controlled use” of asbestos products was not demonstrated and the residual risk to the workers would still be significant; this risk management option could not be relied on to protect workers’ health, and therefore was not a reasonable “alternative” measure to the asbestos ban.
- In determining whether asbestos substitutes such as glass fibre were “like” products, four criteria have been developed by WTO, including the properties and end uses of a substance, and the tastes and habits of consumers. Based on these criteria, the Appellate Body found that the panel had erred in finding that glass fibre products were “like” products: they were not, principally because they were not as carcinogenic.

Source: (European Environment Agency, 2011[12]).

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[2] Cf. https://www.ensreg.eu/nuclear-safety-regulation/eu-instruments/Nuclear-Safety-Directive, retrieved 9 June 2022.

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[4] Beleidsgerei handreikingen voor risico-en veiligheidsvraagstukken Voorzorg Wat komt er allemaal bij voorzorg kijken? and Voorzorg Adequate voorzorg, verantwoorde en zorgvuldige omgang met nieuwe risico's (*Policy tool handouts for risk and safety issues Precaution What is involved in precaution? and Precaution Adequate precaution, responsible and careful handling of new risks*), Ministry of Infrastructure and Water Management.

Understanding and Applying the Precautionary Principle in the Energy Transition

The precautionary principle has been an important aspect of regulatory delivery for nearly four decades. Now widely applied and with a global reach, the principle is often invoked whenever the scientific evidence surrounding the safety of a given technology is not conclusive. It is often applied where a safety risk is known to exist, but the probability and magnitude of harm are uncertain or unknown. The principle thus supports — and is an important element of — risk-based regulation. It is an important principle for the energy transition, in particular, though it is complex to apply in practice. The safety risk of technologies supporting the energy transition is immediate, which can lead regulators to operate and apply the principle over-cautiously — sometimes to the extent of complete inaction. This report examines how the precautionary principle can be used to support flexible decision making by helping regulators and operators manage risk through positive action.

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