WP 2
D2.5 Comparison of case study analysis with results of WP1

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List of abbreviations

CSS	Chemical Safety for Sustainability
CDSS	Clinical Support Systems
EDCs	Endocrine Disrupting Chemicals
GMO	Genetically Modified Organism
LGMO	Law on Genetically Modified Organisms (Bulgaria)
Neonics	Neonicotinoid insecticides
NEST	New and emerging sciences and technologies
IRGC	International Risk Governance Council
PP	Precautionary Principle
RRI	Responsible Research and Innovation
RI	Responsible Innovation (RI)
SPIs	Science Policy Interfaces
SDGs	Sustainable Development Goals
WP	Work Package

Executive Summary

This report of the EU funded project entitled REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders (RECIPES) will compare the results of the inter-case study analysis with the results of WP1. First, the results of the WP1 Taking stock as a basis for the effect of the precautionary principle since 2000[1] are synthesized and compared with the likewise synthesized results of the comparative multiple case study analysis[2]. Second, the report gives an account of the scenario development and the co-creation process. Third, inconsistencies and conflict categories identified in WP1 and the multiple case study analysis are discussed in the context of responsible governance of technologies. Finally, links between identified inconsistencies in WP1 and categories of conflicts in WP2 are discussed.

The synthesis of the results of WP1 emphasizes the importance of key questions to be addressed within the conceptual core that forms the main components of the PP[3] and points to five main inconsistencies, the last under the term of context-specific problems.[4] This can be seen as sound scientific evidence why the identification of needs for regulatory improvement and application of the PP in practice is especially valuable in these fields. Against the backdrop of the analysis in WP1, the findings in the intra-case study analysis[5] point to three main dimensions - relevance, procedures[6] and effects. Within these three dimensions three conflict categories, namely conflicts of interest, conflicts on values and conflicts on knowledge[7] can be distinguished. Further conflicts can rise at distinct levels: within science, at the science-policy interfaces (SPIs), in public discourse.[8] This analytical grid of "dimensions", "conflicts categories" and "level of conflict" can serve as functional indicators for the identification of guidelines and tools.

At this stage task 3.1 of the RECIPES project is anticipated in order to contribute to the identification of a range of stakeholder needs for the future application of the precautionary principle in the EU. Three questions need to be asked in the context of the needs assessment in the RECIPES project.

1. First regarding the dimension of participation[9],

[1] Vos, E., & de Smedt, K. (2020). Report: Taking stock as a basis for the effect of the precautionary principle since 2000 (Deliverable No. WP1). RECIPES Project - REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders. www.recipes-project.eu

[2] Trescher, D., Sikma, T., & Schweizer, P.-J. (2020). *Inter-case study analysis—Identification of issues cutting across case studies* (WP2 Report D2.4.2 and D2.4.3). RECIPES Project. www.recipes-project.eu

[3] cf. Vos, E., & de Smedt, K. (2020, p.19).

[4] cf. Vos, E., & de Smedt, K. (2020, p. 94ff).

[5] Trescher, D., Sikma, T., & Schweizer, P.-J. (2020). Inter-case study analysis—Identification of issues cutting across case studies (WP2 Report D2.4.2 and D2.4.3). RECIPES Project. www.recipes-project.eu

[6] The last context related issue in the analysis of WP1 emphasizes that "a procedural interpretation of the precautionary principle must be added. As the precautionary principle does not dictate a specific outcome, the procedural rules aiming at reducing uncertainty become indeed particularly relevant. Cf. Vos, E., & de Smedt, K. (2020, p. 15).

[7] Böschen, S. (2010). Reflexive Wissenspolitik: die Bewältigung von (Nicht-) Wissenskonflikten als institutionenpolitische Herausforderung. In Umwelt- und Technikkonflikte (pp. 104-122). VS Verlag für Sozialwissenschaften.

[8] Van Enst, W. I., Driessen, P. P., & Runhaar, H. A. (2014). Towards productive science-policy interfaces: a research agenda. Journal of Environmental Assessment Policy and Management, 16(01), 1450007.

[9] Trescher, D., Sikma, T., & Schweizer, P.-J. (2020, p.15).

2 Second with respect to the organization and production of knowledge (networks) and expertise[10] and
3 Third focusing on the conceptional core, namely the uncertainty dimensions[11], surrounding both the likelihoods and outcomes of technological innovation, pointing towards which types of uncertainties and what the scope of those uncertainties are relevant for the application of the PP.

[10] Ibid p. 32
[11] Cf. the chapter on scientific uncertainty and risk on page 13 of this report.

1 Introduction

This document fulfils RECIPES delivery 2.5.1 Comparison of case study analysis with results of WP1.

This report will synthesise the results of the analysis WP 1 Taking stock as a basis for the effect of the precautionary principle since 2000[12] with the insights gained from the comparative multiple case study analysis[13]. Second, the report gives an account of the scenario development and the co-creation process. Third, inconsistencies and conflict categories identified in WP1 and the multiple case study analysis are discussed in the context of responsible governance of technologies. Finally, links between identified inconsistencies in WP1 and categories of conflicts in WP2 are discussed.

The purpose of the scenarios is to outline three different approaches to the implementation of the precautionary principle and how these may interplay with innovation. The scenarios were developed and selected by the consortium based on RECIPES results from a stocktaking exercise, citizen's meetings[14], the annual RECIPES conference in 2020, as well as comments and reviews by the RECIPES Advisory Board[15]. In addition, insights from the nine case studies and preliminary results from the case study comparison on the complexities of applying the precautionary principle in the context of different technologies have contributed to the specifications of challenges faced in each scenario[16]. The scenarios were to be challenged and improved. They are not different versions, let alone predictions, of the future. Importantly, they are not to be conceived as being mutually exclusive - elements of the scenarios can co-exist. Additionally, the scenarios were developed with a view to illustrating both typical and extreme PP implementations - as indicated by D.2.4.2 inter-case analysis[17] and D2.4.3 Identification of issues cutting across case studies.[18]

1.1 Context

This report is part of the EU funded project entitled REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders (RECIPES). The precautionary principle guides decision-makers faced with high risks, scientific uncertainty and public concerns. As a general principle of EU law, it allows deci-

[12] Vos, E., & de Smedt, K. (2020). *Report: Taking stock as a basis for the effect of the precautionary principle since 2000* (Deliverable No. WP1). RECIPES Project - REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders. www.recipes-project.eu
[13] Trescher, D., Sikma, T., & Schweizer, P.-J. (2020). *Inter-case study analysis—Identification of issues cutting across case studies* (WP2 Report D2.4.2 and D2.4.3). RECIPES Project. www.recipes-project.eu
[14] https://recipes-project.eu/sites/default/files/2020-03/Synthesis%20citizens%20meetings.pdf
[15] https://recipes-project.eu/about/advisory-board & https://recipes-project.eu/partners
[16] https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation
[17] Cf. Trescher, D., Sikma, T., & Schweizer, P.-J. (2020, p. 36)
[18] Cf. Trescher, D., Sikma, T., & Schweizer, P.-J. (2020, p. 14)

sion-makers to act despite scientific uncertainty. The precautionary principle has been criticised for hindering technological innovation, therefore some stakeholders have developed an innovation principle, which requires taking into account the potential impacts of precautionary action on innovation.[19] The RECIPES project aims to reconcile science, innovation and precaution by developing guidelines and tools, based on co-creation with stakeholders, to ensure that the precautionary principle is applied while still encouraging and/or aligning with innovation.

The RECIPES project comprises of three research phases. In the framing phase of the project, the RECIPES Consortium has examined the effects and the applications of the precautionary principle since 2000 by combining legal analysis, desk research and a narrative literature review, complemented with a media analysis of the public discourse around the principles of precaution and innovation, in order to understand the different stakeholder perspectives. In the analytical phase of the project, an innovative conceptual framework for comparative multiple case study analysis has been developed, in order to perform case-study analyses. In the co-creative phase of the project, scenario workshops will be combined with a multi-criterion assessment framework to develop and assess the appropriateness of the to-be-proposed guidelines and tools.

1.2 WP2 and this report

The overall aim of WP2 is to understand and lay out the differences in the application or potential application of the precautionary principle in nine different case topics, in a way that reflects the particular context of the case study topic. The multiple case study component of the RECIPES project is one of the key analytical phases of the project.
Within the scope of the entire RECIPES project, WP2 builds on aspects of WP1, in particular the report which presents the stock taking of the precautionary principle since 2000. In addition, WP2 feeds into WP3, the development of new tools and approaches to the PP in a co-creation approach, as well as ensuing communications in other work packages.

This document fulfils delivery 2.5.1 Comparison of case study analysis with results of WP1 and development of scenarios for the future of the precautionary principle and innovation in the EU. WP2 tasks 2.1-2.4 encompass the entire case study analysis component of WP2. Task 2.5.1 is thus the key linkage between WP2 (and aspects of WP1), and WP3 and the ensuing RECIPES project deliverables. The scenarios developed for task 2.5.1 will inform the development of tools and guidelines for policy makers in further RECIPES work packages.

[19] Vos, E., & de Smedt, K. (2020, p. 5)

The following table shows the nine case studies performed within the RECIPES project.

Table 1: Overview of case studies performed in the RECIPES project

D2.4.1: Intra case study analysis of 9 selected case studies	Authors
1. New gene-editing techniques (gene drives)	Rosanne Edelenbosch, Tijs Sikma, Petra Verhoef; Rathenau Institute
2. Genetically Modified Organisms (GMOs)	Ventseslav Kozarev, Zoya Damianova, Desislava Asenova; Applied Research and Communications Fund
3. Endocrine disrupting chemicals (EDCs)	Afke Groen, Christine Neuhold; Maastricht University
4. Neonicotinoid insecticides (Neonics)	Laura Drivdal, Jeroen P. van der Sluijs; University of Bergen
5. Nanotechnologies	André Gazsó, Anna Pavlicek; Institute of Technology Assessment, Austrian Academy of Sciences
6. Glyphosate	Sabrina Röttger-Wirtz, Maastricht University
7. Financial risks in urban infrastructure planning	Fritz-Julius Grafe, Harald A. Mieg; Humboldt-Universität zu Berlin
8. Artificial Intelligence in Health Care, clinical decision support systems (CDSS)	Tijs Sikma, Rosanne Edelenbosch, Petra Verhoef; Rathenau Institute
9. Microplastics in food products and cosmetics	Miriam Urlings, Maastricht University

Delivery 2.2 has detailed the methodological framework for carrying out the RECIPES case studies. Delivery 2.3 has introduced the RECIPES WP2 case studies and explained the case study selection process that was used to select the cases.

The methodological framework for the identification of issues cutting across multiple case studies has been detailed in delivery 2.2. Delivery 2.4.1 presents the intra-case study analysis of each case based on the methodological framework. Delivery 2.4.2 compares the nine case studies along the dimensions identified by the methodological framework. The results are presented at the end of this report in table to provide an at a glance overview and to allow for easier navigation between and across case studies.

In D2.4.3 "Identification of issues cutting across multiple case studies", the research focuses on the complexities and controversies which cut across the cases. They are identified based on epistemological challenges in risk governance, namely complexity, uncertainty and ambiguity. The guiding research questions and the results of the case study comparison can be found in report D2.4.2 in appendix 6.1.

2 Synthesis of WP1

The report WP1 D1.1 provides a comprehensive overview of the application of the PP since 2000.[20] In the following, the main aspects of the conceptual core and the context-specific problems outlined in the report of WP1 are sketched out.

2.1 The conceptual core of the PP

The analysis in WP 1 identified a 'conceptual core'[21] of the principle, based on various definitions and understandings of the principle, that forms the main components of the PP. RECIPES takes scientific uncertainty and risk, scientific evaluation, threshold of damage, cost-effective measures/ proportionality, burden of proof and provisional character to form the main components of the precautionary principle.[22] These key issues are addressed in the following synopsis of the conceptual core.

2.1.1 Scientific uncertainty and risk

The PP deals with scientific uncertainty. Stirling (2008) describes the conventional science-based understanding of risk as the combination of what may happen – the hazards, possibilities, outcomes – with the likelihood that it might happen.[23] This conventional view implies that the outcomes and likelihoods of those outcomes are known, and thus that level of risk can be calculated by combining probability and severity. However, invoking uncertainty surrounding both the likelihoods and outcomes of technological risks, we define risk as uncertainty about and severity of the consequences or outcomes of an activity with respect to something that humans value. [24] It is this latter type of uncertainty within risk that is of relevance in the context of the precautionary principle[25], namely the uncertainty surrounding both the likelihoods and outcomes of technological innovation. However, there is no consensus about the specific features of uncertainty.[26] This raises two main questions. First, which types of uncertainty are concerned? Second, what is the scope of those uncertainties?

[20] Vos, E., & de Smedt, K. (2020). Report: Taking stock as a basis for the effect of the precautionary principle since 2000 (Deliverable No. WP1). RECIPES Project - REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders. www.recipes-project.eu
[21] Cameron, J., 'The Precautionary Principle in International Law', in 'O Riordan, T., Cameron, J., Jordan, A., (eds.) Reinterpreting the Precautionary Principle, London: Cameron May 2001, p. 116.
[22] cf. Vos & Smedt (2020)
[23] Stirling, A., 'Science, precaution, and the politics of technological risk: Converging implications in evolutionary and social scientific perspectives', Annals of the New York Academy of Sciences 1128 (1):95 – 110, May 2008, p. 98.
[24] Aven, T., and Renn, O., Risk Management And Governance, Springer, Berlin, Heidelberg, 2010.
[25] Ibid. Vos & de Smedt (2020), p. 155.
[26] Aven, T, 'On Different Types of Uncertainties in the Context of the Precautionary Principle'. Risk Analysis, Vol. 31, No. 10, 2011, p. 1516.

2.1.2 Scientific grounding

The fact that in cases of scientific uncertainty no full risk assessment can be carried out[27] is no leeway to adopt measures not being based on science. The report of WP1 emphasises, that "[S]ome form of scientific evaluation or analysis is mandatory; imaginary issues are not enough to trigger the precautionary principle. Grounds for concern that can trigger the precautionary principle are limited to those concerns that are plausible or scientifically tenable." The European Commission refers in its Communication[28] to 'reasonable grounds'. The term "reasonable grounds" refers to situations where there are scientific reasons for concern. These concerns are based on empirical input and/or modelling outputs which lead to the plausible scientific hypothesis that serious harm appears possible. In the Pfizer case[29] the European Court requires 'as thorough a scientific risk assessment as possible, account being taken of the particular circumstances of the case at issue'.[30]

2.1.3 Threshold of damage

Another common feature of definitions regarding the precautionary principle concerns the threshold of damage to health or the environment that should be reached before any precautionary measure has to be adopted by the EU authorities or Member States. Numerous international instruments refer to threats of 'serious' or 'irreversible' damage, which constitutes a very high threshold, whereas others only require the existence of a 'significant' damage.[31] What these different clauses have in common is that they express a moral judgement about the acceptability of the harm. The formulation by the EU legislator is more loose and speaks of the 'possibility of harmful effect', whilst the European Courts frame this in loose terms, speaking of 'the existence or extent of risks to human health', 'the possibility of harmful effects on health' and likelihood of real harm to public health'.[32]

2.1.4 Cost-effective measures/proportionality

Most definitions of cost effective measures require an evaluation of the different possible actions, and hold that cost-effective measures should be taken, as for example provided for by Principle 15 of the Rio Declaration. According to some inpre-

[27] This refers to the problem that in cases of scientific uncertainty there are at least limits in the availability of data concerning toxicology or exposition of humans. Therefore a full risk assessment cannot be carried out.
[28] EU Commission. (2000). Communication from the Commission on the precautionary principle. https://op.europa.eu/en/publication-detail/-/publication/21676661-a79f-4153-b984-aeb28f07c80a/language-en
[29] Cash e T-13/99 Pfizer, para 162.
[30] Vos & de Smedt (2020, p. 83)
[31] Grimeaud, D., 'The precautionary principle in international environmental and trade law' in Faure, M., and Vos E., (eds.), Juridische afbakening van het voorzorgsbeginsel: mogelijkheden en grenzen, The Hague, 2003, p. 71.
[32] Vos & de Smedt (2020, p. 156)

tations, in the specific context of Principle 15, this obligation would constitute the obligation of the regulator of an activity to opt for the 'least economically cumbersome' precautionary measures.[33] At EU-level, overall, actions taken on the basis of the precautionary principle should be proportional to the chosen level of protection and the magnitude of the possible harm. This is in line with the Commission's Communication and the Courts' case law.

2.1.5 Burden of proof

Some definitions of the PP also entail a reversal of the burden of proof. Indeed, contrary to the traditional approach[34], whereby the burden of proof would be on the EU authorities to prove that a product is harmful in order to prohibit this product to access the EU market, some precautionary provisions require that the person engaging in a given activity or action, either it be a polluting state or a manufacturer releasing potentially dangerous products or substances into the environment, prove that it will not harm it. The World Charter for Nature, for example, imposes on the person or collective actor wishing to engage in a certain activity to demonstrate that the benefits of this activity will outweigh its costs – and that, consequently, results in a shift of the burden of proof 'from the regulator and onto the regulated party'.[35] The European Commission's view in its Communication is that with prior approval mechanisms, the burden of proof is placed on the manufacturer, whilst in absence of such mechanisms. This should not be the general rule; but may be applied *ad hoc* depending on the specific case.

2.1.6 Provisional character

Both the analyses of international and EU law make state clearly that the PP instructs to adopt only temporary measures that will be reviewed after a certain period of time.

2.2 Context specific issues

The analysis made in WP 1 emphasizes that there is no single definition of the precautionary principle in the EU legal acts. This is advantageous as it leaves ample room for flexibility and ad hoc solutions for context-specific problems to be tackled.

[33] Zander, J., The Application of the Precautionary Principle in Practice, Comparative Dimensions, Cambridge University Press, New York, 2010, p. 37.
[34] The burden of proof normally is on the person who brings a claim in a dispute (in this case, the person who suffers damage). Reversal of the burden of proof means that the manufacturer has to proof that there is no harm.
[35] Zander, J., The Application of the Precautionary Principle in Practice. Comparative Dimensions, Cambridge University Press, New York, 2010, p. 36 and 37.

In this regard the analysis identified context-specific issues which can be summarized in the following line of arguments for the improvement of current institutional practice.

1. Although the European Courts have codified the definitions and requirements for application of the PP, the Court is at times inconsistent in applying the PP. The Court struggles with the application in some specific cases. The Court's review of the application of the PP is limited and leaves ample room for the Commission to exercise its discretionary powers.[36]
2. The Court's review looks at manifest errors and often lacks consistency. Importantly, the Court has largely ignored reviewing the temporary nature of a precautionary measure. The WP 1 report concludes that although the EU courts have followed the 2000 Communication in general, some judgments seem to overlook the "dynamics of science", e.g. new scientific evidence questioning prior judgement. Therefore the Commission's Communication requires that precautionary measures should be provisional measures pending a reduction in the scientific uncertainty. However, this issue still needs to be addressed by the EU Courts.[37]
3. The legal analysis reveals that the criteria for precautionary action, as described in the Communication are not consequently followed by the EU policy makers or the European Courts.[38]
4. Regarding risk assessment and impact assessment the following can be observed. In the case of risk regulation, for non-legislative regulatory initiatives, impact assessments are carried out where there is sufficient discretion and/or the decision deviates from the advice of risk assessors.[39] In the literature it is stressed that the purpose of an impact assessment in the field of risk is to control discretion, especially in cases where risk managers decide to deviate from the advice of risk assessors.[40] Where regulatory initiatives entail significant impacts, the results of risk assessment need to feed into the impact assessments for assessing and selecting different policy options. Both risk assessment and impact assessment aim to control the Commission's discretion[41] (in other words the assessment of the Commission) and to 'rationalize' its choice for a specific risk management (precautionary) measure by subjecting it to scientific and economic expert scrutiny.[42]

[36] cf. Vos & de Smedt (2020, p. 91)
[37] See also Rogers M.D., 'Risk management and the record of the precautionary principle in EU case law', Journal of Risk Research, 14 (4), 2011, p. 481.
[38] cf. Vos & de Smedt (2020, p. 91)
[39] European Commission, Better regulation Toolbox; http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf
[40] Weimer, M., Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology, Oxford, 2019, Oxford University Press, p. 77.
[41] Discreation refers to the term discretionary powers, in other words assemment of the EU Commission and its agencies for risk assessment.
[42] Weimer, M., Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology, Oxford, 2019, Oxford University Press, p. 77.

5 Besides the three interpretations 'weak-moderate-strong'[43] of the precautionary principle, a procedural interpretation of the precautionary principle must be added. As the precautionary principle does not dictate a specific outcome, the procedural rules aiming at reducing uncertainty become indeed particularly relevant.[44] Some scholars argue that the most important procedural aspects of the precautionary principle are the duty of re-examination, proportionality, and cost-benefit consideration.[45]

[43] Vos, E., & de Smedt, K. (2020). Report: Taking stock as a basis for the effect of the precautionary principle since 2000 (Deliverable No. WP1). RECIPES Project - REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders. www.recipes-project.eu

[44] Haritz, M., An Inconvenient Deliberation. The Precautionary Principle's Contribution to the Uncertainties surrounding Climate Change Liability, Wolter Kluwer, 2011, p. 129.

[45] Scott, J., 'The precautionary principle before the European Courts', in Macrory, R. (ed.), Principles of European Environmental Law, Europa Law Publishing, Groningen, 2004, p. 66.

3 Synthesis of inter-case study analysis

The main research goal of WP2 is to better understand the complexities and controversies around the application of the PP. The analysis focuses on the leading questions.

- What are the complexities, uncertainties and ambiguities associated with the case studies?
- How have these issues been discussed by various relevant actors (legal, policy makers, the risk community, NGOs, industry, the public)?

3.1 Core dimensions of complexities, uncertainties and ambiguities

In intra-case studies analysis the main analytical dimensions (complexity, uncertainty and ambiguity[46]) are brought together with the three types of conflicts which gave rise to major controversies.[47] The results of the report indicate that there are three main dimensions which need to be considered in the forthcoming process of the RECIPES project: 1. issues regarding relevance of the PP, pointing towards content-related issues, 2. issues regarding procedures, pointing towards context-related issues, and 3. issues regarding the effects of the PP. These three dimensions can serve as a reasonable analytical grid to contribute to an improved alignment of the PP and responsible innovation.

In the three dimensions the following cross cutting issues emerge.

1. In the dimension relevance of the PP the main issues are: 1. layers of uncertainty, 2. aspects of hazard, 3. weighing of benefits and uncertainties, 4. the difficulty of prevalence and path dependencies.
2. In the dimension procedures regarding the application of the PP the pivotal themes are: 1. the meaning of framing in the discourses, 2. the meaning of the PP and its measures, 3. the organization of knowledge networks, 4. cost benefit analysis and proportionality.
3. In the dimension effects of the application of the PP for responsible innovation two aspects need to be considered: 1. incremental versus radical regulation and/or innovation, 2. alternative innovation pathways.

3.2 Findings in the dimensions relevance, procedures, effect

Against this background five insights can be summarized.

[46] IRGC (2018). Guidelines for the Governance of Systemic Risks. Lausanne: International Risk Governance Center (IRGC).
[47] Böschen, S. (2010). Reflexive Wissenspolitik: die Bewältigung von (Nicht-) Wissenskonflikten als institutionenpolitische Herausforderung. In Umwelt-und Technikkonflikte (pp. 104-122). VS Verlag für Sozialwissenschaften.

1 Informed by the analysis in WP1 the findings in the inter-case study analysis reveal that scientific uncertainty lies indeed at the core of the PP. The key question derived from the insight is how can different types and different scopes of uncertainties be analysed and assessed by risk assessors. A reasonable and conceptual basis to answer is provided by Walker et al. in the uncertainty matrix, a conceptual basis for uncertainty management in model-based decision support.[48] The better regulation tool box of the EU Commission addresses issues of uncertainty in scientific assessments[49], e.g. as outlined in tool #62, which is about the use of analytical models and methods.[50] An amendment to the toolbox may better inform risk assessors on the applicability of the PP in the case of accumulated uncertainties. Understanding the issues of complexity and scientific uncertainty requires a good grasp of the multifaceted social context in which the technology is introduced.[51] For instance, the unpredictability and complexity of a healthcare system, the many variables and interactions at play in ecosystems (EDCs, glyphosate, nanotechnology, GMOs, gene drives) or the intersection of social systems with financial systems (financial risks in water infrastructure planning) point towards the importance of situational context.

2 Another key finding with regard to the issue of the organization of knowledge networks, the scale and scope of the associated issues point to the need for more transdisciplinary knowledge networks. They should, for instance, should be organized so that problems addressed in the Global Sustainable Development Goals (SDGs) gain priority and the development of a specific technology is viewed as one possible way to resolve one or several of these issues. This requires a trusted platform of deliberation to identify, structure, and evaluate the available information on the technology even in an early stage. [52] These transdisciplinary knowledge networks focus on investigating current and future societal needs. Technology development should be focussed on answering these needs and requirements.

3 The analysis of the complexities and controversies in the intra-case study analysis indicate that the two main reasons for controversies and disputes are located at conflicts between claims of evidence and values.[53,54] Therefore dealing with normative issues and assumptions with regard to knowledge, interests and values is crucial because at this point conflicts rise due to pressure from various sources. The core line of conflicts becomes evident when science becomes in-

[48] Walker, W. E., Harremoës, P., Rotmans, J., van der Sluijs, J. P., van Asselt, M. B. A., Janssen, P., & Krayer von Krauss, M. P. (2003). Defining Uncertainty: A Conceptual Basis for Uncertainty Management in Model-Based Decision Support. Integrated Assessment, 4(1), 5–17.
49 cf. Aven, T. (2017). Further reflections on EFSA's work on uncertainty in scientific assessments. Journal of Risk Research, 1–9.
[50] EU Commission. (2017, p. 508). Better regulation tool box. https://ec.europa.eu/info/files/better-regulation-toolbox-1_en / tool #62. The use of analytical models and methods
[51] Trescher, D., Sikma, T., & Schweizer, P.-J. (2020). Inter-case study analysis—Identification of issues cutting across case studies (WP2 Report D2.4.2 and D2.4.3). RECIPES Project. www.recipes-project.eu, p. 12.
[52] ibid, p.20
[53] Linkov, I., Anklam, E., Collier, Z. A., DiMase, D., & Renn, O. (2014). Risk-based standards: integrating top–down and bottom–up approaches. Environment Systems and Decisions, 34(1), 134-137.
[54] Renn, O. (2008). White paper on risk governance: Toward an integrative framework. In Global risk governance (pp. 3-73). Springer, Dordrecht.

volved in policy decisions and when complicating factors such as uncertainty, complexity and ambiguity are brought into the picture.[55] This includes the interplay of human agency[56] within the context of regulation, innovation, legal decision-making, changing societal values, and vested interests, which adds yet another level of complexity than the technological system alone. This raises the question how different knowledge and evidence claims, norms and values can be compared, evaluated and assessed and how the results feed into scientific policy advice and collectively binding legitimate decision making. Therefore, more integrative risk governance frameworks[57] could provide guidance for institutional reform and better regulation.[58]

4 The meaning of evidence is twofold. First, the scientific evidence gained in the intra- and inter-case study analysis, obtained through systematic research and evaluated according to established methodology and rules, is essential for understanding complex natural, technological as well as social phenomena and, therefore, for making informed decision. Second, for the policymaking process the scientific advice itself must always be evidence-based[59]. The results of the intra-case study comparison and the literature indicate that the compiled knowledge needs to build on robust scientific evidence[60] which needs to be contextualized e.g. in participatory processes, so that evidence-based knowledge can evolve into evidence-informed collectively binding legitimate decisions. In other words, besides the evidence gained from scientific research and risk and uncertainty assessment, the knowledge and dialogue with stakeholders in participatory processes can contribute to a better understanding at the science-policy interfaces.[61]

5 The results from the case study comparison indicate that the application of the PP has had a positive effect on incremental innovation in many cases. Furthermore, the application of the PP contributed (if it was applied in the case) often to alternative, more responsible innovation pathways, e.g. green chemistry, new plant protection technologies and non-chemical alternatives to

[55] Renn, O., Baghamian, M., & Capaccioli, M. (2019, p. 46f). Making sense of Science for policy under conditions of complexity and uncertainty. SAPEA.
[56] In the shortest version human agency can be understood as a person's capacity for action. On the capability approach of Sen and Nussbaum and its normative foundation of agency and can reconfirm sociological theory's explanatory capacities. Cf. Gangas, S. (2016). From agency to capabilities: Sen and sociological theory. Current Sociology, 64(1), 22–40.
[57] cf. white paper towards and integrative risk governance framework (Renn 2008) or integrating approaches in Food Safety Governance (Renn & Dreyer 2009)
[58] Trescher, D., Sikma, T., & Schweizer, P.-J. (2020, p. 19)
[59] Renn, O., Baghamian, M., & Capaccioli, M. (2019, p. 82)
[60] Nowotny et al suggest that scientific knowledge, in other words evidence-based knowledge needs to be contextualized, because it is no longer sufficient, because in more open knowledge environments that are now emerging, knowledge also needs to be 'socially robust', because its validity is no longer determined solely, or predominantly, by narrowly circumscribed scientific communities, but by much wider communities of engagement comprising knowledge producers, disseminators, traders, and users.
[61] cf. Renn, O., Baghamian, M., & Capaccioli, M. (2019, p. 45ff.)

pest management, green nanotechnology and safe-by-design approaches in nanotechnologies.[62]

Based on the nine intra-case study analyses, the case study comparison aims to draw lessons from concrete cases in which the precautionary principle was (or could have been) applied in relation to a presumed socio-technological or socio-economic innovation. The lessons from the intra-case study analysis are provided in an overview in report D4.2.3.[63]

[62] Trescher, D., Sikma, T., & Schweizer, P.-J. (2020, p. 13). *Inter-case study analysis—Identification of issues cutting across case studies* (WP2 Report D2.4.2 and D2.4.3). RECIPES Project. www.recipes-project.eu

[63] Ibid. Trescher, D., Sikma, T., & Schweizer, P.-J. (2020, p. 30ff)

4 Development of the scenarios

4.1 1 Aim of the workshop

The overarching goal of the workshop is to identify needs for guidelines and tools for the EU and its member states to best govern uncertain risks related to innovation, with a focus on the precautionary principle.

In the information package, which was sent to all participants prior to the workshop, three scenarios where outlined. The scenarios represent different practical elaborations of viewpoints on how to improve the implementation of the precautionary principle. The scenarios are based on RECIPES results from a stocktaking exercise in WP1, citizen's meetings, internal project workshop, and reviews from the RECIPES Advisory Board[64]. In addition, nine case studies on the complexities of applying the precautionary principle in the context of different technologies have contributed to the specifications of challenges faced in each scenario.[65]

The scenario method is used to develop mutual understanding and to work towards shared solutions. The scenarios are therefore discussed, challenged and improved by the collaborative effort of the participants. In fact, choosing and combining elements from the scenarios may help to construct a fourth scenario with an optimal combination of elements. This shared vision can make it possible to identify solutions to current challenges experienced with the implementation of the precautionary principle. This way, the three scenarios will feed into the RECIPES process of designing new tools and guidelines for the precautionary principle in respect to reconciling precaution and innovation.

4.1.2 Method

For the workshop we use the method called 'Scenario Workshop'. The scenario workshop is a technique for analysing possible future events by considering alternative possible outcomes. The given scenario does not show the exact picture of the future, rather they present several alternative futures by extrapolating from past trends.[66] Thus, scenario workshops aim at supporting improved risk management by allowing consideration of possible future outcomes and their implications. The scenarios focus on future implementation of the PP and responsible technological innovation governance[67] in relation to different technology areas.

The scenario workshop is an instrument for participatory planning, based on dialogue and collaboration between stakeholders, experts, and policy makers. The method aims to stir dialogue, provide the opportunity for exchanging experience

[64] RECIPES advisory board members: https://recipes-project.eu/about/advisory-board and RECIPES project partners https://recipes-project.eu/partners
[65] cf. https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation
[66] Bishop, P., Hines, A., & Collins, T. (2007). The current state of scenario development: An overview of techniques. *Foresight*.
[67] Distinct frameworks are provided by Owen et al. (2012) and Schomberg (2014) and Owen, R., Macnaghten, P., Stilgoe, J. (2012). Responsible research and innovation: From science in society to science for society, with society. Science and Public Policy, 39, 751-760. Von Schomberg, R. (2014). The quest for the 'right' impacts of science and technology: A framework for responsible research and innovation. In: van den Hoven et al. (eds.), *Responsible Innovation I: Innovative Solutions for Global Issues*. Dordrecht: Springer, 33-50.

and knowledge about existing barriers and possible solutions, enhance the understanding on the central topic/problem of discussion, and facilitate consensus on proposed solutions among the involved. A more detailed general overview of the method can be found in the Engage2020 Action Catalogue.[68]

4.1.3 The scenarios in short

Central to the workshop are three scenarios that outline three different approaches to the implementation of the precautionary principle and how this may interplay with innovation.

The three scenarios should not be conceived as being mutually exclusive. Choosing and combining elements from the scenarios may help to construct a fourth scenario with an optimal combination of elements in a shared vision of a desirable future as well as to identify which actions are necessary to fulfil the vision.

The three scenarios and the underpinning key elements occur as a result of process within the RECIPES project which took off with a study on the implementation of the principle in the EU since 2000, 5 member states studies and 9 in depth-case studies on how the precautionary principle was, and is currently implemented, in relation to a series of products and technologies, including some new and emerging technologies.

Box 1: The three scenarios

All scenarios are different possible interplays between technological innovation and the structures and practices for the implementation of the precautionary principle.

- The first scenario describes business as usual, the current situation.
- The second scenario puts more emphasis on the furthering of innovation to benefit sustainability.
- The third scenario focuses on democratic aspects of innovation, promoting a stronger, wider and more inclusive implementation of the precautionary principle.

The purpose of the three scenarios is to facilitate dialogue and discussions amongst a group of invited stakeholders on the three scenarios. These three scenarios were discussed at a series of three workshops amongst stakeholder groups identified in the RECIPES project between June and September 2020.[69] Each scenario was discussed and criticized, and the participants also presented their own visions and suggested thoughts and possible actions to move forward.
Although there are varying perceptions of how successful the current implementation of the precautionary principle is in the EU of today, and thus also on how to

[68] The Engage2020 Action Catalogue is an online decision support tool that is intended to enable researchers, policy-makers and others wanting to conduct inclusive research, to find the method that is best suited for their specific project needs. http://actioncatalogue.eu/method/7453
[69] details on the workshops are detailed in the annex of this report

adjust and improve its implementation, the three scenarios and these deliberations served to fuse together inputs for a proposed vision for the future implementation of the precautionary principle in the EU.
The proposed vision will be used for further deliberations with stakeholder in WP 3 task 3.1 needs assessment.

4.1.4 Workshop structure and overview

The workshop discussions are structured in three phases, that all feed into each other.

Box 2: Workshop structure

1. **Phase 1: Critical Discussion**
   What do the three scenarios lack? What aspects, values and perspectives are not included in the precautionary principle's current forms of implementation? What challenges does it bring?
2. **Phase 2: Formulation** of shared visions for reconciling precaution & innovation
   Based on the critique - How should concerns to innovation, the environment, societal issues be valued in the precautionary principle? What constitutes a good 'tool' and a 'guideline' in this context?
3. **Phase 3: Actions**[70]
   Identifying barriers for your visions and propose how these can be overcome by discussing input and ideas for aspects to be included in tools and guidelines for the implementation of the precautionary principle in relation to innovation.

The four consecutive sessions of the scenario workshop were executed as follows: Introduction (06/09/2020), phase 1: critique (06/10 .06/11/2020), phase 2: visions (06/15 – 06/16/2020), phase 3: actions (September 2020 – February 2021).

In June and September 2020 the RECIPES workshop on Reconciling Precaution and Innovation took place with 18 participants in the June workshop and 28 in the workshop starting September. The overarching goal of the workshop was to identify needs for guidelines and tools for the EU and its member states to best govern uncertain risks related to innovation, with a focus on the precautionary principle. The digital Workshops were organized by the RECIPES project partner Danish Board of Technology Foundation (DBT), a non-profit, common good foundation, with more than 30 years of experience in stakeholder involvement in research and innovation.

Workshop structure and overview
The workshop discussions are structured in three phases, that all feed into each other:
Phase 1: Critical Discussion

[70] Phase 3 took place during the RECIPES workshop from September 2020 until February 2021.

What do the three scenarios lack? What aspects, values and perspectives are not included in the precautionary principle's current forms of implementation? What challenges does it bring?

Phase 2: Formulation of shared visions for reconciling precaution & innovation

Based on the critique - How should concerns to innovation, the environment, societal issues be valued in the precautionary principle? What constitutes a good 'tool' and a 'guideline' in this context?

Phase 3: Actions1

Identifying barriers for your visions and propose how these can be overcome by discussing input and ideas for aspects to be included in tools and guidelines for the implementation of the precautionary principle in relation to innovation.

It is important to acknowledge that this report is being written after the development and execution of task 3.1 which relates to the difficulties resulting from the ongoing pandemic (COVID-19). Therefore the results of this report mainly feed into report D3.2.

The agendas for the workshops and the complete outline of scenarios 1-3 are detailed in annex 6.2 of this report.

5 Discussion of results of the synthesis

5.1 A link between identified inconsistencies in WP1 and categories of conflicts identified in WP2

In the following, the main results of the legal analysis in WP1 and the case study comparison in WP2 are brought together in order to gain insights for the development of guidelines and tools for the realignment of science, precaution and responsible innovation.

As the report WP 1 states it is important to acknowledge the fact that there is no single definition of the PP in the EU legal acts is advantageous because it leaves ample room for the Commission to exercise its discretionary powers.

Nevertheless, the synthesis of the results of WP1 emphasize the importance of key questions to be addressed within the conceptual core of the PP and point to five main inconsistencies, the last under the term of context-specific problems.[71] This can be seen as sound scientific evidence why the identification of needs for regulatory improvement and application of the PP in practice is especially valuable in these fields.

Against the background of the analysis in WP1, the findings in the intra-case study analysis[72] point to three main dimensions - relevance, procedures[73], effects - with three conflict categories, namely conflicts of interest, conflicts on values and conflicts on knowledge[74] at distinct levels: within science, at the science-policy interfaces, in public discourse.[75] These levels of substantial conflict therefore serve as indicators, where it is especially valuable to identify needs for the development of guidelines and tools. First, conflicts perceived as inconsistencies stemming from different types, different scopes of uncertainties and the applicability of the PP in the case of accumulated uncertainties. Second, another key finding is with regard to the issue of the organization of knowledge. These issues point to the need that transdisciplinary knowledge networks. For instance these should be organized so that problems addressed in the Global Sustainable Development Goals (SDGs) gain priority and the development of a specific technology is viewed as one possible way to resolve one or several of these issues. These transdisciplinary knowledge networks are required to focus on investigation of current and future societal needs.

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[71] Cf. Vos, E., & de Smedt, K. (2020). *Report: Taking stock as a basis for the effect of the precautionary principle since 2000* (Deliverable No. WP1). RECIPES Project - REconciling sCience, Innovation and Precaution through the Engagement of Stakeholders. www.recipes-project.eu

[72] Trescher, D., Sikma, T., & Schweizer, P.-J. (2020). Inter-case study analysis—Identification of issues cutting across case studies (WP2 Report D2.4.2 and D2.4.3). RECIPES Project. www.recipes-project.eu

[73] The last context related issue in the analysis of WP1 emphasizes that "a procedural interpretation of the precautionary principle must be added. As the precautionary principle does not dictate a specific outcome, the procedural rules aiming at reducing uncertainty become indeed particularly relevant. Cf. Vos, E., & de Smedt, K. (2020, p. 15).

[74] Böschen, S. (2010). Reflexive Wissenspolitik: die Bewältigung von (Nicht-) Wissenskonflikten als institutionenpolitische Herausforderung. In Umwelt-und Technikkonflikte (pp. 104-122). VS Verlag für Sozialwissenschaften.

[75] Van Enst, W. I., Driessen, P. P., & Runhaar, H. A. (2014). Towards productive science-policy interfaces: a research agenda. Journal of Environmental Assessment Policy and Management, 16(01), 1450007.

Third, most important with regards to the key challenges complexity, uncertainty and ambiguity, the intra-case study analysis indicates that the pivotal link in conflicts lies between claims of evidence and values.[76] Therefore there is a need for integration of competing and controversial knowledge claims. This raises the question how different knowledge and evidence claims, norms and values can be compared, evaluated and assessed? Fourth, the scientific evidence gained in the intra- and inter-case study analysis, is essential for understanding complex natural, technological as well as social phenomena and for making informed decision. Following Newton et al (2001) this means that the compiled knowledge builds on robust scientific evidence [77] which needs to be contextualized e.g. in participatory processes, so that evidence-based knowledge can evolve into evidence-informed knowledge at the science-policy interface, where different roles of scientific evidence such as quality control, questions of efficacy of scientific advice and norm and expectations at intersections of science, policy and practice need to be distinguished.[78]

5.2 Challenges in conflicts over knowledge and values

The results of the intra-case study analysis point towards the importance of conflicting claims over knowledge and or values, sometimes both at the same time. It is important to emphasize that in many cases decisions on important issues must be made under conditions when 'facts are uncertain, values in dispute, stakes high and decisions urgent'. [79] Therefore, value conflicts and competing problem framings need to be resolved or taken into account in decision-making. [80]

The articulation of values and alternative perspectives guides the selection of evidence and helps identify decision alternatives. Clarifying value conflicts is essential to improve the interaction of all actors involved. Responsible Research and Innovation (RRI)[81] or Responsible Innovation (RI) are frameworks which aim to start discussions about values, norms and ethical matters which take different forms of evidence and understanding into account.[82]. Von Schomberg & Hankins argue that "science and innovation policy is most often introduced as a goal in itself, following an ideology based upon the belief that promoting science and technology (notably with financial incentives and support) will contribute to economic growth". Further

[76] Linkov, I., Anklam, E., Collier, Z. A., DiMase, D., & Renn, O. (2014). Risk-based standards: integrating top–down and bottom–up approaches. Environment Systems and Decisions, 34(1), 134-137.
[77] Nowotny et al (2001) suggest that scientific knowledge, in other words evidence-based knowledge needs to be contextualized, because it is no longer sufficient, because in more open knowledge environments that are now emerging, knowledge also needs to be 'socially robust', because its validity is no longer determined solely, or predominantly, by narrowly circumscribed scientific communities, but by much wider communities of engagement comprising knowledge producers, disseminators, traders, and users.
[78] Renn, O., Baghramian, M., & Capaccioli, M. (2019, p. 45ff.). Making sense of Science for policy under conditions of complexity and uncertainty. SAPEA.
[79] Funtowicz & Ravetz (1993)
[80] Grove-White, R., Macnaghten, P., Mayer, S., & Wynne, B. (1997). Uncertain world: Genetically modified organisms, food and public attitudes in Britain. Lancaster: University of Lancaster, Centre for the Study of Environmental Change.
[81] Owen, R., Macnaghten, P., Stilgoe, J. (2012). Responsible research and innovation: From science in society to science for society, with society. Science and Public Policy, 39, 751-760.
[82] Owen, R., Pansera, M. (2019). Responsible Innovation and Responsible Research and Innovation. In: Simon, D., Kuhlmann, S., Stamm, J., Canzler, W. (eds.), Handbook on Science and Public Policy. Edward Elgar Publishing, 6-48.

"RI is critical of the dominant global economic paradigm through highlighting that there are market deficits in delivering innovations on societally desirable goals".[83] Governance understood as a concept to "steer the innovation process towards societally beneficial objectives."[84] Following von Schomberg, the "question on how to define positive outcomes or 'the right impacts' of innovation can be found in the normative anchor points in basic treaties and constitutions." So how can RRI criteria be better embedded and aligned with societal needs? With regards to the question what 'ethical acceptability', 'sustainability', or 'social desirability' mean, however, has yet to be satisfactorily put into deliberative practice. One reason for this is that, in a pluralistic society, normative parameters cannot be defined a priori and cannot be established by experts alone but must instead be deliberated by a broad range of societal actors".[85]

At this stage task 3.1 of the RECIPES project is anticipated in order to contribute to the identification of a range of stakeholder needs for the future application of the precautionary principle in the EU. Three questions need to be asked in the context of the needs assessment in the RECIPES project.

1. First regarding the dimension of participation[86],
2. Second with respect to the organization and production of knowledge (networks) and expertise[87] and
3. Third focusing on the conceptional core, namely the uncertainty dimensions[88], surrounding both the likelihoods and outcomes of technological innovation, pointing towards which types of uncertainties and what the scope of those uncertainties are relevant for the application of the PP.

Against this backdrop two questions are important. First, how to govern technological innovation? This is above all a matter of timing, because before development of a technology, the imagination of good living in democratic society in other words societal values matter, which points to the RRI dimension of inclusion. If "time is considered an indicator of success" (Brey)[89], the tendency that the PP starts to late because technology at question is already developed, has an economic imperative, in many cases of GMO, that the patents in the background strive for long-term utilization, while civil society rejects the products for many other reasons.
Second, how is the inclusion of norms and values embedded in technology development and assessment? The adequate participation of stakeholders and civil society can be done in a reasonable, efficient and ethically sound way, so that information and power imbalances and impacts are embedded in the development and assessment.

[83] Von Schomberg, R. (2019b). Why responsible innovation? In: Von Schomberg, R., Hankins, J. (eds.), The International Handbook on Responsible Innovation. A Global Resource. Cheltenham and Northampton: Edward Elgar Publishing, p. 6.

[84] Von Schomberg, R. (2019a). Introduction to the *International Handbook on Responsible Innovation*. In: Von Schomberg, R., Hankins, J. (eds.), *The International Handbook on Responsible Innovation. A Global Resource*. Cheltenham and Northampton: Edward Elgar Publishing, p. 5.

[85] Bogner, A., Torgersen, H. (2018). Precaution, responsible innovation and beyond – in search of a sustainable agricultural biotechnology policy. Frontiers in Plant Science, 9, 1-10.

[86] Trescher, D., Sikma, T., & Schweizer, P.-J. (2020, p.15).

[87] Ibid p. 32

[88] Cf. the chapter on scientific uncertainty and risk on page 13 of this report

[89] Brey, P. A. E. (2012). Anticipatory Ethics for Emerging Technologies. *NanoEthics*, *6*(1), 1–13. https://doi.org/10.1007/s11569-012-0141-7

Therefore the interdisciplinary research within the RECIPES project aims to realign science, precaution and responsible innovation for improved EU risk regulation, tackling the manifold challenges in the "Age of Uncertainty". [90] Nowotny points out: "If the *agora* has become the space in which science meets and interacts with many more agents, where institutions overlap and interact and where interests, values and actual decisions to be taken are being discussed, negotiated and fought over and somehow settled, then the self-organizing capacity of all participants needs to be enhanced.[91]

In this sense in WP1 and WP2 the capacity of the project partners in the RECIPES project and the invited stakeholders will continuously identify a broad spectrum of stakeholder needs for the future application of the precautionary principle in the EU. An overview of the lessons and the corresponding identified needs is provided in report D2.4.3.[92]

[90] Nowotny, H., Scott, P., & Gibbons, M. (2001). *Re-thinking Science—Knowledge and the Public in an age of Uncertainty*. Polity Press.
[91] Ibid. Nowotny, H., Scott, P., & Gibbons, M. (2001)
[92] Trescher, D., Sikma, T., & Schweizer, P.-J. (2020, p. 30ff)

6. Annex

6.1 Agendas for the RECIPES Scenario Workshop

Introduction to the RECIPES Workshop on Precaution and Innovation

Meeting	**Place: Online event** **Date: June 9th 2020**

09:50	You can enter zoom room.
10:00	Welcome
10:10	Introduction to RECIPES Project by Kristel De Smedt
10:20	Introduction to the Scenario Workshop and the different phases by Søren Gram
10:30	Introduction to the three scenarios by Søren Mark
10:45	Questions to the three presenters
10:55	Wrapping up.
11:00	Thank you and see you soon

Phase 1 Critique - A critical discussion of the three scenarios

Meeting	Place: Online event Date: June 10th and 11th, 2020

Morning Sessions 1 & 2	Afternoon Sessions 1 & 2	
09:50	13:50	You can enter zoom room.
10:00	14:00	Welcome and introduction
10:10	14:10	Critical discussion of the three scenarios
10:55	14:55	Break
11:10	15:10	Continuation of discussion
11:55	15:55	Wrapping up.
12:00	16:00	Thank you and see you soon

Phase 2 Vision - Formulation of shared visions for reconciling precaution & innovation

Meeting	Place: Online event Date: June 15th and 16th, 2020

Morning Sessions 1 & 2	Afternoon Sessions 1 & 2	
09:50	13:50	You can enter zoom room.
10:00	14:00	Welcome and Introduction
10:10	14:10	Discussion on desirable future visions on precaution and innovation
10:55	14:55	Break
11:10	15:10	Continuation of discussion
11:55	15:55	Wrapping up.
12:00	16:00	Thank you and see you soon

6.2 Scenario 1 Current practices and challenges - baseline

6.2.1 Introduction

Since the year 2000 the implementation of the precautionary principle in the EU has been guided by a Commission communication[93]. Although the communication was only a guiding document, it constituted an important codification of the EU institution's understanding and agreement on the principle at the time it was adopted. The communication states that three prerequisites should be established before invocation of the principle:

- the identification of possible negative effects;
- the performance of a scientific evaluation;
- the existence of scientific uncertainty.

The Commission also provides guidelines in the communication on precautionary measures, to be followed by policy-makers. The precautionary measures should be:

- proportional to the chosen level of protection;
- non-discriminatory in their application;
- consistent with similar measures taken;
- based on an examination of the potential benefits and costs of action and inaction;
- subject to review in light of new scientific data;
- capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

There is little doubt that the implementation of the precautionary principle, underpinned by the Commission´s communication, has played a positive role in avoidance and/or reduction of many and multifarious health and environmental hazards. However, several studies, including studies undertaken by the European Environment Agency and recently by RECIPES, show that the principle is not always interpreted and implemented consistently in the various regulatory sector schemes in the EU (chemicals, GMOs, pesticides, biocides, foods, cosmetics, etc.) and that there are sometimes inconsistencies in how the guidelines are interpreted and implemented by the EU and the member states' authorities in specific cases[94] [95].
The inconsistencies in the implementation can create uncertainties for producers and consumers, and there is general agreement that a more systematic and consistent implementation is desirable and could provide for a fairer and more sustainable implementation.
The recent launch of the European Green Deal and the soon to come 8th European Environment Action programme (8th EAP) offer relevant frameworks for updating

[93] European Commission, "*EU Commission Communication on implementation of the precautionary principle" (COM/2000/0001 final).*
[94] European Environment Agency (EEA) "*Late Lessons learned from Early Warnings. Science, Precaution, Innovation*.", Vol II, 2013, ISBN 978-92-9213-349-8
[95] RECIPES Project, the 9 Case studies, Available on RECIPES website when published, https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation

and for further developing and reshaping guidelines, regulations and practices related to the precautionary principle[96] [97] [98] [99].
The need for such adjustments is further emphasized by the fast and massive development of new and emerging technologies (e.g. artificial intelligence, nanotechnology, precision gene editing, synthetic biology) which are only partly regulated and pose new kinds of risks and regulatory challenges. Also, new EU policies and strategies for innovation and the current discussions on the "innovative principle" underscore the need for further clarification and for establishment of guidelines and regulatory frameworks for the interplay between precaution and innovation[100] [101] [102] [103].
Among the first steps in moving in the direction of more consistent implementation of the precautionary principle and clarification of the interplay between innovation and precaution could take the form of a new strategy from the Commission to supplement the communication from 2000.

6.2.2 Challenges

This section will present some of the current and immediate challenges to the implementation of the precautionary principle. The challenges are mainly identified in and extracted from the RECIPES case studies.
The RECIPES case studies describe how the precautionary principle is currently applied in relation to both well-known products and technologies and to new and potent emerging technologies. The products and technologies analysed represent a wide range of potential risks and impacts and are in very different stages of development and implementation of the precautionary principle.
A total of nine in-depth RECIPES case studies were undertaken and focussed on Glyphosate, neonicotinoids, endocrine disruptors, microplastics in food products and cosmetics, genetically modified organisms, new gene-editing techniques with focus on CRISPER-Cas9 gene drives, nanotechnologies, use of artificial intelligence

[96] Council of the European Union, "*The 8th Environment Action Programme - Turning the Trend Together*". Council conclusions, 2019 (12795/19). https://www.consilium.europa.eu/media/40927/st12795-2019.pdf
[97] Ellen Vos & Kristel De Smedt, *"Taking stock as a basis for the effect of the precautionary principle since 2000",* Final version, 15 February 2020, https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20as%20a%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf
[98] Renda A. & Simonelli F., "Study supporting the interim evaluation of the innovation principle", EU Commission, Directorate -General for Research and Innovation, Independent Expert Report, Aug. 2019.
[99] *Towards an Innovation Principle Endorsed by Better Regulation*" Strategic Note, The European Political Strategy Centre, 2016.
[100] European Commission *"The Precautionary Principle: decision-making under certainty"*, Future Brief, Science for Environmental Policy, Sep. 2017, Issue 18.
[101] J. Pelkmans & A. Renda, *"Does EU regulation hinder or stimulate innovation"*, Centre for European Policy Studies, Special Report, No 96, November 2014. https://www.ceps.eu/ceps-publications/does-eu-regulation-hinder-or-stimulate-innovation/
[102] Renda A. & Simonelli F., *"Study supporting the interim evaluation of the innovation principle"*, EU Commission, Directorate -General for Research and Innovation, Independent Expert Report, Aug. 2019.
[103] "*Towards an Innovation Principle Endorsed by Better Regulation*" Strategic Note, The European Political Strategy Centre, 2016).

in healthcare, and on precaution and financial risks in relation to urban waste water treatment[104].

6.2.3 Disparate regulation

The case studies demonstrate that different categories of products and technologies often have many different forms and properties, have wide ranges of sources and are used in multiple ways. This for instance is the case for endocrine disruptors, microplastics and nano-materials which today are regulated in the EU under several different regulatory schemes. Endocrine disruptors for instance, depending on their use, are regulated under EU directives and regulations on food, pesticides, biocides, chemicals, and cosmetics. Approaches to the implementation of the precautionary principle vary between these schemes as does the definition of what constitutes an endocrine disruptor.

The current complexity of the regulatory framework in some instances results in replacement of refused or banned products with other products with the same or even higher risks. An example of this is when new crop plant varieties with the same genetic make-up (DNA) become subject to either minimal risk assessment procedures or very strict and demanding requirements depending on whether the plant is a result of traditional breeding or modern gene-editing.

Another example is when a "regrettable substitution" occurs when one endocrine disruptor (bisphenol A) is substituted by another less stringently regulated endocrine disruptor (bisphenol S), although the latter has the same or higher level of risk. Decisions made on products or technologies can further vary when approval decisions are under the authority of the individual EU member states. Some products can therefore be banned in some member states while being lawfully applied in others. This for instance is the case for some pesticides and biocides.
Although much effort goes into ensuring and improving regulatory coordination the case studies demonstrate that the complexity of the current regulatory schemes in some cases leads to inconsistent processes and decision-making.

6.2.4 Scientific uncertainty

Many of the new technological products analysed in the case studies have very complex and partly unknown routes and fates in organisms and the environment and may pose potential direct or indirect negative health or environmental impacts (e.g. neonicotinoids, endocrine disruptors and microplastics). In all the cases, although to a varying degree, there is scientific uncertainty about potential risks and how to manage these.
In some cases, the scientific knowledge on possible risks and acceptable thresholds is very limited (e.g. human health impacts from microplastics in foods and impacts of endocrine disruptors in humans, including on reproductive health) while there is

[104] RECIPES Project, the 9 Case studies, Not published to date 02-06-2020: Available on RECIPES website when published, https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation

much scientific evidence available in other cases, though no conclusive or concordant conclusions on risks (e.g. on the human health risks of glyphosate).
As scientific uncertainty about the risks is a main trigger for the invocation of the precautionary principle and is at the same time often very difficult to define and put on formula, further analyses of cases and identification of best practices may be helpful and used to update and develop more detailed guidelines on how to manage scientific uncertainty.

6.2.5 Timely implementation of the precautionary principle

Many of the case studies undertaken by the European Environment Agency have demonstrated that the invocation of the precautionary principle has been instrumental to avoid hazards to human health and the environment, but also that earlier invocation of the principle should have taken place and would have saved humans and the environment from serious harm (e.g. asbestos, PCB and lead in gasoline). The RECIPES case studies further reveal that the precautionary principle over time has become an increasingly important issue in several cases and that it in some instances may be expected to be invoked and become implemented more in the future. This could for instance be the case for endocrine disruptors, neonicotinoids, and glyphosate. To illustrate, glyphosate, which for several decades has been the most commonly used active substance in herbicides in the EU (and the rest of the world) was only granted a 5-year renewal in the EU in 2017 while earlier renewals were for 10 or 15 years. A number of member states, including Germany and France, hold the position that glyphosate should be phased out or banned due to its negative impacts on nature (decline of biodiversity) and its potential negative impact on human health (potential carcinogenic properties). Thus, glyphosate may be banned in the EU or is at least likely to be subject to stricter risk management requirements after 2022.

While glyphosate has been lawfully applied until now and has a track record of being cost effective, not many useful alternatives have been developed, which could have stimulated innovations related to integrated pest management and organic farming. For microplastics an EU ban (under REACH) is on its way for intentionally added microplastics in cosmetic products and several companies have already started to use healthy alternatives. Intentionally added microplastics in cosmetics, however, only constitute a minor part of the pollution with microplastics and more prevention and/or implementation of the precautionary principle may be expected in the future. All in all, it seems that both consumers and innovative researchers and producers in many instances could benefit from earlier invocation and implementation of the precautionary principle.

6.3 Scenario 2 Sustainable Innovation with Precaution

6.3.1 Introduction

This scenario focuses on the interplay between innovation and the precautionary principle.

"Innovation" can be defined in multiple ways but is generally understood as the creation of something new that provides value for someone. While innovation may provide benefits to some, it may, however, also have no impact or even negative impacts on others [105] [106] [107] [108].
Evidently, some innovations can contribute to achieving for instance the UN's sustainable development goals (SDGs) or the objectives of EU's new Green Deal while other innovation may have the opposite effect.
This scenario looks into challenges and options for adjusting precautionary requirements towards further stimulation of desirable innovations.
Some private sector stakeholders including the "European Risk Forum", a think tank which works for 10 multinational companies and 16 trade associations, started in 2013 to advocate for the introduction of an "innovation principle" in the EU *acquis* to help create "a more innovation-friendly regulatory regime" and to balance the principle of precaution. Thus, the forum asked that for whenever policy or regulatory decisions would come under consideration, that the impact on innovation as a driver for jobs and growth should be considered and addressed [109] [110] [111].
The European Risk Forum expressed that unclear and long-lasting processing of product applications and a too stringent implementation of the precautionary principle in decision-making lead to weakening of European companies' competitiveness compared to counterparts in other countries with faster and/or less stringent precautionary regulations. This, the forum stated, hampered technological innovation, and in some instances also green transformation, by de-motivating both investors and researchers to engage in development of needed products and new technologies.
The EU Commission has supported the concept of the innovation principle. Accordingly, the principle, although still not well-defined, was recently and for the first time introduced in an EU legal text, i.e. in the "Horizon Europe Regulation and Program" which succeeds "Horizon 2020" and lays out the future rules for financing the EU's research and innovation program [112] [113] [114] [115].

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[105] Ellen Vos & Kristel De Smedt, *"Taking stock as a basis for the effect of the precautionary principle since 2000",* Final version, 15 February 2020, https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20as%20a%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf
[106] European Commission *"The Precautionary Principle: decision-making under certainty"*, Future Brief, Science for Environmental Policy, Sep. 2017, Issue 18.
[107] Renda A. & Simonelli F., *"Study supporting the interim evaluation of the innovation principle"*, EU Commission, Directorate -General for Research and Innovation, Independent Expert Report, Aug. 2019.
[108] "*Towards an Innovation Principle Endorsed by Better Regulation*" Strategic Note, The European Political Strategy Centre, 2016).
[109] Ellen Vos & Kristel De Smedt, *"Taking stock as a basis for the effect of the precautionary principle since 2000",* Final version, 15 February 2020, https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20as%20a%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf
[110] European Risk Forum (ERF), "The Innovation Principle - Overview" http://www.riskforum.eu/uploads/2/5/7/1/25710097/innovation_principle_one_pager_5_march_2015.pdf
[111] J. Pelkmans & A. Renda, *"Does EU regulation hinder or stimulate innovation"*, Centre for European Policy Studies, Special Report, No 96, November 2014. https://www.ceps.eu/ceps-publications/does-eu-regulation-hinder-or-stimulate-innovation/
[112] Ellen Vos & Kristel De Smedt, *"Taking stock as a basis for the effect of the precautionary principle since 2000",* Final version, 15 February 2020, https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20as%20a%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf

Concerns have been raised by the EU Parliament, consumer associations, green NGOs and some think tanks that the introduction of the innovation principle could lead to a de-regulatory approach that could weaken the precautionary approach. They argue that the principle must be defined and managed in a way that fully respects the precautionary principle and stimulate technological innovations which are safe and fulfil public health, environmental and societal objectives.[116] [117]
The critics have further emphasized that there exists no solid evidence that the precautionary approach hampers innovation in Europe and that studies and analyses document the opposite, namely that the precautionary approach can help to stimulate desirable technological innovation.
The relationship between precaution and innovation is one of the issues analysed in the RECIPES case studies and while some of the case studies find that precaution may hinder innovations (e.g. GMOs) other case studies find that precaution seem to stimulate technological innovations (healthy alternatives to microplastics, emergence of initiatives such as Green Chemicals etc.).[118]

6.3.2 Challenges

In the following section focus is on how sustainable technological innovation can be stimulated more by adjustments to the way the precautionary principle is currently implemented. The presented challenges are mainly based on lessons learned from the RECIPES case studies.

6.3.3 Long duration of risk assessments and decision-making processes

Several of the RECIPES case studies are about technological products which have been subject to risk assessment for several decades (e.g. endocrine disruptors, GM crop plants, glyphosate and neonicotinoids).
Long-lasting and unresolved risk assessment and approval processes are not only a problem for investors and researchers but also create uncertainties for citizens who may use products which may be banned at a later stage (e.g. endocrine disruptors, glyphosate and secondary microplastics).

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[113] European Commission, "Proposal for a Regulation on the European Parliament and of the Council – establishing Horizon Europe – the Framework Programme for Research and Innovation laying down its rues for participation and dissemination", 2018, (COM/2018/435 final).
[114] Olena Nedozhogina & Hans Horak, *"RRI implementation in Horizon 2020 and the future of RRI in Horizon Europe"*, Policy Brief #04, University of Tarty, Aug 2019. https://www.hubit-project.eu/policy-briefs/download/ce9d3985c4da470c77ecbc7f682c7dbf.pdf
[115] "*Towards an Innovation Principle Endorsed by Better Regulation*" Strategic Note, The European Political Strategy Centre, 2016).
[116] Ellen Vos & Kristel De Smedt, *"Taking stock as a basis for the effect of the precautionary principle since 2000",* Final version, 15 February 2020, https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20as%20a%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf
[117] Renda A. & Simonelli F., *"Study supporting the interim evaluation of the innovation principle"*, EU Commission, Directorate -General for Research and Innovation, Independent Expert Report, Aug. 2019.
[118] RECIPES Project, the 9 Case studies, not published to date 02-06-2020: Available on RECIPES website when published, https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation

The case studies suggest that faster decision-making in such situations, based on the best possible current knowledge, could help to reduce uncertainties and, in cases where decision-making results in non-approval, also the risk of ultimately unproductive and unsuccessful investments.
In some instances, the cases also establish that new scientific knowledge is not considered (e.g. 30 years of safe use experiences from cultivation of GM crop plant cultivation in many countries outside of the EU). This demonstrates that there is a need for consideration on how new scientific knowledge is more consistently acknowledged and taken into account.
These findings seem to call for intensification of resources and capacities to undertake risk assessments and perform decision-making by relevant authorities and to undertake and update risk assessments and decisions when new and relevant scientific knowledge becomes available.

6.3.4 One-size-fits-all risk assessments or a more gradated approach

The private sector has also raised concerns about authorities' request for huge amounts of costly research data for their risk assessments.[119] [120]

This may deter smaller companies and small research institutions to get involved in research and development and in some instances leave the playing field to only a few and large multinational companies. This in particular seems to be the case for development of GMOs and other products stemming from modern gene technologies.

One possible approach to reduce these problems could be to gradate the requirements of data for risk assessments and in this way move away from a "one-size-fits-all approach" of risk assessments, which today is prevalent for some kind of products.

For instance, today genetically modified crop plants are all subject to the same requirements of year-long testing and provision of comprehensive research data independently of their new characteristics, there capability to interbreed with wild plant relatives, or their survivability outside cultivated fields.

A more gradated approach to risk assessments could therefore be considered and be based on an initial screening for potential risks and establishment of risk classes with different levels of requirements of provision of data.

Products with similar characteristics to previously approved products with safe track records or with minimal or moderate risk characteristics could then enter less demanding and faster application procedures.

[119] European Risk Forum (ERF), *"The Innovation Principle - Overview"* http://www.riskforum.eu/uploads/2/5/7/1/25710097/innovation_principle_one_pager_5_march_2015.pdf
[120] J. Pelkmans & A. Renda, *"Does EU regulation hinder or stimulate innovation"*, Centre for European Policy Studies, Special Report, No 96, November 2014. https://www.ceps.eu/ceps-publications/does-eu-regulation-hinder-or-stimulate-innovation/

6.3.5 Consideration of more than potential environmental and health risks

In many of the RECIPES case studies other concerns than the potential health or environmental risks play a major role for member states' positions and decisions although the rules and regulatory framework does not cater much for such concerns to be considered, investigated or addressed. [121]

For example, citizens' discomfort with the present status of and future development pathway for agricultural technology in the EU plays a major political role when it comes to glyphosate and genetically modified crop plants.

Similarly, concerns about citizens' rights play a role in the discussion on the precautionary principle related to artificial intelligence.

Also, broader concerns about the biodiversity and climate crises may play a role while such consequences are not yet directly addressed in most of the EU and member states' schemes for risk assessments.

Inclusion of such considerations, however, is generally asked for by the public, by green NGOs and some think tanks and, to an increasing extent, also by decision-makers as expressed in EU strategies such as the Green Deal and EU's 8th Environment Action Programme.

6.4 Scenario 3 Stronger, wider and more inclusive implementation of precaution

6.4.1 Introduction

This scenario emphasizes the need for development of a significantly stronger and more widespread implementation of the precautionary principle in the EU.

Proponents of this view also often find that the principle should be used more and in a way that enables and encourages more inclusive, transparent and thus democratic decision-making processes. [122] [123] [124] [125] [126]

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[121] RECIPES Project, the 9 Case studies, Not published to date 01-06-2021: Available on RECIPES website when published, https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation

[122] Ellen Vos & Kristel De Smedt, *"Taking stock as a basis for the effect of the precautionary principle since 2000",* Final version, 15 February 2020, https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20as%20a%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf

[123] Palsberg A. et al., *Citizens' values and opinions in relation to Precaution and Innovation - Results from citizen' meetings in the Norway, Denmark, Italy, the Netherlands and Bulgaria* https://recipes-project.eu/sites/default/files/2020-03/Citizens_Meeting_Briefing_Report_Final.pdf

[124] Palsberg A. et al., *"Five citizens meetings"* RECIPES Project Synthesis report, https://recipes-project.eu/sites/default/files/2020-03/Synthesis%20citizens%20meetings.pdf

The conclusion in the European Environment Agency's analyses of case studies in 2013 is that there is a need for more frequent invocation of the precautionary principle as well as for stronger implementation of precautionary measures. The Agency further emphasised that the implementation of the precautionary principle should have been invoked earlier in many cases and that it only rarely has been applied in cases where it later showed that risks were not significant. [127]

The proponents of a stronger implementation of the precautionary principle further find that earlier and more stringent implementation of the precautionary principle will help investors and researchers to set ambitious targets and spur sustainable innovation.[128] [129]
One positive example of such innovation is the emergence of "Green Chemicals", a movement which took off in the mid-90s in Europe amongst private sector companies and in research societies. It aims to design chemical products and processes that reduce or eliminate the generation and use of hazardous substances.

Presently, as it has become clear that major changes are needed for production and consumption patterns in the EU in order to achieve political goals related to the climate and biodiversity crises, the precautionary principle with its overt recognition of uncertainties and its negotiated nature of decision-making can be reckoned to be more important than ever.

Updated guidelines for stronger, wider and more inclusive implementation of the precautionary principle could be introduced in a new communication from the EU Commission replacing the communication on the principle from 2000.

6.4.2 Challenges

Some of the most important challenges to applying a stronger, wider and more inclusive implementation of the precautionary principle are presented below. The identified challenges are mainly extracted from the RECIPES case studies.[130]

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[125] *RECIPES' Case Studies: Aligning Precaution and Innovation* – Not published to date 02-06-2020– in finalization process, Available on RECIPES website when published https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation
[126] Renda A. & Simonelli F., "Study supporting the interim evaluation of the innovation principle", EU Commission, Directorate -General for Research and Innovation, Independent Expert Report, Aug. 2019.
[127] European Environment Agency. (2013). *Late lessons from early warnings :science, precaution, innovation.* Publications Office. https://data.europa.eu/doi/10.2800/73322
[128] Ellen Vos & Kristel De Smedt, *"Taking stock as a basis for the effect of the precautionary principle since 2000",* Final version, 15 February 2020, https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20as%20a%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf
[129] *RECIPES' Case Studies: Aligning Precaution and Innovation* – Not published to date 01-16-2021– in finalization process, Available on RECIPES website when published https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation
[130] *RECIPES' Case Studies: Aligning Precaution and Innovation* – Not published to date 01-16-2021– in finalization process, Available on RECIPES website when published https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation

6.4.3 Emerging technologies – guidelines

The RECIPES case studies demonstrate that application of the existing regulations and guidelines for health and environmental risk assessments related to chemicals, foods, microplastics in cosmetics, GMOs etc. cannot automatically be considered to be relevant and sufficient to be used in relation to developments within new and emerging fields (such as CRISPR-Cas9, gene drive, artificial intelligence and nano-technology).

Development is fast in these fields and may pose different kinds of risks, which may often be related to socio-economic or ethical issues.

The emerging technologies presently deliver products that are mostly regulated under existing EU sector regulations for older technologies. For example, many nano-materials and products are regulated under REACH and the EU regulation on chemical classification, labelling and packaging (CLP) while new organisms developed by CRISPR Cas9 are regulated under EU's GMO directives.

However, for nano-materials for instance there exists no agreed specification of what defines nano or nano-scale, and there is therefore uncertainty as to whether relevant and sufficient risk assessment and risk management requirements can be generally anticipated as a result of the present regulation.

Similarly, there has been a controversy about a recent decision by the European Court of Justice in which it was determined that new organisms developed by modern gene editing methods (e.g. CRISPR Cas9) are to be considered to be GMOs and regulated under the GMO regulatory framework.

Some critics have argued that such organisms are genetically well-defined, do not contain new DNA and pose no significant risks and should therefore not fall under the strict GMO regulatory schemes. At the same time other critics have emphasized that entirely new, and hitherto unknown organisms could be developed in near future by application of CRISPR Cas9 in combination with other modern synthetic biological technologies and that such organisms should not be compared to GMOs and may pose different kinds of risks.

For organisms to be developed with gene drive, which presently are also regulated according to the existing GMO regulations, these are fundamentally different from previous GMOs in the sense that they are deliberately designed to spread their new genetic traits to their offspring and following generations in laboratories or in the wild. Such spreading of genes is usually avoided by risk mitigation measures for GMOs and may pose very complex and entirely new kinds of risks assessment challenges.

As such technologies progress, they may result in new products that will no longer belong under the already existing sector regulations and instead need to be regulated under either revised or expanded existing schemes or under new specific regulatory schemes, which may better reflect the specific risks they present and precautionary measures they require.

Further analyses of how fast and to what extent such developments can be expected to take place seem needed to establish timely precaution.

6.4.4 Transparency

In the RECIPES case study on glyphosate it is found that lack of access for the public to health data provided by the producer to the EU authority responsible for undertaking the risk assessment (The European Food Safety Authority, EFSA) has resulted in public mistrust of both the applicant and the authority.

Meanwhile good governance, broad participation and in particular transparency in relation to the developments in nanotechnologies and in waste water infrastructure development in Milan resulted in less conflict and more sustainable solutions.[131]

6.4.5 Participation

The case studies on genetically modified organisms (GMOs) and nanotechnologies describe very different situations in terms of participation. Whereas participation has been limited and first started late when products, such as genetically modified crop plants, were ready for marketing approval the development of nano-materials have from the outset been characterized by more open and inclusive dialogues and participation of a broad range of relevant stakeholders.

Much of this dialogue and inclusion happened under the umbrella of Responsible Research and Innovation[132] (RRI) activities in Horizon 2020 and can be expected to continue under the Horizon Europe Regulation and Program.

The RRI approach aims to ensure systematic and adequate multi-stakeholder participation and responsible research and innovation through assessment of potential implications and societal expectations with regard to research and innovation. [133] [134] [135]

[131] RECIPES Project, the 9 Case studies, not published to date 01-16-2021: Available on RECIPES website when published, https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation

[132] Cf. Stirling, A. (2016). Addressing scarcities in responsible innovation. Journal of Responsible Innovation, 3 (3), 274-281; Owen, R., Macnaghten, P., Stilgoe, J. (2012). Responsible research and innovation: From science in society to science for society, with society. Science and Public Policy, 39, 751-760; Von Schomberg, R. (2019b). Why responsible innovation? In: Von Schomberg, R., Hankins, J. (eds.), The International Handbook on Responsible Innovation. A Global Resource. Cheltenham and Northampton: Edward Elgar Publishing, p. 6; Von Schomberg, R. (2019a). Introduction to the *International Handbook on Responsible Innovation*. In: Von Schomberg, R., Hankins, J. (eds.), *The International Handbook on Responsible Innovation. A Global Resource*. Cheltenham and Northampton: Edward Elgar Publishing, p. 5.

[133] Ellen Vos & Kristel De Smedt, *"Taking stock as a basis for the effect of the precautionary principle since 2000",* Final version, 15 February 2020, https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20as%20a%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf

[134] Forsberg E.M. et al., *"Including RRI in the development and implementation of Horizon Europe"*, RRI Tools Blog. Position Paper. February 2020. https://blog.rri-tools.eu/-/including-rri-in-the-development-and-implementation-of-horizon-europe

The present negative public sentiments towards genetically modified plants and the more nuanced public perceptions of nano-materials may to some extent be caused by these differences in approach to dialogue and inclusion.

That this could be the case is underlined by experiences with citizen participation related to genetically modified crops undertaken by the Danish Board of Technology. In 1999 the board held a so-called consensus conference where randomly selected citizens during three weekends discussed the pros and cons of different forms of and potential uses of GMOs with experts and other stakeholders. [136]
As part of the process regarding drafting of Danish legislation in the field of GMOs the citizens agreed on a long list of recommendations to the Danish parliament containing their views on the most controversial issues regarding GMOs.

The citizens ended up being not generally against GM crop plants. While many of the participants were against cultivation of pesticide-tolerant crops they looked more positively on possible approval of crops made less dependent on pesticides, e.g. on fungus-resistant potatoes, if these had first been subject to risk assessments and found to pose no significant risks.

Another positive example of participation and innovative solutions is from the RECIPES case study on neonicotinoids where Italian farmers collectively established an insurance scheme against yield losses from no use of neonicotinoids in maize fields. It turned out that yield losses in general were minimal but that the scheme could be helpful in bad years.[137]

Based on the general experiences from the RECIPES case studies it seems relevant to strengthen RRI and other relevant approaches, in order to experiment with and develop models for more transparency and more systematic and qualified stakeholder participation in the future implementation of the precautionary principle.

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[135] Olena Nedozhogina & Hans Horak, *"RRI implementation in Horizon 2020 and the future of RRI in Horizon Europe"*, Policy Brief #04, University of Tarty, Aug 2019. https://www.hubit-project.eu/policy-briefs/download/ce9d3985c4da470c77ecbc7f682c7dbf.pdf

[136] The Danish Board of Technology Foundation, *"Gensplejsede fødevarer - Slutdokument og ekspertindlæg fra konsensuskonferencen 12. - 15. marts 1999"*. 1999 (only available in Danish language) https://tekno.dk/wp-"content/uploads/2019/01/p99_genspl.pdf

[137] RECIPES Project, the 9 Case studies, available on RECIPES website when published, https://recipes-project.eu/results/recipes-case-studies-aligning-precaution-and-innovation

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