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ARTICLE

Transparency and Participation in the Face of Scientific Uncertainty: Concluding Remarks

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I. Introduction

Openness of decision-making and policy-shaping activities is a fundamental tenet of the European integration project. Article 1 TEU expressly defines the European Union (EU) as a Union in which “decisions are taken as openly as possible”.¹ Openness, and its corollary principles of transparency and participation, are essential parts of the EU’s constitutional commitments to democratic principles of representative and participatory democracy.² According to Article 11 TEU, the institutions shall give citizens and representative associations the opportunity to voice and publicly exchange their views in all areas of Union action. Citizen participation is, however, possible only where transparency and access to information are ensured to the public, being through access to documents or publication of information. Thus, Article 15 TFEU clearly establishes “a right of access to documents of the Union’s institutions, bodies, offices and agencies, whatever their medium” – a right later enshrined also in Article 42 of the EU Charter of Fundamental Rights. Such fundamental commitments to transparency and participation apply to legislative³ as well as to administrative activities.⁴

The benefits of decision-making procedures based on an open and transparent dialogue with citizens are widely recognised in the literature, which connects them to aspects relating to input-, throughput⁵ and output-orientated legitimacy.⁶ Transparency, in particular,

¹ This commitment is repeated in Art 10(3) TEU.

² On the interconnections between and definitions of openness, transparency and participation, see A Alemanno, “Unpacking the Principle of Openness in EU Law: Transparency, Participation and Democracy” (2014) 39 *European Law Review* 72. See also D Curtin and J Mendes, “Transparence et participation: des principes démocratiques pour l’administration de l’Union Européenne” (2011) 137–38 *Revue française d’administration publique* 101; J Mendes, *Participation in EU Rule-Making: A Rights-Based Approach* (Oxford, Oxford University Press 2011).

³ Art 15(1) TFEU, last sentence.

⁴ See Art 298(1) TFEU: “the institutions, bodies, offices and agencies of the Union shall have the support of an open, efficient and independent European administration” (emphasis added).

⁵ VA Schmidt, “Democracy and Legitimacy in the European Union Revisited: Input, Output and ‘Throughput’” (2013) 61 *Political Studies* 2.

⁶ D Naurin, “Transparency and legitimacy” in L Dobson and A Follesdal (eds), *Political Theory and the European Constitution* (London, Routledge 2004) p 139.

is considered by the literature as a fundamental tenet of any democratic system.⁷ It can be understood, in the context of EU governance, as the provision of information, the right of access to documents or the visibility of decision-making.⁸ As a “trust-enhancing principle”,⁹ it is linked to accountability and fairness of decision-making. Opening up closed decision-making arenas allows public control over the exercise of public power, enabling the public to detect arbitrary decisions and hold to account decision-makers.¹⁰ Transparency hence is an important precondition not only for public participation, but also for the accountability of public authorities.¹¹ When decisions are based on scientific studies or data, the transparency of these data enables the reproducibility of the relevant studies, thus contributing to ensuring the epistemic quality of these data and, ultimately, experts’ accountability through public scrutiny.¹²

Participation is an equally fundamental aspect of democratic governance. The reasons for participatory engagement, however, are linked not only to normative-democratic considerations, but also to its added value in instrumental and substantial terms.¹³ It is deemed to be particularly valuable for EU institutions to gather information on the factual situation, especially when the sector or issue to be regulated is particularly complex from a technical or scientific perspective.¹⁴ The input from civil society or representative associations can thus fill the gaps in knowledge or resources of the decision-maker. The involvement of natural or legal persons which will be subjected to regulation may also enhance the quality of decisions, making them more responsive to social and economic needs and more in accordance with the public interest.¹⁵ This, in turn, may increase trust in the institutions, as well as compliance, and facilitate the implementation of the rules so openly conceived.¹⁶ As effectively summarised by the Court of Justice of the European Union (CJEU) in *Turco*, openness in general “enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen in a democratic system”.¹⁷

Considering especially the promises of enhanced fact-gathering and legitimacy, transparency and participation appear to be particularly valuable in those situations where the EU institutions are called to take decisions surrounded by technical and scientific

⁷ Alemanno, *supra*, note 2, 72; C Hood, “Accountability and Transparency” (2010) 33 *West European Politics* 989; P Craig, “Transparency” in *EU Administrative Law* (3rd edition, Oxford, Oxford University Press 2018) p 388; P Birkinshaw, *Freedom of Information: The Law, the Practice and the Ideal* (4th edition, Cambridge, Cambridge University Press 2010); D Curtin, “Judging EU Secrecy” (2012) 2 *Cahiers de Droit Européen* 457; A Buijze, “The Six Faces of Transparency” (2013) 9 *Utrecht Law Review* 3.

⁸ K Lenaerts, “‘In the Union We Trust’: Trust Enhancing Principles of Community Law” (2004) 41 *Common Market Law Review* 317.

⁹ *ibid.*

¹⁰ M Morvillo, “Why Should Citizens Trust EU Regulatory Expertise? Legal Warrants, Science and Politics in EU Food Governance” in R Barradas de Freitas and S Lo Iocono (eds), *Trust Matters – Cross-Disciplinary Essays* (Cheltenham, Hart 2021) p 229.

¹¹ On the relationship between transparency and accountability, and its ambiguities, see Hood, *supra*, note 7, 989.

¹² E Hickey and M Weimer, “The transparency of EU agency science” (2002) 59 *Common Market Law Review*, 673; A Smith et al, “Communicating to and engaging with the public in regulatory science” (2019) 17 *EFSA Journal* 1.

¹³ Smith et al, *supra*, note 12, 8.

¹⁴ J Mendes, “Participation and participation rights in EU law and governance” in H Hofmann and A Türk (eds), *Legal Challenges in EU Administrative Law: Towards an Integrated Administration* (Cheltenham, Edward Elgar Publishing 2009) pp 257, 259. See also Mendes, *supra*, note 2.

¹⁵ Smith et al, *supra*, note 12, note 8. See also U Felt and M Fochler, “Machineries for making publics: inscribing and de-scribing publics in public engagement” (2010) 48 *Minerva* 219–38, 220.

¹⁶ Mendes, *supra*, note 14, 259; S Akerboom and RK Craig, “How law structures public participation in environmental decision making: a comparative law approach” (2022) 32 *Environmental Policy and Governance* 232, 233.

¹⁷ Joined Cases C-39/05 P and C-52/05 P, *Sweden v Turco*, ECLI:EU:C:2008:374, para 45.

complexity, uncertainty and societal contestation. From the authorisation of pesticides or vaccines to the adoption of the European Climate Law,¹⁸ EU institutions have recently faced an array of epistemic and political challenges in adopting complex decisions based on a certain amount of scientific uncertainty. In the context of those “wicked problems”,¹⁹ such as climate change or risk regulation, characterised by incomplete or contradictory knowledge and an inherent interconnectedness with other problems, recent legislative or administrative proceedings have become the arena for controversies and contestation of EU decision-making.²⁰ As a reaction, calls for greater involvement of stakeholders and transparency have been voiced,²¹ eventually resulting in some institutional transformations with the view to strengthening the legitimacy and acceptability of EU decision-making.

While it is believed that openness allows for the inclusion of a wider variety of values and perspectives and favours trust in the independence and epistemic quality of regulatory assessments, these debates have not been immune from the influence of post-factual narratives and from the increasing contestation of expertise as an impartial source of knowledge, which participatory mechanisms could further amplify.²² The proliferation of information sources and the rise of disintermediated media in science communication, catalysed through technological changes, have led to information overload and confirmation bias in citizens, in turn resulting in strong polarisation on scientific (or pseudo-scientific) topics.²³ Especially in cases with elements of scientific uncertainty, non-contextualised communication on complex scientific topics may easily lead to loss of confidence in science and in its role in the decision-making process.²⁴ The understanding of scientific advice and expertise in relation to the public perception and confidence is thus crucial in the regulation of wicked problems. Yet, the nexus between science, transparency and participation – and the epistemic and normative value of the latter²⁵ – still needs to be extensively explored in EU legal literature.²⁶

Against this backdrop, this special issue aims to fill this gap in the existing literature and explore how participation and transparency play out in situations of scientific complexity or uncertainty by presenting reflections pertaining to the entire policy cycle from the inception of policy development to its *ex post* evaluation. How participatory and

¹⁸ Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 (“European Climate Law”) [2021] OJ L243/1.

¹⁹ See H Rittel and M Webber, “Dilemmas in a general theory of planning” (1973) 4 Policy Sciences 155; J Alford and B Head, “Wicked and Less Wicked Problems: A Typology and a Contingency Framework” (2017) 36 Policy and Society 397; J Lönngren and K van Poeck, “Wicked problems: a mapping review of the literature” (2021) 28 International Journal of Sustainable Development & World Ecology 481.

²⁰ For the discussions concerning the glyphosate reapproval, see *inter alia*, GC Leonelli, “The glyphosate saga and the fading democratic legitimacy of European Union risk regulation” (2018) 25 Maastricht Journal of European and Comparative Law 582; V Paskalev, “The Clash of Scientific Assessors: What the Conflict over Glyphosate Carcinogenicity Tells Us About the Relationship between Law and Science” (2020) 11 European Journal of Risk Regulation 520; M Morvillo, “Glyphosate Effect: Has the Glyphosate Controversy Affected the EU’s Regulatory Epistemology?” (2020) 11 European Journal of Risk Regulation 422; T Van Den Brink, “Danger! Glyphosate May Expose Weaknesses in Institutional Systems: EU Legislation and Comitology in the Face of a Controversial Reauthorisation” (2020) 11 European Journal of Risk Regulation 436.

²¹ For the discussions concerning vaccine approval, see S Tanveer et al, “Transparency of COVID-19 vaccine trials: decisions without data” (2022) 27 BMJ Evidence-Based Medicine 199; P Doshi, F Godlee and K Abbasi, “Covid-19 vaccines and treatments: we must have raw data, now” (2022) BMJ Evidence-Based Medicine 376.

²² C Armeni and M Lee, “Participation in time of climate crisis” (2021) 48 Journal of Law and Society 549.

²³ Smith et al, *supra*, note 12, 6.

²⁴ *ibid.*

²⁵ For an analysis for the epistemic function of transparency, see Hickey and Weimer, *supra*, note 12, 707.

²⁶ Different, for instance, from US scholarship; see E Hammond, “Public Participation in Risk Regulation: The Flaws of Formality” (2016) Utah Law Review 169; TO McGarity, “Public Participation in Risk Regulation” (1990) 1 RISK 103.

transparent is the EU policymaking process? What is the role of transparency and participation in the solution of wicked problems? Are there any notable variations identifiable at specific moments of the policy cycle? What are the success stories or concerning developments? Does the scientifically loaded nature of risk regulation or climate change policy lead to an increase or, conversely, a decrease of participation and transparency at the various stages of the policy process?

In the following, after a brief overview of the state of the art of the literature, we will highlight the main findings and trends emerging from the special issue, before drawing conclusions on the possible future evolution of the principles of transparency and participation in EU administrative governance.

II. Participation, transparency and scientific uncertainty in EU literature: a brief overview

Transparency and participation, as foundational values of the EU system of (administrative) governance, have been studied from several different perspectives. While some have highlighted their contribution to the democratic foundations of the EU,²⁷ others, especially with respect to transparency, have delved more into their role as general principles of EU administrative law.²⁸ Some studies have further discussed transparency and participation in specific moments of the policy cycle,²⁹ or with reference to specific administrative actors³⁰ or policy fields,³¹ with critical views currently being expressed as to the effective fulfilment of the potential of these principles in contemporary EU governance.³² We

²⁷ Alemanno, *supra*, note 2, 72. See also Curtin and Mendes, *supra*, note 2, 101; Mendes, *supra*, note 2; C Braun and M Busuioc, "Stakeholder engagement as a conduit for regulatory legitimacy?" (2020) 27 *Journal of European Public Policy* 1599.

²⁸ S Prechal and M de Leeuw, "Dimensions of Transparency: The Building Blocks for a New Legal Principle?" (2007) 1 *Review of European Administrative Law* 51; Craig, *supra*, note 7; A Berthier, "Transparency in EU Law-Making" (2016) 17 *ERA Forum* 423.

²⁹ Eg with respect to consultations, see A Bunea, "Explaining Interest Groups' Articulation of Policy Preferences in the European Commission's Open Consultations: An Analysis of the Environmental Policy Area" (2014) 52 *Journal of Common Market Studies* 1224; A Alemanno, "Levelling the EU Participatory Playing Field: A Legal and Policy Analysis of the Commission's Public Consultations in Light of the Principle of Political Equality" (2020) 26 *European Law Journal* 114; C Quittkat, "The European Commission's Online Consultations: A Success Story?" (2011) 49 *Journal of Common Market Studies* 653. In relation to trilogues, see D Curtin and P Leino, "In Search of Transparency for EU Law-Making: Trilogues on the Cusp of Dawn" (2017) 54 *Common Market Law Review* 1673; J Greenwood and C Roederer-Rynning, "In the Shadow of Public Opinion: The European Parliament, Civil Society Organisations, and the Politicisation of Trilogues" (2019) 7 *Politics and Governance* 316.

³⁰ M Chamon, "Transparency and Accountability of EU Decentralised Agencies and Agencification in Light of the Common Approach on EU Decentralised Agencies" in S Garben et al (eds), *Critical Reflections on Constitutional Democracy in the European Union* (London, Bloomsbury 2015) pp 245, 251; Hickey and Weimer, *supra*, note 12, 673; L Leone, "EFSA under Revision: Transparency and Sustainability in the Food Chain" (2020) 39 *Yearbook of European Law* 536.

³¹ D Obradovic, "EC rules on public participation in environmental decision-making operating at the European and national levels" (2007) 36 *European Law Review* 829; L Squintani and G Perlaviciute, "Access to Public Participation: Unveiling the Mismatch between What Law Prescribes and What the Public Wants" in M Peeters and M Eliantonio (eds), *Research Handbook on EU Environmental Law* (Cheltenham, Edward Elgar Publishing 2020) p 139; J-L Pissaloux, "La démocratie participative dans le domaine environnemental" (2011) *Revue française d'administration publique*, 123; L Liu et al, "Effects of trust and public participation on acceptability of renewable energy projects in the Netherlands and China" (2019) 53 *Energy Research & Social Science* 137; M Cardwell, "Public Participation in the Regulation of Genetically Modified Organisms: A Matter of Substance or Form?" (2010) 12 *Environmental Law Review* 12.

³² See, *inter alia*, H Hofmann and P Leino-Sandberg, "An Agenda for Transparency in the EU" (*European Law Blog*, 23 October 2019) <<https://europeanlawblog.eu/2019/10/23/an-agenda-for-transparency-in-the-eu>>; E de Capitani, "Council's new legislative transparency – actual progress or window dressing?" (*Agence Europe*, 17 July 2020) <<https://agenceurope.eu/en/bulletin/article/12529/31>>.

contribute to this ongoing debate by unveiling the operation of these two principles in current policy debates and with specific reference to situations in which policymakers are confronted with scientific or technical complexity or uncertainty, such as risk regulation or climate change policy.

In this respect, the openness of decision-making processes and of the actors involved in policymaking (especially EU agencies) has been particularly contested after the revelation of the “Monsanto papers”,³³ which unveiled undisclosed links between regulators and industry. Moreover, the request for the re-approval of glyphosate fostered strong debate about the independence and transparency of regulatory science,³⁴ with clear reactions not only from institutional actors,³⁵ but also from civil society.³⁶ Also, in the context of the COVID-19 pandemic, the openness of the decision-making processes for the approval and purchase of vaccines has been under intense public scrutiny.³⁷ Similar contestation of EU measures appears to emerge in the context of climate change-related initiatives,³⁸ leading to similar questions in relation to the interplay between regulatory science, participation and decision-making processes. Particularly in the field of risk regulation, these emerging tensions have affected the existing transparency commitments and participatory mechanisms of EU institutions and bodies, either in law or in practice. For instance, to meet the expectations of public opinion, the European Medicines Agency (EMA) introduced the practice of holding public meetings online to inform citizens and stakeholder groups about the development, evaluation, approval, roll-out and safety monitoring of COVID-19 medicines.³⁹ Conversely, as a direct consequence of the glyphosate debate, the European Food Safety Authority’s (EFSA) legislative framework has been reformed in terms of the proactive publication of information, including scientific studies and data.⁴⁰

³³ The term refers to a series of documents concerning the industry’s influence over scientific studies. See Morvillo, *supra*, note 20, 423.

³⁴ A Arcuri and YH Hendlin, “The Chemical Anthropocene: Glyphosate as a Case Study of Pesticide Exposures” (2019) 30 *King’s Law Journal* 234, 239–41; A Arcuri and YH Hendlin, *Symposium on the Science and Politics of Glyphosate*, (2020) 11 *European Journal of Risk Regulation*; Morvillo, *supra*, note 20, 422–23.

³⁵ See European Parliament, Resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (D044281/01 – 2016/2624(RSP)); European Parliament, Resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (D053565-01 – 2017/2904(RSP)); European Parliament Special Committee on the Union’s authorisation procedure for pesticides, *Draft Report on the Union’s authorisation procedure for pesticides* (2018/2153(INI)) (17 September 2018).

³⁶ European Citizens’ Initiative, “Ban Glyphosate and Protect People and the Environment from Toxic Pesticides” (6 October 2017) <https://europa.eu/citizens-initiative/initiatives/details/2017/000002/ban-glyphosate-and-protect-people-and-environment-toxic-pesticides_en>.

³⁷ See European Ombudsman, Decision in case 175/2021/DL on how the European Commission ensures transparency in relation to the team responsible for negotiating “advanced purchase agreements” with pharmaceutical companies for vaccines against COVID-19.

³⁸ See, for instance, the “Fridays for Future” campaign against the reform of the Common Agricultural Policy; see <<https://fridaysforfuture.org/change-the-cap/>>.

³⁹ EMA, *Stakeholder Engagement Biennial Annual Report 2020–2021: Engaging with patients, consumers, healthcare professionals and academia*, EMA/562976/2021, 5.

⁴⁰ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC [2019] OJ L231/1. For an assessment, see BN Cearnigh, “Piecemeal Transparency: An Appraisal of Regulation (EU) No. 2019/1381 on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain” (2021) 12 *European Journal of Risk Regulation* 699; I Canfora, “L’evoluzione delle regole europee sulla trasparenza” (2020) 14 *Rivista di diritto alimentare* 4.

This has been praised in the literature as a paradigmatic shift from a passive to an active understanding of transparency, presented as the new “gold standard” for openness in the EU.⁴¹ In these policy areas, participation and transparency were therefore perceived as crucial to (re-)ensure legitimate public action in situations of scientific uncertainty.

From this perspective, while in the EU law literature extensive attention has been paid to scientific complexity and uncertainty from the perspective of judicial review or of governance models,⁴² or to the participation of experts in decision-making,⁴³ the transparency of risk assessment has only recently gained some scholarly interest, mainly due to EFSA’s reform.⁴⁴ A specific reflection on the role of transparency and the participation of *civil society* in situations characterised by scientific complexity or uncertainty is still under-developed. In light of the important policy reforms that risk regulation areas are currently undergoing,⁴⁵ such a reflection is ever more needed to strengthen the effectiveness of open EU decision-making.

The reflections contained in this special issue therefore meet at the intersection of the literature on transparency and participation in EU administrative governance and that on uncertainty and risk regulation in EU law. The special issue aims to approach these issues from a plurality of disciplinary perspectives, featuring contributions both from lawyers and political scientists. We aim, thereby, to uncover the current challenges facing the notions of transparency and the participation of civil society in EU policy processes related to situations characterised by both complexity and uncertainty, such as risk regulation or climate change.

III. Tackling uncertainty and ensuring participation and transparency in EU policymaking: a story of (some) successes and (more) missed opportunities

The special issue opens with a preface by the European Ombudsman Emily O’Reilly, highlighting the importance of transparency and participation for the legitimacy of the EU and for public confidence. The many inquiries carried out by this body in fields related to risk regulation and climate change are discussed, testifying to the central role of the European Ombudsman in the upholding of these principles and the relevance of policy fields characterised by scientific complexity and uncertainty in her agenda.

⁴¹ Hofmann and Leino-Sandberg, *supra*, note 32; see also Hickey and Weimer, *supra*, note 12, 673.

⁴² See, *inter alia*, T Paloniitty and M Eliantonio, “Scientific knowledge in environmental judicial review: safeguarding effective judicial protection in the EU Member States” (2018) 27 *European Energy and Environmental Law Review* 108; M Weimer, *Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology* (Oxford, Oxford University Press 2019); A Alemanno, *The Shaping of European Risk Regulation by Community Courts* (New York, New York University School of Law 2008); M Krajewski, “Judicial and Extra-Judicial Review: The Quest for Epistemic Certainty” in M Chamon, A Volpato and M Eliantonio (eds), *Boards of Appeal of EU Agencies: Towards Judicialization of Administrative Review?* (Oxford, Oxford University Press 2020) p 273.

⁴³ See, *inter alia*, C Joerges, K-H Ladeur and E Vos, *Integrating Scientific Expertise into Regulatory Decision-Making: National Traditions and European Innovations* (Baden-Baden, Nomos 1997); M Morvillo, “Why Should Citizens Trust EU Regulatory Expertise? Legal Warrants, Science and Politics in EU Food Governance” in R Barradas de Freitas and S Lo Iacono (eds) *Trust Matters. Cross-Disciplinary Essays* (Cheltenham, Hart 2021) p 229; M Weimer and G Pisani, “Expertise as Justification: The Contested Legitimation of the EU “Risk Administration”” in M Weimer and A de Ruijter (eds), *Regulating Risks in the European Union: The Co-production of Expert and Executive Power* (Cheltenham, Hart 2017) p 167.

⁴⁴ On the transparency of regulatory science, see, however, Hickey and Weimer, *supra*, note 12, 673.

⁴⁵ European Commission, Communication A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM/2020/381; European Commission, Communication Pharmaceutical Strategy for Europe, COM/2020/761.

The articles in the special issue are organised according to the phases of the policy cycle. They begin with discussion of the preparatory phases of policymaking, moving through to transparency and participation in the negotiation and adoption stages of legislative measures and concluding with implementation and evaluation. They discuss transparency and participation mechanisms employed by different institutions and bodies, including the European Commission, the EU co-legislators and the EU agencies. While some contributions discuss extensively participation and stakeholders involvement, others focus more specifically on the principle of transparency, thus providing a varied and complementary picture of openness in EU policymaking in its different declinations.

Starting from the phase of legislative proposal, Odile Ammann and Audrey Boussat explore the participation of civil society in the EU's environmental law-making processes as a response to one of the most pressing issues of our time: climate change. In addition to scientific uncertainty, recommendations of climate change experts may be contested or clash with the priorities of citizens, interest groups and political institutions. The European Green Deal, mainstreaming sustainability throughout all EU policies, makes this a pertinent topic to investigating the legal framework for civil society actors in EU law-making processes under Article 11(3) TEU. Ammann and Boussat focus on two European Commission consultations on the European Climate Law, evaluating them according to the EU primary law principles of democracy, openness and transparency. They find that, on the positive side, a significant amount of information was transparently available online; that the timing and duration of the consultations allowed for open grassroots participation; and that respondents came from various sectors and Member States. However, they suggest areas for improvement regarding greater transparency on how consultation responses influenced the law-making process; the translation of questionnaires to give the opportunity to counteract the overrepresentation of some Member States; and the length and biased formulation of the questions. Ammann and Boussat propose early and effective consultation to create legislation that is both evidence-based and democratically legitimate.

Annalisa Volpato and Astrid Offermans offer a fruitful interdisciplinary perspective on stakeholder participation, drawing from law and sustainability science to investigate the reform of the Sustainable Use of Pesticides Directive.⁴⁶ Going beyond the traditional legal approach to participation as a formal consultative opportunity with homogeneous institutional arrangements across policy fields and problems, they propose a combined approach based on the type of problem and grounded in four principles from sustainability science: (1) modesty about the role of scientific knowledge and giving attention to problem frames; (2) early and structural engagement with relevant stakeholders from the problem definition phase onwards; (3) involvement of stakeholders as knowledge producers rather than merely as knowledge receivers; (4) enabling social learning. Applying this framework to an illustrative case study, they find that, in relation to the first principle, the Commission does attach great value to scientific knowledge and scientists as knowledge providers, and that different perceptions are acknowledged. However, to strengthen the co-creation of knowledge and solutions, the authors propose increasing opportunities to share problem frames. In common with Ammann and Boussat's contribution, they identify timing as a key factor in successful stakeholder engagement. Regarding the second principle, while early

⁴⁶ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides [2009] OJ L309/71.

engagement does increase trust and transparency, Volpato and Offermans propose even earlier participation, from the problem definition stage, to shape the normative framework. Concerning the third principle, they note that more could be done to involve stakeholders as knowledge producers. With respect to the fourth principle, their conclusion is that the lack of organised dialogue to foster social learning is a missed opportunity to deliver more credible and accepted solutions.

Moving from the proposal to the legislative decision-making phase, Päivi Leino-Sandberg provides an analysis of trilogues and their (lack of) transparency, a topic that has been high on the agenda of the European Ombudsman.⁴⁷ She compares and contrasts the applicable legal rules on transparency with the institutional practices and explores how positions (especially when technical knowledge is required) are prepared and communicated in the three institutions participating in the trilogues. She finds that, when technical dossiers are at stake, MEPs often lack sufficient knowledge and rely on lobbyists to provide information. This might in itself engender a number of transparency concerns when it results in concrete legislative amendments whose origins are uncertain. When it comes to the Council, ambassadors tend to pick their battles on technical topics, and public scrutiny is completely absent. Finally, the Commission, as the main holder of the expert knowledge, is the one whose proposals are most often followed by the European Parliament, which seems to skew somewhat the power equilibria in the legislative process, especially because the Commission's internal position-building is covered by high levels of confidentiality. Leino-Sandberg concludes that trilogue transparency is currently a democratic problem in the EU, but also – again – a missed opportunity for ensuring that risks and alternatives are properly assessed in the decision-making process.

Three articles in the special issue tackle executive action and its participation and transparency credentials. This phase of the policy cycle is specifically investigated in respect of the Commission's soft law and agencies' contributions to Commission decision-making procedures related to various authorisation procedures.

With respect to the former, Danai Petropoulou Ionescu and Mariolina Eliantonio explore the participation and transparency of the Commission's soft law-making process in the field of climate change. Soft law is used very frequently by the European Commission to aid with the transposition, interpretation and application of EU (environmental) legislation, and it has become an integral part of the legislative framework of EU climate law. By looking at thirty-nine guidance documents adopted to support the implementation of several legislative measures in the field of EU climate policy, they find that the majority of the soft law instruments examined are available on the Commission's website, but their drafting process is very untransparent. Furthermore, they find that the transparency of the soft law-making process is severely impacted by the partial lack of an attributable author and the complete lack of a procedural framework for the adoption of soft law. When it comes to participation, Petropoulou Ionescu and Eliantonio find a rather limited contribution of civil society to the soft law-making process, and, when participation does take place, it is organised in an informal – and hence untraceable – fashion. They conclude that, at a time in which soft law is expected to play a key role in the implementation of the European Green Deal, greater participation and transparency would be welcome with respect to these measures.

⁴⁷ European Ombudsman strategic inquiry on the transparency of trilogues: follow-up and first results, Case OI/8/2015/JAS.

The transparency and participation of European agencies' action have been explored in the articles of Alie de Boer, Marta Morvillo and Sabrina Röttger-Wirtz and of Matthew Wood, respectively.

With respect to transparency, de Boer, Morvillo and Röttger-Wirtz examine the regimes of disclosure of scientific data by EFSA and EMA in order to identify common patterns and sectoral specificities. By carrying out an in-depth analysis of the legislative frameworks of various authorisation procedures in the field of risk regulation, they note that both agencies have moved from a framework of *ad hoc* disclosure of information towards an increasingly "systemic" notion of transparency. This, in turn, signals a move towards a more active approach concerning transparency, which is premised on the understanding that scientific data belong within the public domain unless there are clear, compelling and adequately motivated interests for keeping these data confidential. At the same time, they raise concerns regarding a situation of "persisting fragmentation" in the various legislative frameworks, specifically with respect to the variations in the level of discretion entrusted to EMA and EFSA by the respective sectoral legislation and the potential over-reliance on guidance documents to guide the exercising of this discretion. This fragmentation of the transparency regimes is deemed problematic by the authors in light of the increasing trend towards an integrated approach to health and environmental concerns in risk regulation, on the basis of which agencies are required to cooperate regarding several cross-cutting issues. They call, therefore, for further coherence to ultimately increase the legitimacy of the output provided by European agencies.

With respect to the participation of civil society in the actions of EU agencies, Wood provides an insightful analysis of a distinctive participatory approach employed by EMA, namely public hearings integrated within safety reviews of medicinal products. Through a case study concerning a type of antibiotic, the author shows that this system of public hearings enabled a group of patients who had been victims of health problems associated with the antibiotic to criticise the existing scientific evidence base around the safety of the drug. In turn, this critique was effective in advancing knowledge in this area of risk regulation, as it led EMA to change its guidelines with respect to the drug. While admittedly this system can only successfully work in situations in which the "target group" of the hearing is easily identifiable, the conclusion here is that this mechanism can serve as good practice for future reflections on stakeholder engagement in risk regulation policy because of the targeted way in which the relevant groups are engaged.

The special issue is closed with a contribution by Paul Stephenson on the evaluation step of the policy cycle. The author recalls a number of procedural and institutional innovations (such as digitisation and professionalisation) that have enhanced transparency and participation in EU *ex post* evaluation. The Commission in this respect has taken measures to broaden participation in the evaluation process and secure the involvement of a broad range of stakeholders. However, challenges in this respect do remain, particularly regarding the inclusiveness of citizens and the quality of input in open consultation processes, especially when it comes to risk regulation or environmental policy, which are characterised by their technical nature and complexity of regulation, making it harder to secure citizen participation in consultation exercises. With respect to transparency at the evaluation stage, Stephenson concludes that, while procedural transparency is currently ensured, the Commission needs to be more proactively transparent, promoting and providing education regarding the tools and procedures in place.

IV. Conclusions

The findings of the contributions to this special issue present a mixed picture of the interplay between transparency, participation and scientific complexity or uncertainty, with some recurring shortcomings across phases and with some significant developments, especially in the field of risk regulation.

In relation to transparency, the presence of scientifically complex or uncertain issues and of societal contestation appears to have underpinned legislative choices to increase transparency in certain policy fields, such as climate change law and risk regulation. Especially in relation to the reform of the transparency rules applicable to EFSA, scientific uncertainty and contestation have thus arguably acted as catalysts for enhancing transparency, determining a paradigmatic change from a passive to an active understanding of this principle that entails an increased emphasis on the need for the proactive publication of information, documents and data (as opposed to passive disclosure). Such a proactive approach to transparency is present also in the environmental field, in line with the provisions of the Aarhus Convention. During the legislative proposal phase in particular it is acknowledged that the relevant information has been disclosed and made available to the public in relation to the analysed initiatives linked to the European Green Deal. However, this level of transparency is not adequately preserved in the legislative negotiation phase, where the opaqueness and secrecy that characterise the trilogues are not challenged when wicked problems are at stake, but rather are intensified when the subject matter is technical in nature. Similarly, the adoption of soft law measures in the environmental field is considered to be neither adequately transparent nor inclusive. As highlighted by Petropoulou Ionescu and Eliantonio, there the issue is not only the availability of information and documents, but also their intelligibility to citizens. This aspect of intelligibility, which represents a fundamental element of transparency,⁴⁸ certainly deserves more attention in the context of scientifically complex and uncertain issues, as the mere proactive publication of large amounts of technical information, documents and data without explanation may be counterproductive.⁴⁹ In a sense, effective engagement of citizens in decision-making requires providing them not only with open data and facts, but also with the instruments, knowledge and opportunities to make sense of those data and facts.⁵⁰

In relation to participation, the contributions to this special issue clearly highlight the limits of the existing mechanisms in place to ensure participation in the solution of wicked problems. Notably, the fact that scientific complexity or uncertainty may constitute an additional challenge to open and transparent dialogue with citizens has proven to be more problematic for participation than for transparency. While during the legislative negotiation phase (where consultation is structurally not envisaged) technical complexity sometimes leads MEPs to use lobbying as a source of expertise, during the other phases it is found that the envisaged formal mechanisms of consultation do not systematically translate into effective engagement of citizens. For this purpose, the decisive factors are the

⁴⁸ See, *inter alia*, Hofmann and Leino-Sandberg, *supra*, note 32. See Case T 329/17, *Hautala v EFSA* [2019] ECLI:EU:T:2019:142, para 97. See also European Ombudsman, Press Release No 1/2021 of 9 February 2021, “Ombudsman calls on ECDC to be more open about its work as vaccine rollout begins”.

⁴⁹ The limits of the so-called “fishbowl transparency” have been highlighted especially in the literature on artificial intelligence; see, *inter alia*, C Coglianese and D Lehr, “Transparency and Algorithmic Governance” (2019) 71 *Administrative Law Review* 1. For a warning of the risks of shifting the logic of transparency from visibility to explanation, see M Busuioac, D Curtin and M Almada, “Reclaiming Transparency: Contesting the Logics of Secrecy within the AI Act” (2022) *European Law Open* 1.

⁵⁰ Smith et al, *supra*, note 12, 8. See also Busuioac et al, *supra*, note 49, 1.

timing (early engagement), the scope (targeted group of people) and the mode of consultation that should lead to a proper dialogue and a process of the co-creation of solutions to wicked problems. Equally important are the perception of a “willingness to listen” and the clear communication of the ways in which stakeholders’ input is being taken into account, which do not appear to be present at the moment. Although some of these concerns seem to have been taken into account in the recent Commission Communication on Better Regulation of 2021,⁵¹ in this respect more could be done to achieve the objective of “open, transparent and regular dialogue with representative associations and civil society” enshrined in Article 11 TEU.

⁵¹ European Commission, “Communication from the Commission – Better Regulation: Joining forces to make better laws”, COM(2021) 219 final, 4.