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Weimer, M.; Morvillo, M.

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CORE ANALYSIS

Who shapes the CJEU regulatory jurisprudence? On the epistemic power of economic actors and ways to counter it

Marta Morvillo[1] and Maria Weimer[2]*

[1]Department of European Studies, University of Amsterdam, Amsterdam, The Netherlands and [2]Amsterdam Centre for European Law and Governance, University of Amsterdam, Amsterdam, The Netherlands
*Corresponding author. E-mail: m.weimer@uva.nl

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Abstract

What role does the Court of Justice of the European Union (CJEU) play in holding European Union (EU) regulatory science, ie the science underpinning public regulation, to account for its epistemic quality? Since *Pfizer*, CJEU case law has strengthened the role of science in both EU risk regulation and litigation, whilst intensifying judicial scrutiny of scientific reasoning based on procedural standards. Scholars often welcome this approach as striking an adequate balance between effective judicial protection and institutional competence. Some praise the Court as an 'information catalyst' promoting procedures, in which epistemic quality is ensured through diligent consideration of and deliberation among all relevant voices. These debates, however, overlook the role of economic actors as information providers, in and challengers of EU risk regulation. This paper re-evaluates the modern post-*Pfizer* approach from a new, socio-legal perspective by studying, for the first time, the interactions between judicial review and the epistemic power of economic actors, ie their relative ability to influence what EU regulators know at the expense of other actors. We combine an epistemologically informed comparative institutional analysis with doctrinal critique of CJEU case law. Our findings show the need to rethink both legal standing and procedural review in EU risk regulation. Instead of catalysing inclusive procedures that open regulatory science to public scrutiny, the modern approach fosters an *exclusive* bilateral information exchange between the administration and the regulated industry. The Court reduces the function of process values, such as duty of care and reason-giving, to the protection of a small circle of actors, neglecting the public interest dimension of such values. Thus, the modern approach fails to address, and instead further entrenches the epistemic power imbalances inherent in EU risk regulation. We end by sketching out a normative and doctrinally sound vision of how CJEU review could contribute to EU expert accountability in a more publicly oriented way.

Keywords: administrative law; risk regulation; regulatory science; epistemic power; expert accountability; judicial review

1. Introduction

Scientific advice plays a crucial role in risk regulation. As the current health and environmental crises demonstrate, no modern regulatory system can achieve its goals without it. At the same time, the problem-solving potential of public regulation critically hinges upon the epistemic quality of scientific advice. European Union (EU) regulatory science – ie the science used and produced for regulatory purposes[1] – is held to the high standards of independence, transparency,

[1]S Jasanoff, *The Fifth Branch. Science Advisors as Policymakers* (Harvard University Press 1990) 76 ff.

and excellence as formulated by the EU General Court in *Pfizer*.[2] Scholars and policy actors alike widely recognise that accountability mechanisms must reach beyond the final, political decision-makers, to the expert advisors who act backstage, yet often de-facto pre-determine final decisions on risk and technology.[3] European courts play an important role in holding experts to account by probing the scientific foundations of regulatory decisions as part of their legality review. Over roughly the last two decades, the Court of Justice of the European Union (CJEU) has both acknowledged the importance of science in regulation and intensified judicial scrutiny of its quality. Scholars have praised this line of jurisprudence as overall a welcome response to the realities of a maturing EU risk regulatory state. Some have applauded the Court for upholding individual rights and ensuring judicial protection even against highly complex regulations. Others have celebrated the Court as a catalyst of EU regulatory reform. The Court has been described as an 'information catalyst' promoting procedures which generate deliberation among all relevant experts thereby ensuring that the science behind regulatory decisions meets the standards of independence, excellence, and transparency.[4]

In this paper, we re-evaluate the CJEU's record in holding EU regulatory science to account over the last 20 years. We study the Court's jurisprudence through a new, socio-legal lens by analysing the interactions between judicial review and the epistemic power of economic actors (ie the regulated industry)[5] in EU risk regulation. We start with two important observations. Firstly, the CJEU modern approach to reviewing science-based regulation has been almost exclusively a response to litigation brought and framed by the regulated industry. The intensified judicial review, which resulted from that litigation, has reduced the EU administration's discretionary space regarding factual findings and assessments and has mostly benefited economic actors who seek to challenge EU regulation.[6] Secondly, the regulated industry plays a crucial role in the construction of EU regulatory science. Highly resourceful economic actors provide the scientific information on which decisions are based, comment on the decision-making process and litigate against decisions which in their view have not duly considered their information inputs. While the second observation has triggered debates about the risk of epistemic capture, the first observation has been largely neglected in debates about the role of the Court in risk regulation. In a first analysis of this kind, this paper examines the ways in which the CJEU doctrine on legal standing and procedural review of discretion is both shaped by the economic actors' institutional position as information providers and further entrenches that position. In other words, we are interested in the institutional effects of judicial review on the epistemic power of economic actors, understood as the relative influence they can exert on what EU regulators believe, think, or know about health and environmental risks. This is an important question for EU expert accountability more generally. A lot has been written about the need for inclusive deliberation, epistemic diversity, and broad public scrutiny as ways to ensure non-biased, independent, and excellent regulatory science.[7] EU regulation has been reformed over the years to provide many channels of public

[2]Case T-13/99, *Pfizer Animal Health SA v Council of the European Union* ECLI:EU:T:2002:209, para 159.

[3]Eg A Arcuri, 'Three Dimensions of Accountability for Global Technocracy' in A Arcuri and F Coman-Kund (eds), *Technocracy and the Law. Accountability, Governance and Expertise* (Routledge 2021); see also European Commission, 'Communication from the Commission on the Collection and Use of Expertise by the Commission: Principles and Guidelines. "Improving the Knowledge Base for Better Policies"', COM (2002) 713 final.

[4]J Scott and S Sturm, 'Courts as Catalysts. Re-Thinking the Judicial Role in New Governance' 13 (2006) *Columbia Journal of European Law* 565, 583.

[5]In the following we use both terms interchangeably. We refer to economic actors following the terminology adopted by B Hutter, 'The Role of Non-State Actors in Regulation' (2006) *CARR Discussion Papers* No. 37 and by C Abbott and M Lee, 'Economic Actors in EU Environmental Law' 34 (1) (2015) *Yearbook of European Law* 26.

[6]By benefiting we do not mean to say that the industry applicant wins the case, but rather that they get an opportunity to challenge and to present their framing of the regulatory problems at hand.

[7]See eg C Holst and A Molander, 'Public Deliberation and the Fact of Expertise: Making Experts Accountable' 31 (3) (2017) Social Epistemology 235; J Lentsch and P Weingart (eds) *The Politics of Scientific Advice: Institutional Design for Quality Assurance* (Cambridge University Press 2011); Arcuri (n 3) 62.

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participation including at the stage of scientific assessments. Yet to what extent EU judicial review contributes to the participatory nature and broad public scrutiny of EU regulatory science remains an open question.

In recent years, there have been growing concerns over undue corporate influence on and epistemic capture of EU risk regulation. Numerous controversies, such as cases of conflict of interests in European agencies,[8] the EU glyphosate re-authorisation amidst concerns over industry manipulated studies,[9] the authorisation of endocrine disruptors,[10] and the drafting of the EU bee guidance,[11] just to name a few examples, have reignited the debate about the adequacy of existing rules and practices regarding the composition and independence of expert bodies, the integrity of authorisation procedures, as well as about the role of economic actors in EU regulation. These controversies have triggered responses by the EU legislature – for example, a special parliamentary inquiry on the authorisation of glyphosate and, as a direct response to that, a recent reform of the EU General Food Law, which strengthens the rules on the transparency and independence of risk assessments.[12] The EU Ombudsman has also intervened in important ways.[13] Debates about regulatory capture, however, tend not to engage with the role of courts in holding experts to account.[14] Neither have debates on courts in risk regulation directly engaged with the issue of capture.

Our paper closes this gap. We argue that the challenge of ensuring a high-quality and publicly interested regulatory science requires a comprehensive view – one that bridges disciplinary debates and juxtaposes doctrinal developments with interdisciplinary insights about regulation. To achieve this task, we follow a hybrid methodological approach, which combines legal doctrinal analysis of over a decade of CJEU case law with a comparative institutional analysis.[15] The latter

[8]Such concerns are longstanding and the lack of a clear framework for the management of conflicts of interests has been criticised by the European Court of Auditors: see European Court of Auditors, 'Management of Conflict of Interests in Selected EU agencies' (2012) Special Report n 15, <https://www.eca.europa.eu/Lists/ECADocuments/SR12_15/SR12_15_EN.PDF> accessed 21 July 2022.

[9]The 'Monsanto papers' scandal, which emerged in the context of US litigation against Monsanto, suggested the company's manipulation of the scientific studies underpinning the marketing of the weedkiller glyphosate. For its implications at EU level see <https://www.euractiv.com/section/agriculture-food/news/eu-agencies-accused-of-cherry-picking-evidence-in-glyphosate-assessment/> accessed 21 July 2022.

[10]Conflict over endocrine disruptors has resulted in the European Parliament blocking the identification criteria proposed by the Commission for inadequately addressing health and environmental concerns: <https://www.europarl.europa.eu/news/en/press-room/20171002IPR85122/identifying-endocrine-disruptors-meps-block-plans-exempting-some-pesticides> accessed 21 July 2022.

[11]The implementation of EFSA's 2013 bee guidance has been deadlocked. The Member States, supported by the regulated industry, endorse a partial implementation of the Agency's guidance. The European Parliament, on the other hand, asks for a more stringent implementation and has rejected the Commission's proposal in 2019: <https://www.politico.eu/article/eu-battle-over-bees-pesticides-heads-for-another-brick-wall/> accessed 21 July 2022.

[12]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 (the GFL reform). M Morvillo, 'Glyphosate Effect: Has the Glyphosate Controversy Affected the EU's Regulatory Epistemology?' 11 (2020) *European Journal of Risk Regulation* 422; E Hickey and M Weimer, 'The Transparency of EU Agency Science – Towards a New Proactive Approach' 59 (2022) Common Market Law Review 1–38.

[13]M Lee, 'Accountability and Co-production Beyond Courts: The Role of the European Ombudsman' in M Weimer and A de Ruijter (eds), *Regulating Risks in the European Union: The Co-production of Expert and Executive Power* (Hart Publishing 2017) 217. See in particular Decision of the European Ombudsman in her strategic inquiry OI/6/2014/NF concerning the composition and transparency of European Commission expert groups, November 2017.

[14]See for example Abbott and Lee (n 5).

[15]N Komesar, *Imperfect Alternatives: Choosing Institutions in Law, Economics, and Public Policy* (University of Chicago Press 1994); N Komesar and W Wagner, 'The Administrative Process from the Bottom Up: Reflections on the Role, If Any, for Judicial Review' 69 (4) (2017) *Administrative Law Review* 891; for its legal realist variant, G Shaffer, 'Comparative Institutional Analysis and a New Legal Realism' 2 (2013) *Wisconsin Law Review* 607.

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analyses judicial review from the perspective of institutional choice, ie from the perspective of the question of who decides and what the relative merits of 'always imperfect alternative decision-making processes'[16] (eg judicial review v. the administrative process) are. We adopt an epistemologically[17] informed variant of comparative institutional analysis, ie we focus on a particular problem among a wider set of concerns around the modern administrative state, namely the ability of economic actors to participate in and to influence the construction of scientific knowledge underpinning EU risk regulation at the expense of other actors.[18] We then juxtapose this with the participation and epistemic influence of economic actors in EU judicial review of risk regulation. Overall, we seek to understand the institutional effects of certain doctrinal choices on the epistemic power of economic actors in EU risk regulation. This hybrid approach allows us to offer both an internal (doctrinal) and external (interdisciplinary) critique of the CJEU approach, and of its ultimate contribution to EU expert accountability.

When addressing these questions, we also investigate whether and to what extent the Court can be expected to address epistemic power imbalances in the production of EU regulatory science. The ways in which the epistemic foundations of EU risk regulation come together are complex and so are the ways in which judicial review interacts with these processes. Law is always only one part of broader institutional realities, and it follows its own doctrinal logic. The reason why the epistemic power of economic actors has not yet been addressed in discussions about judicial review of EU risk regulation is probably because this is assumed to be a question of empirical reality that falls outside the formal legal-normative realm. We aim to show however that at the very least doctrinal approaches can be complicit in either ignoring epistemic power imbalances in risk regulation or in failing to address them. If so, they are ill-adjusted to the reality of modern risk regulation and its challenges. As we show, judicial understandings of who should have access to the Court (legal standing) and to the administrative process (procedural rights and principles) as well as understandings of administrative discretion are all but neutral. They have consequences for the balance between private and public interests in EU regulation and for the quality of its scientific basis. In our view, any normative engagement with the case law must consider these consequences.

We develop our argument in four steps. We first set out the context for our case law analysis by explaining the ways in which the regulated industry exercises epistemic power over the EU regulatory process, and how the latter involves economic actors as key information providers (Section 2). We then explore how EU judicial review contributes to strengthening the role of economic actors as information providers thereby reinforcing their epistemic power. We focus on the Court's approach, first, to the standing of private applicants (Section 3) and second, to the review of fact and discretion in litigation involving challenges to EU administrative rulemaking (Section 4). We analyse risk regulation case law between 2010 and 2020 to show the evolution of the Court's post-*Pfizer* approach and of the three administrative principles which constitute the hallmark of the Court's procedural review of regulatory science, ie the duty of care, the duty to state reasons, and the right to be heard. We then evaluate our findings combining doctrinal critique with an interdisciplinary perspective on expert accountability (Sections 5 and 6). We argue that, in contrast to previous expectations, the Courts' current doctrinal understanding of procedural review fails to catalyse inclusive deliberation and, therefore, procedures able to secure independent and excellent scientific assessments. Coupled with an intensified review of technical discretion, the post-*Pfizer* modern approach is problematic, because it entrenches economic actors' epistemic

[16]Komesar and Wagner (n 15) 893.

[17]Based on interdisciplinary research comprising political epistemology, political sociology, philosophy of knowledge, studies of regulation and governance, science and technology studies as well as law: see eg Holst and Molander (n 7); Lentsch and Weingart (n 7); Jasanoff (n 1); A Arcuri 'Three Dimensions of Accountability for Global Technocracy' in Arcuri and Coman-Kund (n 3) 62; Weimer and de Ruijter (n 13).

[18]This is inspired by the bottom-up approach to comparative institutional analysis adopted in Komesar and Wagner (n 15).

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power at the expense of other relevant actors. We sketch out a normative vision for EU judicial review of risk regulation that, while being doctrinally coherent, would contribute to expert accountability in a more meaningful way.

2. The epistemic power of economic actors in EU risk regulation

In the EU, the qualitative and quantitative bulk of risk regulation takes place in the implementation phase of the policy cycle. Here, the Commission, assisted by a network of EU regulatory agencies, specifies the technical aspects of legislation.[19] Despite the appearances, the implementation phase is not merely about technicalities: EU legislation is often formulated in an open-ended way,[20] and the definition of substantive, often contentious issues, is frequently allocated to non-legislative acts. Recurrent instances of politicisation, such as with pesticides and authorisations of genetically modified organisms (GMO), show that despite implementation's lower political salience, stakes remain high.[21]

Economic actors play an important role in this context. As applicants, they apply for the authorisation of products, such as GMOs, chemicals, and pharmaceuticals, which may cause harm to consumers or the environment. As lobbyists, they seek, together with other interest groups, such as civil society organisations (CSOs), to influence EU legislation and its implementation.[22] In both cases, economic actors act as information providers vis-à-vis EU regulators, by deploying the technical knowledge they generate with their economic activities (ie developing and manufacturing their products).[23] Such technical knowledge is a valuable asset, as risk regulation largely hinges on technical assessments. EU institutions, and in particular the Commission and European agencies, are notoriously understaffed[24] and therefore dependent on the technical information provided by external actors, ie private and public interest groups and economic actors.[25] Regulators' informational needs are indeed one of the reasons for the involvement of economic actors in regulation.[26]

[19]See Art 291(2) and (3) TFEU.

[20]Eg Art 1(3) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009, concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L309/1 (the Pesticides Regulation): 'the purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production'. See also Art 5, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1 (the General Food Law, GFL).

[21]J Tosun and F Varone, 'Politicizing the Use of Glyphosate in Europe: Comparing Policy Issue Linkage across Advocacy Organizations and Countries' 23 (5–6) (2020) *Journal of Comparative Policy Analysis* 607. See also J Zeitlin et al, 'EU Pesticides Regulation: How Public Support Can Be Rebuilt' (2021) *LSE European Politics and Policy Blog*, <https://blogs.lse.ac.uk/europpblog/2021/06/14/eu-pesticides-regulation-how-public-support-can-be-rebuilt/> accessed 21 July 2022.

[22]On the motivations behind interest groups' engagement with EU agencies, see R Joosen, 'Persuading the Independent: Understanding Why Interest Groups Engage with EU Agencies' 10 (1) (2021) *Interest Groups & Advocacy* 19.

[23]Abbott and Lee (n 5) 34.

[24]H Klüver, *Lobbying in the European Union. Interest Groups, Lobbying Coalitions, and Policy Change* (Oxford University Press 2013) 41.

[25]On EU regulators' need for external technical information, see S Arras and C Braun, 'Stakeholders Wanted! Why and How European Union Agencies Involve Non-State Stakeholders' 25 (9) (2018) *Journal of European Public Policy* 1257; H Hermansson, 'The European Commission's Environmental Stakeholder Consultation: Is Lobbying Success Based on What You Know, What You Own or Who you Know?' 5 (3) (2017) *Interest Groups & Advocacy* 177, 179; A Dür and G Mateo, *Insiders Versus Outsiders: Interest Group Politics in Multilevel Europe* (Oxford University Press 2016), 153; Klüver (n 24) 219; R Eising, 'Institutional Context, Organizational Resources and Strategic Choices. Explaining Interest Group Access in the European Union' 8 (3) (2007) *European Union Politics* 329, 356.

[26]This also reflects a more decentered approach to regulation, acknowledging economic actors' role as information providers, standard-setters, and enforcers, see Abbott and Lee (n 5) 26.

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By deploying their technical knowledge in a contested regulatory space, economic actors exert a form of epistemic power. Epistemic power is the ability to influence what others believe, think, or know and to enable and disable others from exerting epistemic influence.[27] In EU risk regulation, economic actors contribute to shaping both the regulators' information base, by feeding information into the regulatory process, and their regulatory epistemology,[28] by promoting new regulatory paradigms, such as evidence-based regulation or the innovation principle.[29] In this way, they contribute to shaping the very way in which institutional actors think about risks and how to regulate them.

Economic actors exert epistemic power both when lobbying EU institutions and when acting as applicants for products authorisations. As lobbyists, economic actors have easy – albeit not exclusive – access to EU institutions. Empirical findings on lobbying in the implementation phase show that economic actors enjoy an advantage in terms of access to regulators vis-à-vis public interest groups.[30] Institutional efforts to enhance the latter's access to EU decision-making are gradually creating a more level playing field,[31] but public interest groups are still outnumbered by economic actors. The latter's advantage has been found to be substantial regarding executive actors, in particular the European Commission and EU agencies, which dominate the implementation phase.[32]

Generally, access to decision-making does not automatically translate into actual influence on policy outcomes.[33] Research on the legislative phase, for example, suggests that, notwithstanding economic actors' advantages in terms of access, there is a relative balance in terms of the influence exerted by both economic and non-economic actors.[34] High political salience and the European

[27]A Archer et al, 'Celebrity, Democracy, and Epistemic Power' 18 (1) (2020) *Perspectives on Politics* 27, 29.

[28]D Winickoff and D Bushey, 'Science and Power in Global Food Regulation: The Rise of the Codex Alimentarius' 35 (3) (2010) *Science, Technology, & Human Values* 356, 360; A Arcuri, 'Global Food Safety Standards: The Evolving Regulatory Epistemology at the Intersection of the SPS Agreement and the Codex Alimentarius Commission' in P Delimatsis (ed), *The Law, Economics and Politics of International Standardisation* (Cambridge University Press 2015) 79.

[29]On the emergence of the innovation principle as a result of industry lobbying see K Garnett et al, 'Towards an Innovation Principle: An Industry Trump or Shortening the Odds on Environmental Protection?' 10 (1) (2018) *Law, Innovation and Technology* 1. On the role of evidence-based decision-making in the Commission's better regulation agenda, see K Wegrich, 'Which Results? Better Regulation and Institutional Politics' 6 (3) (2015) *European Journal of Risk Regulation* 369, 370; U Pachl, 'Repercussions of the European Commission's Better Regulation Agenda on Consumer Interests and Policy' 6 (3) (2015) *European Journal of Risk Regulation*, 375.

[30]Economic actors are however active throughout the policy cycle, by trying to prevent, shape, make, or revoke rules, see S Eckert, *Corporate Power and Regulation* (Palgrave 2019) 22. On economic actors' prevalence in the implementation phase, see A Gornitzka and U Sverdrup, 'Societal Inclusion in Expert Venues: Participation of Interest Groups and Business in the European Commission Expert Groups' 3 (1) (2015) *Politics and Governance* 151, 161; J Beyers and S Arras, 'Who Feeds Information to Regulators? Stakeholder Diversity in European Union Regulatory Agency Consultations' 21 (1) (2019) *Journal of Public Policy* 22.

[31]D Pakull et al, 'Shop Till You Drop? Venue Choices of Business and Non-Business Interests in the European Union 9 (2020) *Interest Groups & Advocacy* 520, 536; RS Salgado, 'Rebalancing EU Interest Representation? Associative Democracy and EU Funding of Civil Society Organizations' 52 (2) (2014) *Journal of Common Market Studies* 337; C Mahoney, 'The Power of Institutions. State and Interest Group Activity in the European Union' 5 (4) (2004) *European Union Politics* 441, 446.

[32]Dür and Mateo (n 25) 151, 168; A Rasmussen and B Carroll, 'Determinants of Upper-Class Dominance in the Heavenly Chorus: Lessons from European Union Online Consultations' 44 (2013) *British Journal of Political Science* 445; A Dür, 'Interest Groups in the European Union: How Powerful Are They?' 31 (6) (2008) *West European Politics* 1212, 1215.

[33]On access as a structural condition for influence see P Bouwen, 'Corporate Lobbying in the European Union: The Logic of Access' 9 (3) (2002) *Journal of European Public Policy* 365–6. However, access does not automatically imply influence: see A Dür and D De Bièvre, 'Inclusion Without Influence? NGOs in European Trade Policy' 27 (1) (2007) *Journal of Public Policy* 79; B Kohler-Koch and B Finke, 'The Institutional Shaping of EU–Society Relations: A Contribution to Democracy via Participation?' 3 (3) (2007) *Journal of Civil Society* 205, 216.

[34]H Klüver 'Biasing Politics? Interest Group Participation in EU Policy-Making' 35 (5) (2012) *West European Politics* 1114, 1126; H Klüver, *Lobbying in the European Union* (n 24) 206–7; A Dür et al, 'Interest Group Success in the European Union: When (and Why) Does Business Lose?' 48 (8) (2015) *Comparative Political Studies* 951; A Dür et al, *The Political Influence of Business in the European Union* (University of Michigan Press 2019) 4; C Rauh, 'EU Politicization and Policy Initiatives of the European Commission: The Case of Consumer Policy' 26 (3) (2018) *Journal of European Public Policy* 344–65; D Marshall, 'The Diminishing Power of Big Business' in H Zimmermann and A Dür (eds), *Key Controversies in*

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Parliament (EP)'s involvement play to the advantage of public interest groups, mitigating access asymmetries.[35] In the implementation phase, however, political salience is low, the EP's involvement marginal and policy-relevant technical information scarce. Economic actors' chances to translate their access advantage into actual influence therefore increase.[36] There is 'strong evidence to suggest that business groups attempt to mitigate any losses they might have incurred during the legislative phase' through regulatory lobbying in the implementation phase.[37] In addition to regulators' need for technical information, low political salience opens opportunities for 'loophole lobbying'[38] with economic actors maximising the impact of the technical information they provide to the Commission and EU agencies.

Besides lobbying, regulatory design plays a role in entrenching economic actors' epistemic power. Authorisation and registration procedures invite – or even require – economic actors to feed information into the regulatory process. Such procedures concern the allocation of health and environmental risks in society and often result in acts of general application: when a substance is approved to be included in a positive list, for example, it can be sold, bought, and used in the manufacture of products throughout the EU. At the same time, risk-regulatory procedures are individualised, meaning that they are set in motion by an individual producer (or by a group of producers) applying for the registration or marketing authorisation of a specific substance or product. This special character of risk-regulatory acts poses challenges in terms of the classical distinction in administrative law between individual and general determinations,[39] an issue to which we will return.

As applicants, economic actors are expected to include in the application dossier the scientific studies demonstrating their products' compliance with the relevant regulatory requirements.[40]

European Integration (Palgrave 2016) 121, 123. *Contra* see L Horn and A Wigger, 'Business as Usual – The EU Is (Still) Driven by Corporate Interests' ivi, 116.

[35]M Rasmussen, 'The Battle for Influence: The Politics of Business Lobbying in the European Parliament' 53 (2) (2015) *Journal of Common Market Studies* 365; M Hanegraaff and J Berkhout, 'More Business as Usual? Explaining Business Bias Across Issues and Institutions in the European Union' 26 (6) (2019) *Journal of European Public Policy* 843, 858.

[36]Dür et al, *The Political Influence of Business* (n 34) 86 and 160–1; Dür and Mateo (n 25) 153; Dür et al, *Interest Group Success* (n 34) 974; I Michalowitz, 'What Determines Influence? Assessing Conditions for Decision-Making Influence of Interest Groups in the EU' 14 (1) (2007) *Journal of European Public Policy* 132. In particular, according to Klüver, *Lobbying in the European Union* (n 24) 216, business groups 'have a good chance to influence policy-making in the European Union if they dispose of a high degree of economic powers and provide a lot of information to the European Commission, the Council and the European Parliament'. At the same time, catalytic subgroups struggle to reproduce the same level of knowledge in the public sphere. See Eckert (n 30) 33 and Klüver, *Biasing Politics* (n 34) 1116.

[37]Pakull et al (n 31) 537, see also 535 at n 36; The development of REACH guidance documents and information technology tools provides a good example in these regards, with ECHA asking the regulated industry to directly draft guidance on good practice. See Dür et al, *The Political Influence of Business* (n 34) 91–2; on lobbying and participation in the context of REACH, see S Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar 2015); O Fuchs, 'REACH. A New Paradigm for the Management of Chemical Risks' (2009) *IFRI Health and Environment Reports, n 4*, <https://www.ifri.org/sites/default/files/atoms/files/reachnewparadigm.pdf> accessed 21 July 2022; T Persson, 'Democratizing European Chemicals Policy: Do Consultations Favour Civil Society Participation?' 3 (3) (2007) *Journal of Civil Society* 223; D Pesendorfer, 'EU Environmental Policy Under Pressure: Chemicals Policy Change Between Antagonistic Goals?' 15 (2006) *Environmental Politics* 95. Beyond REACH, see also Kimmel's account of stakeholders' participation in the Technical Working Groups drafting the Best Available Techniques Reference documents (BREFs) in the context of the Industrial Emissions Directive. Here, notwithstanding efforts to foster the process's inclusiveness, industry actors still enjoy an advantage vis-à-vis public interest groups, especially regarding the provision of technical information (J Kimmel, 'Assessing the Democratic Quality of New Modes of EU Governance: The Industrial Emissions Directive as a Test Case' 17 (2) (2016) *European Political Science* 240–257). See also D Truijens, *Interest Groups and Experimentalist Governance in the EU* (Palgrave Macmillan 2021) 55.

[38]Loophole lobbying focuses on 'very narrow, often highly technical aspects, in which few, if any, other actors have any interest'; see Dür et al, *The Political Influence of Business* (n 34) 84.

[39]M Krajewski, *Relative Authority of Judicial and Extra-Judicial Review: EU Courts, Boards of Appeal, Ombudsman* (Hart Publishing 2021), 25 speaks in these regards of 'hybrid acts'.

[40]Eg Art 7 and 9 Pesticides Regulation (n 20); Art 10 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L396/1 (REACH); Art 6 Regulation (EC)

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That is because in EU risk regulation, the burden of proof as to the safety of products is allocated to applicants. As a result, scientific assessments rely widely on the evidence generated, sponsored, and presented by the regulated industry.[41] That is not to say that industry's epistemic power is exclusive or unfettered. Publicly available scientific literature is also included in the application dossiers[42] and legal safeguards are in place to ensure the scientific quality and independence of the studies relied on.[43] However, concerns over the independence of industry studies remain, as shown by the glyphosate controversy, and legal safeguards have been found to be insufficient, either by design or because of their inconsistent application.[44]

Economic actors' epistemic power is deployed throughout the authorisation procedure. They maintain frequent contacts with the regulators, regularly exchange correspondence with and attend the expert meetings of EU and Member States' agencies.[45] Most regulatory frameworks have sought to actively widen the range of actors involved, by providing opportunities for public participation (eg through public consultations).[46] However, economic actors' role as applicants reinforces their epistemic agency as compared to other actors. This poses accountability and legitimacy issues as their involvement as information providers might result in biased regulatory outcomes.[47] We refer to this as the risk of a 'minoritarian bias', ie the 'over-representation of concentrated interests to the detriment of majorities'.[48]

The above discussion does not prove the actual existence of a minoritarian bias in EU risk regulation. Yet, it confirms that such risk is present. Economic actors exert epistemic power over EU institutions on technical matters, by feeding information into the regulatory process, and by strategically mobilising their epistemic and other resources to push their (de)regulatory agendas. In the implementation phase, this occurs both de facto, through lobbying, and *de jure*, through legal anchoring of their position as information providers. This is the context, in which industry

No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1 (Pharmaceuticals Regulation).

[41]This is evident also from Case T-610/17 *ICL-IP Terneuzen and ICL Europe Coöperatief v Commission* ECLI:EU:T:2019:637 para 91, where the Court stated that 'the data in the registration dossier constitute the main source of information for the prioritisation exercise carried out by ECHA'. While more research in the field is needed, studies have shown cases of preponderance of industry-funded studies and of selective use and omission of data: see Claire Robinson et al, 'Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions' 11 (2020) *European Journal of Risk Regulation* 450, 455.

[42]Eg Art 8(5) Pesticides Regulation (n 20).

[43]See Art 1(6) GFL reform (n 12), introducing the obligation for economic actors to notify EFSA of the studies commissioned or carried out by them to support an application or notification.

[44]Abbot and Lee (n 5) 52. See also Robinson et al, 'Achieving a high level of protection' (n 41), in particular at 456–8.

[45]Examples of such regular exchanges are well documented in Case T-125/17 *BASF Grenzach v ECHA* ECLI:EU:T:2019:638, paras 5–7; Case T-67/18 *Probelte v Commission* ECLI:EU:T:2019:873, paras 96–100; Case T-636/17 *Plastics Europe v ECHA* ECLI:EU:T:2019:639, paras 10–12; Case T-211/18 *Vanda Pharmaceuticals v Commission* ECLI:EU:T:2019:892, paras 10–14; Case T-100/15 *Dextro Energy v Commission* ECLI:EU:T:2016:150, paras 9–10; Case T-689/13 *Bilbaína de Alquitranes and Others v Commission* ECLI:EU:T:2015:767, paras 4–5; Case T-446/10 *Dow Agrosciences and Dintec Agroquímica – Produtos Químicos v Commission* ECLI:EU:T:2015:629, paras 7–11; Case T-269/11 *Xeda International SA v Commission* ECLI:EU:T:2014:1069, paras 13–19; Case T-483/11 *Sepro Europe v Commission* ECLI:EU:T:2013:407, paras 15–18; Case T-71/10 *Xeda International and Pace International v Commission* ECLI:EU:T:2012:18, paras 14–29.

[46]Eg Art 64(2) and (3) REACH Regulation (n 40). See V Heyvaert, 'The EU Chemicals Policy: Towards Inclusive Governance?' (2008) *LSE Law, Society and Economy Working Papers 7/2008*, 12, <https://www.lse.ac.uk/law/working-paper-series/2007-08/WPS2008-07-Heyvaert.pdf> accessed 21 July 2022.

[47]Abbott and Lee (n 5) 38.

[48]Here we follow the terminology developed in the US by Komesar and Wagner (n 15). The notion of minoritarian bias goes back to the literature on interest group theory of politics. It reflects the ability of small but concentrated interest groups, ie industry organisations or multinational corporations, to dominate both the legislative and the administrative process to the detriment of the majority, ie the broader citizenry. This typically occurs in the field of health and environmental regulation. As a result, concentrated minorities are overrepresented in these processes as compared to the 'dormant' majority; for an in-depth discussion, see Komesar (n 15).

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challenges to EU risk regulation take place. In the following sections, we consider how, in the adjudicative phase, economic actors' epistemic power meets the CJEU's understanding of the administrative process, starting with its doctrine on legal standing.

3. Access to the Court – who gets to challenge EU regulatory science?

The two most salient features of EU risk regulation litigation are its prominent focus on regulatory acts and its being quantitatively dominated by economic actors. Between 2010 and 2020, European Courts (Court of Justice and General Court) decided on the merits of 102 validity challenges (actions for annulment and preliminary rulings on validity) to risk regulation measures.[49] The vast majority of these judgements (89 out of 102) concerns actions for annulment against non-legislative (ie implementing and delegated) measures,[50] most of which are administrative acts of general application, with a minority of individual acts.[51] Of these, 68 were initiated by economic actors, 7 by Member States, and 14 by public interest litigants. The divide is even starker when excluding access to documents litigation[52] and actions brought by Member States,[53] with economic actors initiating 60 challenges against 4 being brought by non-privileged public interest applicants.[54] Economic actors' dominance is partly a matter of resources. Compared to public interest groups, economic actors are financially better equipped to secure access to legal expertise[55] and engage in costly and frequently lengthy legal proceedings.[56] In addition, litigation is an increasingly appealing strategy for economic actors.[57] The judicial declaration of a measure's illegality results in a revocation of an 'unfavourable' rule altogether. Even more importantly, it may affect future regulatory outcomes by producing an anticipatory chilling effect,[58] with the

[49]These include the validity challenges to legislative and non-legislative acts decided on the merits between 01.01.2010 and 31.12.2020 in the areas of food safety, chemicals and pharmaceuticals regulation. Preliminary rulings on interpretation are excluded, and so are decisions of inadmissibility. The findings presented in Sections 3 and 4 are based on a systematic analysis of the quantitatively most significant sub-group of judgements (50 judgements), ie actions for annulment (excluding access to documents cases) initiated by non-privileged applicants against non-legislative measures of general application.

[50]Out of 102 judgements considered, six concern the validity of legislative acts (eg Case C-477/14 *Pillbox 38 UK v The Secretary of State for Health* ECLI:EU:C:2016:324) while the remaining 96 concern non-legislative acts.

[51]On the difference between individualised acts and acts of legislative nature (ie containing a general rule that is intended to apply to all those falling within a certain factual situation), see P Craig, *EU Administrative Law* (Oxford University Press 2012) 110. Out of 96 challenges to non-legislative acts, 50 are against acts of general application (regulations, directives, decisions addressed to Member States, eg Commission Implementing Regulation (EU) No 781/2013 of 14 August 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, challenged in Case T-584/13 *BASF Agro and others v Commission* ECLI:EU:T:2018:279); 13 are against individualised acts (eg Commission Implementing Decision C(2019) 4858 final of 20 June 2019 granting marketing authorisation for the medicinal product for human use Trecondi-treosulfan, addressed to Medac Gesellschaft für klinische Spezialpräparate mbH and challenged in Case T-549/19 *Medac v Commission* ECLI:EU:T:2020:444). The remaining 19 are access to documents cases.

[52]According to Art 8(1) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2001] OJ L145/43 (the Transparency Regulation), applicants who are denied access to documents upon confirmatory application can institute court proceedings against the institution denying access. As addressees of the contested decision, they fulfill the standing requirements set out in the first limb of Art 263(4) TFEU.

[53]For standing purposes, Member States are considered privileged applicants (Art 263(2) TFEU).

[54]For a broader empirical analysis of the actors bringing cases to the CJEU, confirming this pattern, see Krajewski (n 39) 77.

[55]Eckert (n 30) 26; P Bouwen and M Mccown, 'Lobbying versus Litigation: Political and Legal Strategies of Interest Representation in the European Union' 14 (3) (2007) *Journal of European Public Policy* 422, 427.

[56]Bowen and Mccown (n 55) 432.

[57]While the EU is not characterised by the same degree of adversarial legalism as the US, litigation is an increasingly common strategy. See RD Kelemen, *Eurolegalism: The Transformation of Law and Regulation in the European Union* (Harvard University Press 2011); Bouwen and Mccown (n 55) 438; J De Figueiredo and R De Figueiredo, 'The Allocation of Resources by Interest Groups: Lobbying, Litigation and Administrative Regulation' 4 (2) (2002) *Business and Politics* 343; R Kagan, *Adversarial Legalism: The American Way of Law* (Harvard University Press 2001) 6 ff.

[58]Eckert (n 30) 26.

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Commission being more attentive to concentrated interests' arguments than to those of dispersed interests and thus reinforcing the former's epistemic power.

Such a polarised litigation pattern, however, is not a matter of resources and strategy alone. The Court's interpretation of legal standing reinforces the industry's position as litigant and, in doing so, enables the propagation of its epistemic influence from the administrative into the adjudicative phase. In this section, we analyse how the position of the regulated industry as applicants in authorisation procedures also translates in their privileged access to judicial review as compared to other actors who are affected by and might want to contest the science behind EU regulation.

The Court's strict interpretation of standing requirements is subject to a long-standing scholarly debate, and we must limit ourselves to the main points relevant for this paper's argument. The bone of contention is the interpretation of Article 263(4) TFEU, which happens to be the main procedural gateway to challenge EU risk regulation measures.[59] According to this provision, the standing of plaintiffs other than the addressee of an act is subject to the double requirement of direct and individual concern. Since its ruling in *Plaumann* in 1963, the Court has held that '[i]n order for a measure to be of individual concern to the persons to whom it applies, it must affect their legal position because of a factual situation which differentiates them from all other persons and distinguishes them individually in the same way as a person to whom it is addressed'.[60] Direct concern, on the other hand, has been interpreted as meaning that the plaintiff's legal situation must be affected as a direct consequence of the contested act, without the intermediation of additional rules.[61]The strict interpretation of individual concern significantly curtails the possibility for persons other than the (quasi-)addressee to bring actions for annulment. This is especially problematic for public interest groups, such as CSOs or patients' associations.[62] In *Granosalus*, an association of wheat producers and consumers seeking to challenge glyphosate's authorisation was found not to be individually concerned, because 'the contested act affects the applicant's members by reason of their objective status as consumers, citizens of the EU or wheat producers in the same way as any other consumer, citizen of the EU or wheat producer who is actually or potentially in the same situation.'[63] Associations and public interest groups are therefore structurally incompatible with the individualised approach followed by the Court,[64] no matter how strongly they are affected by the decision at hand.

[59]Actions for annulment amount to 89 out of 96 judgements concerning non-legislative measures (including access to documents cases and actions against agencies' Board of Appeals decisions). The remaining are preliminary rulings on validity (4), actions for damages (2), actions for failure to fulfil obligations (1).

[60]Case 25/62 *Plaumann v Commission* ECLI:EU:C:1963:17 p 100.

[61]Cases 41–44/70 *International Fruit Co v Commission* ECLI:EU:C:1971:53, paras 23–28.

[62]Among many, see Ioanna Hadjiyianni, 'Judicial Protection and the Environment in the EU Legal Order: Missing Pieces for a Complete Puzzle of Legal Remedies' 58 (3) (2021) Common Market Law Review 777; M van Wolferen and M Eliantonio, 'Access to Justice in Environmental Matters – The EU's Difficult Road Towards Non-Compliance With the Aarhus Convention' in M Peeters and M Eliantonio (eds), *Research Handbook on EU Environmental Law* (Elgar 2020), 148; S Röttger-Wirtz and M Eliantonio, 'From Integration to Exclusion: EU Composite Administration and Gaps in Judicial Accountability in the Authorisation of Pharmaceuticals' 10 (2019) European Journal of Risk Regulation 393; L Krämer, 'The Environmental Complaint in EU Law' 6 (1) (2009) Journal of European Environmental & Planning Law 13; N de Sadeleer et al, *Access to Justice in Environmental Matters and the Role of NGOs: Empirical Findings and Legal Appraisal* (Europa Law Publishing 2005).

[63]Case T-125/18 *Associazione nazionale granosalus v Commission* ECLI:EU:T:2019:92, para 61.

[64]The very nature of the public interest claims made by NGOs and organisations 'makes it impossible for an applicant to show that he is actually affected in a way that differentiates him from all other persons [. . .] since the aim of the claim is exactly to protect goods of interests which belong to the collective in general (such as the environment)' European Parliament (2012) *Standing up for Your Right(s) in Europe. Locus standi*, 39, <https://www.europarl.europa.eu/RegData/etudes/etudes/join/2012/462478/IPOL-JURI_ET(2012)462478_EN.pdf> accessed 21 July 2022. The Court has however refused to introduce exceptions for public interest litigants (see Case T-585/93 *Stichting Greenpeace Council (Greenpeace International) and others v Commission* ECLI:EU:T:1995:147, para 50). In general, actions brought by associations have been found admissible in three cases, all of which are rare: '(a) when a legal provision grants procedural rights to these associations; (b) where every single

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The Lisbon Treaty has partly relaxed the rules on *locus standi* for regulatory acts, to the effect that private applicants can challenge 'a regulatory act which is of direct concern to them and does not entail implementing measures'.[65] The Court interprets the term 'regulatory act' as referring to non-legislative acts[66] of general application.[67] However, this partial relaxation has not brought about significant change in the ability of interest groups to challenge regulatory acts. The direct concern requirement remains an obstacle. It requires that the act must directly affect the plaintiff's legal situation and leave no discretion as to its addressees, who are entrusted with the task of implementing it, such implementation being purely automatic.[68] Risk regulatory acts, such as positive lists of authorised substances and products, often require further implementation at the national level or are part of two-stage procedures, such as in the case of pesticides. In *Pesticide Action Network Europe v Commission,* a group of environmental CSOs challenged the inclusion of sulfoxaflor in the list of authorised active substances under the Pesticides regulation and was denied standing due to the lack of direct concern. The Court found that the contested act, a Commission implementing regulation[69] and an act of general application, only affects the legal situation of the Member States (enabled to authorise the placing on the market of products containing the active substance) and that of potential applicants for such authorisations. According to the Court, the act had 'neither the purpose nor the consequence' of granting rights or imposing obligations on other subjects.[70]

Notwithstanding the Lisbon amendment, the Court invariably draws the circle of both individually and directly concerned applicants very narrowly: as of 2021, no public interest group has been considered directly concerned by the risk regulation measure it sought to challenge via Article 263(4).[71] Despite widespread criticism from academia,[72] international organisations[73]

member of the association would be directly and individually concerned or (c) where the association's interests, and especially its position as a negotiator, is affected by the measure', Ibid., 42.

[65]Art 263(4) TFEU.

[66]Case T-18/10 *Inuit Tapiriit Kanatami and Others v Parliament and Council* ECLI:EU:T:2011:419, para 56.

[67]General application meaning that the act 'applies to objectively determined situations and it produces legal effects with respect to categories of persons envisaged in general and in the abstract', Case T-262/10 *Microban International Ltd v Commission* ECLI:EU:T:2011:623, para 23.

[68]*Microban* (n 67) para 27. Where an act entails implementing measures, it can be challenged in front of national courts.

[69]Commission Implementing Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor, 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 Commission Implementing Regulation (EU) No 540/2011 [2015] OJ L199/8.

[70]Case T-600/15 *Pesticide Action Network Europe v Commission* ECLI:EU:T:2016:601, paras 25–7. See also *Granosalus* (n 63) para 65 ff.

[71]A partial mitigation of the Court's strictness can be seen in the emerging practice of granting environmental NGOs leave to intervene in the proceedings, provided that they can prove 'a direct and present interest in the result of the case', based either on the scope of their activities or on their direct involvement in studies and programs concerning the subject matter (see Order in Case T-429/13 *Bayer CropScience v Commission* ECLI:EU:T:2014:920; Order in Case T-451/13 *Syngenta Crop Protection and Others v Commission* ECLI:EU:T:2014:951; Order in Case T-185/17 *PlasticsEurope v ECHA* ECLI:EU:T:2017:863; Order in Case T-636/17 *PlasticsEurope v ECHA* ECLI:EU:T:2018:154; Order in Case T-207/18 *PlasticsEurope v ECHA* ECLI:EU:T:2018:731). Interventions are however limited to supporting the form of order sought by one of the main parties, do not confer interveners procedural rights and, most importantly, do not equate the possibility of directly bringing an action to the Court (Art 142, Rules of procedure of the General Court, Art 40 Statute of the CJEU). See also Krajewski (n 39), 81.

[72]See n 62.

[73]On the institutional level, the Courts' strict approach to *locus standi* has been criticised by the Aarhus Convention Compliance Committee (ACCC), which found the EU to be in breach of Art 9, para 3 of the Aarhus Convention on access to environmental justice, primarily because of the obstacle represented by the Courts' interpretation of Art 263(4) TFEU for environmental NGOs to challenge EU acts (Economic Commission for Europe, Meeting of the Parties to the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, *Findings and Recommendations of the Compliance Committee with Regard to Communication ACCC/C/C/2008/32 (part II) Concerning Compliance by the European Union*, ECE/MP.PP/C.1/2017/7). Subsequently, Regulation (EU) 2021/1767 of the European Parliament and of the Council of 6 October 2021 amending Regulation (EC) No 1367/2006 on the application of the provisions of the Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters to Community institutions and bodies [2021] OJ L356/1 has been adopted, amending the Aarhus

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and the Court's Advocate Generals,[74] the Court has not been willing to change its interpretative stance.

The Court's approach reinforces the regulated industry's position as main information provider. Economic actors exert epistemic power by feeding information into the regulatory process and they are the only actors, according to the Court, who are entitled to ask for a review of whether such information was duly considered by the administration. In the next section we look at how the Court reviews administrative discretion in risk regulation. We show that a similarly narrow and individualised understanding of administrative procedures characterises its doctrinal approach to the review of regulatory science. Like with *locus standi*, this ultimately privileges the regulated industry and entrenches its epistemic power in both the regulatory process and its judicial review.

4. Judicial review of EU regulatory science – technical discretion and the function of administrative process guarantees

A. The CJEU's modern approach – the synergy between substantive and procedural review

The CJEU has played an important role in shaping the EU's approach to risk regulation,[75] particularly in the aftermath of the bovine spongiform encephalopathy (BSE) crisis and the ensuing overhaul of EU food and product safety legislation.[76] The case law developed against the background of growing powers of the EU administrative state characterised by the transfer of more legislative as well as direct administrative powers to the EU level,[77] the growth of EU agencies,[78] and the increasing techno-scientific complexity of administrative decision-making on health, safety, and the environment. In response, the Court has gradually defined its modern approach to the review of discretion in risk regulation, thereby developing principles that ought to govern the intricate interplay between science, politics, and law in this field.

EU risk regulation case law, therefore, is often understood as a response to a maturing and expanding EU administrative state. It is often neglected, however, that this very understanding has been reinforced by the way in which economic actors have framed their litigation before the Court. As discussed above, industry challenges against EU administrative rulemaking dominate the litigation. Such challenges are typically framed along the lines of a classic (neo-)liberal conception of the administrative state, which emphasises the dangers of an administration unbound,[79] ie of too much intrusion into the private sphere and freedom of citizens. Industry

Regulation regarding access to justice. The 'new' Aarhus Regulation addresses some of the criticism raised by the ACCC, by loosening the objective and subjective requirements for internal review of EU administrative acts. However, NGOs' access to Court based on the Aarhus Regulation remains indirect and limited to environmental matters, thus providing only a limited answer to the problem of public interest litigants' standing in front of the CJEU. See GC Leonelli, 'Access to the EU Courts in Environmental and Public Health Cases and the Reform of the Aarhus Regulation: Systemic Vision, Pragmatism, and a Happy Ending' 40 (1) (2021) *Yearbook of European Law* 1, 230.

[74]Advocate Generals have, on several occasions, offered more flexible interpretations, see most recently AG Bobek in Case C-352/19 P *Région de Bruxelles-Capitale v European Commission* ECLI:EU:C:2020:588, Opinion of AG Bobek. The case concerned a regional authority's challenge to the renewal of the pesticide glyphosate and was declared inadmissible due to lack of direct concern (Case C-352/19 P *Région de Bruxelles-Capitale v European Commission* ECLI:EU:C:2020:978).

[75]A Alemanno, 'The Shaping of European Risk Regulation by Community Courts' (2008) *The Jean Monnet Working Papers n. 18/2008*.

[76]E Vos, 'EU Food Safety Regulation in the Aftermath of the BSE Crisis' 23 (3) (2000) *Journal of Consumer Policy* 227.

[77]On the evolution of the EU risk regulatory state see M Weimer, *Risk Regulation in the Internal Market* (Oxford University Press 2019) Ch 2.

[78]M Simoncini, *Administrative Regulation Beyond the Non-Delegation Doctrine* (Hart Publishing 2018); M Busuioc, *European Agencies. Law and Practices of Accountability* (Oxford University Press 2013).

[79]A paraphrasing of the book title by E Posner and A Vermeule, *The Executive Unbound* (Oxford University Press 2011).

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challenges tend to focus on concerns over arbitrary or biased use of administrative power, allegedly not grounded in 'sound science,' but in political opportunism or faulty public perceptions of risk.[80] Wide discretion and the precautionary principle, both deeply interrelated, are in this conception the symptoms of an ailing regulatory system, and the antidote presented in response is evidence-based regulation.[81] Control of the exercise of administrative discretion and the need for 'evidence-based' decisions are seen as crucial in avoiding administrative overreach into individual rights of citizens, or in this context, the industry's economic rights.

As a result of industry litigation, the Court's case law over the last twenty years has been focused on addressing such concerns and showed to be responsive to them. EU risk regulation case law is characterised by an emphasis on scientific evidence as a check on the exercise of administrative discretion as well as the willingness of the Court to review such exercise more intensely. Overall, two main features define the Court's modern approach.[82] The first is an intensified substantive review of discretion. Looking at the evolution of the case law, there has been a significant shift from a highly deferential, light-touch approach,[83] to a more intense scrutiny of the substance of risk regulatory measures. This applies particularly to the review of facts and of assessments of facts, and hence of the scientific basis underlying decisions.[84] This shift, perhaps surprisingly, did not occur because of the Court explicitly changing the applicable standard of review, but in a subtler way through the Court's re-interpretation of the applicable standard.[85]

In both early and contemporary case law, the Court has continuously applied the same 'manifest error of assessment' test to the review of both fact and discretion. The mantra repeated in much of the case law is that in cases of high techno-scientific complexity the administration enjoys a broad discretion, which the Court is bound to respect. Hence, the Court should not substitute its judgement for that of the EU administration on questions of fact and discretion and only carry out a limited review. Instead, the party challenging the rule must show that the latter is 'vitiated by a manifest error or misuse of powers' or that the administrative body has 'manifestly exceeded the limits of its discretion'.[86] However, the

[80]*Pfizer* (n 2) is emblematic for this kind of argumentation, see para 127 ('Pfizer maintains that the Community institutions did not correctly assess that risk and complains essentially that they adopted a decision for reasons of political expediency without a proper scientific basis'). More recently, see for example Case T-539/10 *Acino v Commission* ECLI:EU:T:2013:110, para 94.

[81]See H Strassheim, 'Behavioural expertise and regulatory power in Europe' in Weimer and de Ruijter (n 13) 143, 146.

[82]This is observed particularly with regard to the General Court, competent in first instance for actions for annulment.

[83]Exemplified by cases such as Case C-331/88, *Fedesa and others* ECLI:EU:C:1990:391and Case C-157/96, *National Farmers' Union and others* ECLI:EU:C:1998:191.

[84]A Türk, 'Oversight of Administrative Rulemaking: Judicial Review' 19 (1) (2013) *European Law Journal* 141; Craig (n 51) 416; P Dabrowska-Kłosińska, 'EU Courts, Global Risks, and the Health and Environmental Safety Revisited: On Nuances of a Less Deferential Standard of Review' 63 (2013) *EUIRSCAS* 1–8, with a focus on Member States' measures; for an overview of the different stages of CJEU case law, see E Vos, 'The European Court of Justice in the Face of Scientific Uncertainty and Complexity' in M Dawson, B De Witte and E Muir (eds), *Judicial activism at the European Court of Justice: Causes, Responses and Solutions* (Edward Elgar 2013), 145 ff.

[85]According to Craig (n 51) 439, however, that is a common technique employed by Courts, because it helps to show doctrinal continuity and requires less explicit justification: 'It is axiomatic that if the courts operating in any system of administrative law wish to expand the scope of substantive review they can do so in one of two ways. They might choose to add new heads of substantive review to those currently available within that system, a classic example being the recognition of proportionality review. They might also expand the reach of substantive review by taking existing heads of review and giving them a more expansive interpretation than hitherto.'

[86]See Craig (n 51) 408 ff. *Pfizer* (n 2) paras 168–9; more recently see, for example, Case T-574/18 *Agrochem Maks v Commission* ECLI:EU:T:2020:226, para 61–3; Case T-207/18 *Plastics Europe v ECHA* ECLI:EU:T:2020:623, para 94; Case T-108/17 *ClientEarth v Commission* ECLI:EU:T:2019:215, para 246; *Vanda* (n 45) para 51; Case T-115/15 *Deza v ECHA* ECLI:EU:T:2017:329 para 163; *Dextro Energy* (n 45), para 31; *Bilbaína v Commission* (n 45), para 23; Case T-456/11 *International Cadmium Association (ICDA) et al v Commission* ECLI:EU:T:2013:594, para 45; Case T-457/07 *Dow Agrosciences et al v Commission* ECLI:EU:T:2011:445, paras 151–2.

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meaning of this test has changed over time. In early cases, such as *Fedesa*, the Court would not engage with the science underpinning the contested measures, typically rejecting the allegation of manifest error in a brief manner unless some flagrant error could be shown on the face of the decision.[87] This changed around the turn of the millennium, when cases such as *Pfizer*,[88] *Alpharma*,[89] and *Artegodan*[90] signalled the opening of a new chapter in the Court's case law. From then on, the Court typically ascertains whether there is a manifest error by engaging in a more searching review of both the scientific evidence and the administrative reasoning.[91]

The second feature of the CJEU's modern approach is its procedural nature. The intensification of substantive review via the manifest error of assessment test went hand in hand with – or rather, was achieved through – an emphasis on procedural standards flowing from the right to a good administration, most notably the duty of a careful and impartial examination, the duty to give reasons, and the right to be heard.[92] The Court's reliance on procedural guarantees emerged as a form of compensation for its limited review of the merits in cases entailing complex technical assessments. This approach was first articulated in *Technische Universität München*,[93] where the Court stated that:

> since an administrative procedure entailing complex technical evaluations is involved, the Commission must have a power of appraisal in order to be able to fulfil its tasks. However, where the Community institutions have such a power of appraisal, respect for the rights guaranteed by the Community legal order in administrative procedures is of even more fundamental importance. Those guarantees include in particular the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case, the right of the person concerned to make his views known and to have an adequately reasoned decision.[94]

Procedural guarantees acquired a particular meaning in the field of risk regulation, as the Court clarified in *Pfizer*. Here, it established that:

> a scientific risk assessment carried out as thoroughly as possible on the basis of scientific advice founded on the principles of excellence, transparency and independence is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude arbitrary measures.[95]

Commentators have highlighted that, under the label of procedural review, the Court started using substantive and procedural standards in a synergetic way.[96] In other words, procedural standards invite the Court to engage with risk assessments, which in turn facilitates substantive scrutiny, leading to an overall intensification of judicial control over EU regulatory science.

[87] *Fedesa* (n 83) para 9: 'the claim based on the existence of scientific evidence demonstrating the safety of the five hormones in question cannot be upheld. It is not necessary to order any measures of inquiry to verify the accuracy of that allegation'. See Craig (n 51) 409.

[88] *Pfizer* (n 2).

[89] Case T-70/99, *Alpharma Inc. v Council of the European Union* ECLI:EU:T:2002:210.

[90] Joined cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00, T-141/00, *Artegodan GmbH et al v Commission of the European Communities* ECLI:EU:T:2002:283.

[91] Vos (n 84); Dabrowska (n 84) 9 ff. See for example Case T-75/06, *Bayer CropScience AG v Commission* ECLI:EU:T:2008:317 (263 paragraphs); Case T-326/07 *Cheminova et al v Commission* ECLI:EU:T:2009:299 (268 paragraphs).

[92] For a good overview of substantive and procedural review of EU administrative rule-making see Türk (n 84), 126–42.

[93] Case C-269/90 *Technische Universität München* ECLI:EU:C:1991:438 para 14.

[94] *Technische Universität München* (n 93) para 13–14.

[95] *Pfizer* (n 2) para 172. Subsequently see also *Dow Agro* (n 86) para 153; *Cheminova* (n 91) para 224 ff.

[96] Craig (n 51) 443; HP Nehl *Principles of Administrative Procedure in EC Law* (Bloomsbury Publishing PLC 1999) 107–9.

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The modern approach has been consolidated in the subsequent case law. The intensified scrutiny under the manifest error of assessment test[97] and procedural review[98] are now constant features of EU risk regulation jurisprudence and have been widely discussed among legal scholars. The modern approach has been dubbed as substantially deferential, but procedurally activist,[99] because it would allow the Court to respect the administration's discretion, hold the decision-makers to account for the way in which they collected and used scientific information, as well as review the adequacy of administrative reasoning based on that evidence, all at the same time. In this way, the Court's case law has often been seen as achieving a sort of *Goldilocks* balance between the Court's task of ensuring judicial protection, on the one hand, and its duty, flowing from the principle of institutional balance, to respect the administration's prerogatives as decision-maker, on the other hand.[100]

On some accounts, the Court's approach in cases such as *Pfizer*,[101] *Alpharma*,[102] and *Artegodan*,[103] is seen as having a more far-reaching catalytic effect on the legitimacy of the EU administrative process. In this view, the Court's case law is seen as part of a broader governance trend whereby judicial review fulfils a quasi-regulatory function by promoting the adherence to deliberation-enhancing procedural standards, such as participation, inclusion, and transparency.[104] With regard to regulatory science, the Court acts as an 'information catalyst' seeking to ensure, through the use of the principles of care and reason-giving, that the evidence underpinning risk decisions is of high epistemic quality.[105] In Corkin's words, the Court is 'the "catalyst" that enhances [decision makers'] capacity to regulate legitimately by articulating norms that prompt them to involve affected parties, regulate from an adequate informational base and do so in a principled (deliberative), accountable, and transparent manner'.[106]

While the Court's case law does indeed catalyse procedural principles, the extent to which the use of such principles serves to involve *all* affected parties and to promote *inclusive* deliberation in EU risk regulation is doubtful. Studies since *Pfizer* have mostly attempted to make sense of the case law or to evaluate it either from the deliberative governance point of view or from the judicial protection of the applicant's rights point of view or a mixture of both. While we do not negate the importance of both deliberation in the administrative process and judicial protection of rights, we are concerned about the narrow circle of beneficiaries drawn by the Court's doctrinal approach and the potential institutional consequences for the epistemic power economic actors are able to exercise over both the regulatory and judicial process. In fact, the role of the industry in both

[97]Eg *Plastics Europe* (n 86) (273 paragraphs); *BASF v ECHA* (n 45) (480 paragraphs); *ClientEarth v Commission* (n 86) (310 paragraphs); *Bayer CropScience v Commission* ECLI:EU:T:2018:280 (623 paragraphs); *Dow Agrosciences* (n 86) (292 paragraphs).

[98]The importance of procedural guarantees features regularly in the 2010–2020 case-law. See eg *Agrochem* (n 86) paras 62–5; *Vanda* (n 45) para 52; Case T-400/17 *Deza v Commission* ECLI:EU:T:2018:712 para 25; *BASF v Commission* (n 51) para 95; *Deza v ECHA* (n 86) para 164; Case T-134/13 *Polynt et al v ECHA* ECLI:EU:T:2015:254 para 53; Case T-268/10 RENV *Polyelectrolyte v ECHA* ECLI:EU:T:2015:698 para 74; Case T-135/13 *Hitachi chemical Europe GmbHet al v ECHA* ECLI:EU:T:2015:253 para 53; *Bilbaína v Commission* (n 45) para 24; Case T-94/10 *Rütgers v ECHA* ECLI:EU:T:2013:107 para 99 and para 100; Case T-95/10 *Cindu chemicals and others v ECHA* ECLI:EU:T:2013:108 para 106; Case T-368/11 *Polyelectrolyte v Commission* ECLI:EU:T:2013:53 para 31; Case T-93/10 *Bilbaína v ECHA* ECLI:EU:T:2013:106 paras 76–7.

[99]This notion was coined by J Corkin, 'Science, Legitimacy and the Law: Regulating Risk Regulation Judiciously in the European Community' 33 (3) (2008) *European Law Review* 359, 383. Note however, that the foundations of the procedurally activist approach go back to the older case law, namely *Technische Universität München* (n 93). For an overview of the different stages of CJEU case law, see Vos (n 84) 145 ff.

[100]Even though scholars often disagree whether the Court's case law, or a specific judgement, tilts the balance towards one end or the other.

[101]*Pfizer* (n 2).

[102]*Alpharma* (n 89).

[103]*Artegodan* (n 90).

[104]Scott and Sturm (n 4) 565–94.

[105]Scott and Sturm (n 4) 582 ff.

[106]Corkin (n 99) 360.

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shaping the Court's approach and benefiting from it has remained under the radar so far. As we show in the following, the way procedural grounds of review, such as the duty of care, the duty to state reasons, and the right to be heard, are understood and utilised in the case law makes them an effective mechanism in the hands of the regulated industry to challenge EU agency science and therefore public regulation, while no comparable mechanisms are available to other actors, most notably civil society. The consolidated litigation strategy of the regulated industry pushes the Court to intensify its review of the factual basis underpinning the administration's decision. *Vanda*, a case concerning the authorisation of the schizophrenia treatment Fanaptum, is emblematic of how industry applicants exploit the synergy between a more searching scrutiny and procedural review:

> the applicant submits that the Commission is seeking, by putting forward an excessively restrictive interpretation of the extent of judicial review, to adopt a 'strategy of obfuscation' intended to convince the Court not to examine the merits of the pleas and to prevent it from addressing several fundamental questions concerning the compatibility of the contested decision with EU law. The applicant submits that it is apparent from the case-law that the EU judicature is in a position to assess the legality of the scientific evaluation made by the CHMP [Committee for Medicinal Products for Human Use] [...] and, where appropriate, to determine whether the unlawfulness of that assessment constitutes a breach of an essential procedural requirement rendering the Commission's decision unlawful.[107]

In the following, we look more closely into how the Court understands the purpose and scope of the process values it deploys in responding to industry challenges. We consider the actions for annulment, excluding cases on access to documents, brought by non-privileged applicants between 2010 and 2020 against administrative rulemaking and decided on the merits. Here, the most frequently invoked grounds of review are (manifest) errors of assessment (33 times) and breach of the principle of proportionality (27 times). Other frequently invoked grounds are the duty to state reasons (14 times); the rights of the defence (including the right to be heard and the right to a fair hearing) (14 times); the principle of good or sound administration (10 times); and, although more rarely, the precautionary principle (5 times). Being concerned with economic actors' epistemic power, our focus is on challenges to risk assessments (ie the epistemic foundation of risk regulation measures), occurring mainly through complaints about manifest errors of assessment and the invocation of the procedural principles of duty of care, reason giving, and the right to be heard.[108] We look at how these principles have been understood and utilised in the case law between 2010–2020 and how that affects the epistemic power of the regulated industry.

B. Case law 2010–2020: To whom does the EU administration owe care?

In the EU legal order, the duty of care is 'the duty of the administration to impartially and carefully collect and examine the information needed for its decision-making'.[109] In risk

[107] *Vanda* (n 45) para 49. For the Commission's push for a more limited review see Case C-691/15 P *Commission v Bilbaína* ECLI:EU:C:2017:882 paras 57–8.

[108] The duty of care is seldom invoked explicitly, but, it is part and parcel with the manifest error of assessment test. Another, less frequent (2 times) ground invoked to invite the Court to review the administration's factual assessments is the breach of the requirement of excellence of scientific advice. On the Court's approach to the precautionary principle and the principle of proportionality in risk regulation case law, see GC Leonelli, 'Acknowledging the Centrality of the Precautionary Principle in Judicial Review of EU Risk Regulation: Why It Matters' 57 (6) (2020) Common Market Law Review 1773.

[109] Nehl (n 96) 107. For the first formulation of the principle see Case C-16/90, *Nölle v Hauptzollamt Bremen-Freihafen*, ECLI:EU:C:1991:402, para 13.

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regulation it has been interpreted by the Court as entailing the administration's duty to carry out a thorough risk assessment based on the principles of excellence, independence, and transparency.[110]

In the context of administrative rulemaking, the duty of care is an objective procedural requirement which 'contributes to a factually accurate decision and thereby to achieving the public interests laid down by its legislative mandate'.[111] In *Arizona Chemical*, a case concerning the exclusion of a chemical substance from the positive list of authorised substances, the Court explicitly differentiated between the role of the duty of care in procedures resulting in the adoption of an administrative act of individual application as opposed to acts of general application. In the former, following the *T.U. München* approach,[112] the duty of care operates as a procedural guarantee individuals can invoke against discretionary acts which adversely affect their legal sphere; in the latter, the duty of care is 'essentially an objective procedural guarantee arising from an absolute and unconditional obligation on the Community institution relating to the drafting of an act of general application and not the exercise of any individual right'.[113] The differentiation in *Arizona Chemical* between the objective and individual dimensions of the duty of care depending on the act to which it is applied remains rare. As we discuss in the following, the Court has settled for the *T.U. München* approach to the duty of care also when reviewing acts of administrative rulemaking, emphasising its protective and compensatory dimension to the benefit of the individual applicant, rather than its objective and public interest nature.

As mentioned in the previous section, the Court's review based on the duty of care is enmeshed with the substantive review of administrative discretion. Duty of care is rarely invoked explicitly as a self-standing ground of review but is rather mediated through the manifest error of assessment test. This has been the case since *Pfizer*:

> The Community judicature is not entitled to substitute its assessment of the facts for that of the Community institutions, on which the Treaty confers sole responsibility for that duty. Instead, it must confine itself to ascertaining whether the exercise by the institutions of their discretion in that regard is vitiated by a manifest error or a misuse of powers or whether the institutions clearly exceeded the bounds of their discretion. [. . .] However [. . .] in such circumstances, the guarantees conferred by the Community legal order in administrative proceedings are of even more fundamental importance. Those guarantees include, in particular, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case.[114]

When assessing whether a manifest error of assessment has been committed by the EU administration, the Court does so by checking whether all the relevant evidence has been carefully and impartially considered ie whether the duty of care has been fulfilled.[115] Notwithstanding the Court's stated limited review, the procedural scrutiny carried out under the manifest error of assessment test has enabled the Court to go further into the review of regulatory science. In *Pfizer*, it was used by the Court to thoroughly (230 paragraphs, 71 pages) engage with scientific

[110] *Pfizer* (n 2) paras 171–2. See also *Alpharma* (n 89) paras 183 and 211; *Bayer* (2008) (n 91) para 250. More recently, *Agrochem* (n 86) para 65; *BASF v Commisison* (n 51) para 96; *Bayer* (2018) (n 97) para 147; Case T-296/12 *Health Food Manufacturers' Association and Others v Commission* ECLI:EU:T:2015:375 para 130.

[111] Türk (n 84) 128.

[112] *Technische Universität München* (n 93). See also Nehl (n 96) 117.

[113] Case Case T-369/03 *Arizona chemical v Commission* ECLI:EU:T:2005:458, para 86.

[114] *Pfizer* (n 2) paras 171–2.

[115] Specifically as to the importance of a careful and impartial examination of the facts, see eg *BASF v Commission* (n 51) paras 93–5; *Bayer* (n 97) para 146; *Dow Agrosciences* (n 45) para 27; *Xeda* (n 45) paras 42–3; *Sepro Europe* (n 45) para 39; *Xeda* (n 45) para 70–1; Case T-291/04 *Enviro Tech Europe and Enviro Tech International v Commission* ECLI:EU:T:2011:760 para 62; *Dow Agrosciences* (n 86) para 154.

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arguments of the parties in order to review the substantive rationality (ie their non-arbitrary nature) of the administrative rule in question. It scrutinised the presence of factual errors, the adequacy of the scientific data, as well as the reasoning of the Commission when assessing the scientific evidence and drawing conclusions from it.[116]

Since *Pfizer*, the Court's framing of its review of complex technical assessments has become more sophisticated and demanding. Over the last decade, the Court has started qualifying the manifest error of assessment test by formulating a plausibility requirement. Since the early 2010s, it has increasingly required that

> in order to establish that the Commission committed a manifest error of assessment in assessing complex facts such as to justify the annulment of a decision which is contested, the evidence adduced by the applicant must be sufficient to make the factual assessments used in the decision implausible.[117]

Arguably, plausibility requires a subtler engagement with the substance of the case, compared to a 'simple' manifest error of assessment test. The Court's duty to control whether the relevant aspects of the individual case have been carefully and impartially examined has developed into a more refined scrutiny of:

- whether the evidence relied on is factually accurate, reliable, and consistent,
- whether that evidence contains all the information which must be considered to assess a complex situation, and
- whether it can substantiate the conclusions drawn from it.[118]

While intensifying the scrutiny in this way, the Court continues to emphasise the protective individual dimension of the principle of duty of care also when reviewing acts of administrative rule-making. The Court invariably reiterates the reasoning according to which wide discretion entails limited review, limited review entails enhanced procedural scrutiny, and procedural review entails 'the obligation to examine carefully and impartially all the relevant elements of the individual case' to ensure the scientific objectivity and lack of arbitrariness of the measures adopted.[119] Rather than operating as an objective procedural guarantee, aimed at protecting the public interest in good administration, the duty of care is seen as protecting the applicant against arbitrary exercises of administrative discretion.

Let us now consider, first, the type of scenarios that prompt the Court's procedural review based on the duty of care and, second, how the Court carries it out in practice. Economic actors challenging the scientific basis of regulatory measures lament two main forms of manifest errors of assessment: the risk assessor (ie the relevant agency) did not consider all the relevant evidence; the assessment methods adopted by the risk assessor are not adequate. In the following, we analyse the Court's response to these challenges.

[116] *Pfizer* (n 2) paras 174–404.

[117] *Dow AgroSciences* (n 86) para 152. Subsequently also T-201/13 *Rubinum v Commission* ECLI:EU:T:2015:311 para 72; *BASF v Commission* (n 51) para 94; *Bayer* (n 97) para 145; *Client Earth v Commission* (n 86) para 246; *ICL-IP* (n 41) para 160; *Vanda* (n 45) para 131; *Agrochem* (n 91) para 63; *Plastics Europe* (2020) (n 86) para 94.

[118] *Dow Agrosciences* (n 86) para 154. See also *Bilbaína* (n 98) para 77; *ICDA* (n 86) para 45–6; *Cindu* (n 98) para 106; *Polynt* (n 98) para 53; *Plastics Europe* (n 86) para 94.

[119] *Bayer* (n 97) para 146; *Basf v Commission* (n 51) paras 93–5; *Xeda* (n 45) paras 42–3; *Sepro Europe* (n 45) para 39; *Xeda* (n 45) para 70–1; *Dow Agrosciences* (n 86) para 154.

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B.1 Challenges to the completeness of the information basis

The first type of manifest errors of assessment invoked by economic actors is the incompleteness of the information underpinning the contested measure. According to litigants, such incompleteness indicates a manifestly erroneous or implausible assessment where the agency has not carefully considered all the relevant information, typically studies submitted by the applicant in the application, or has failed to carefully consider the comments submitted by the applicant during public consultations or other exchanges with the agency. Failure to consider such evidence, so the argument goes, affects the assessment's correctness, in so far as, if duly considered, such information would have led to a different regulatory outcome. This type of challenges results in the Court engaging in a searching review of the administration's determinations. While in most cases the Court acknowledges the administration's wide discretion,[120] it reaches this conclusion after having dissected the scientific underpinnings of the contested decision.

Such dissection can take the form of a box-ticking exercise, aimed at verifying whether the allegedly neglected studies formally feature in the contested risk assessment,[121] or engage directly with its substance. *Bayer*[122] is a good example of the latter. Here, several pesticides producers challenged the Commission's decision to prohibit the sale and use of seeds treated with plant protection products containing three active substances deemed to be lethal to bees. The applicants lamented the lack of consideration of specific studies and monitoring data included in their applications. When reviewing EFSA's opinion, on which the contested decision was based, the Court assessed whether and how the agency considered the applicant's data. It found that the European Food Safety Authority (EFSA) had taken such data into account but that, nevertheless, such data could not 'have a decisive influence on the outcome of the risk assessment and, in particular, cannot establish with sufficient certainty the safety of the substances covered'.[123] Hence, there was no manifest error of assessment. This shows that the Court holds regulatory science to account by scrutinising the agency's use of evidence but does so only with respect to the scientific studies invoked by the industry applicant.

Paradoxically, the Court's exclusive approach to the duty of care applies also to the evidence submitted in the context of public consultations, which are specifically aimed at broadening the range of information considered in the regulatory process. Several risk regulation regimes provide for public consultations and, in general, economic as well as other actors can submit information to risk assessors. However, only the industry applicants can challenge unfavourable regulatory outcomes on the ground that such information has not been duly considered.

A typical scenario is that in *ICL-IP*.[124] The case concerned the classification of a chemical compound, nPB (1-bromopropane), as a substance of very high concern according to Article 57(c) REACH. Among other grievances, the applicants lamented that the Commission had breached the principle of sound administration and committed a manifest error of assessment by 'relying exclusively on the data concerning the volumes contained in the registration file and not on the data submitted in the context of the public consultation and, subsequently, during the procedure

[120]See for example *PlasticsEurope* (n 86) in particular para 64.

[121]See for example *Xeda* (n 45). Here, the applicant lamented that the Commission had failed to consider two reports, drawn by the Joint Meetings of the Food and Agricultural Organisation of the United Nations (FAO) and the World Health Organisation (WHO) on Pesticides Residues (JMPR) and by the United States Environmental Protection Agency (EPA) respectively, and had hence erroneously decided not to include the active substance ethoxyquin in Annex I to Council Directive 91/414/EEC, due to health and environmental concerns. The Court (para 93 ff) considered the Draft Assessment Report prepared by the Rapporteur Member State and EFSA's peer review report and was satisfied to find references to both the JMPR and the EPA reports, thus confirming that they had indeed been taken into account.

[122]*Bayer* (n 97).

[123]Ibid., para 380.

[124]*ICL-IP* (n 41). See also *Bilbaina v ECHA* (n 98) paras 106–107; *Cindu* (n 98) para 134; *Rütgers* (n 98) paras 127–8 and 128–9; *Dow agrosciences* (n 45) paras 46–7; *Hitachi* (n 98) paras 84–90; *Polynt* (n 98) paras 86–8.

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leading to the adoption of the contested regulation'.[125] The applicants had actively interacted with the European Chemicals Agency (ECHA) and the Commission by submitting comments and letters supporting the case for nPB's non-inclusion as a substance of very high concern. In so doing, they had submitted new information, some of which contradicted that originally included in the registration dossier. The Court considered the issue extensively (in a total of 58 paragraphs). First, it reviewed ECHA's responses to the applicants' public consultation comments to establish whether it had considered that additional information.[126] It found that the agency had replied to the comments and established that they did not call into question its conclusions.[127] Second, the Court considered whether the Commission had committed a manifest error of assessment by not using the additional information submitted in the context of the public consultation. Here, the Court concluded that the EU administration could not be criticised for having relied primarily on the information included in the registration dossier submitted by the applicant, instead of that submitted, again by the applicant, during the public consultation. It should be noted that references to information submitted by other actors are absent from the Court's reasoning. Even when embedded in participatory mechanisms such as public consultations, the Court uses the principle of duty of care only to ascertain that the decision-maker considered information submitted by the applicant. While this might not be surprising, as the Court is reacting to the applicants' requests, it obscures the fact that the Court could, by acting *ex officio*, use the duty of care to scrutinise the decision's epistemic basis in a more comprehensive fashion, reaching beyond the applicant's requests and verifying instead whether *all* the information submitted during the public consultation has been duly considered.[128] As of today, however, the Court's focus remains narrow: in the Court's words, 'it is true that the public consultation provided for in Article 58(4) of Regulation No 1907/2006 enables *all interested parties* to provide relevant data. It therefore enables *the registrants* to produce additional information concerning the uses to be exempted from the authorisation requirement.'[129]

The judgements dealing with allegations of incompleteness confirm that despite the Court's expressed respect for the administration's broad discretion concerning factual assessments, a relatively intense scrutiny of such assessments takes place under the principle of duty of care. The latter is, moreover, interpreted as protecting the interests of the applicant rather than an objective procedural guarantee. In theory, careful and impartial consideration is owed to 'all the relevant evidence'. In practice, the dissection of the science behind the contested measures is conducted exclusively on the grounds of a limited set of evidence, ie that submitted by economic actors as applicants in the administrative process and subsequently invoked by them as litigants in the adjudicative phase. Rather than promoting a more epistemically diverse information basis, the Court's enhanced scrutiny is limited to double-checking whether the information submitted by the same narrow circle of actors has been duly considered.

B.2 Challenges to the choice of the assessment method

The cases considered above respond to legal challenges pivoted on the allegation of incomplete information. A second line of complaints based on the principle of duty of care challenges the

[125] *ICL-IP* (n 41) para 42.

[126] Ibid., paras 68–126.

[127] Ibid., paras 70–2.

[128] See for example Case C-367/95 *Sytraval* ECLI:EU:C:1998:154, para 62 on state aid, where the Court of Justice found that the duty of care might, where necessary, oblige the decision-maker to examine facts beyond those brought to their attention by the complainant; see also Case T-95/04 *Chambre Syndicale Nationale des Entreprises de Transport de Fonds et Valeurs and Brink's France SARL v Commission of the European Communities* ECLI:EU:T:1995:172, para 78.

[129] *ICL-IP* (n 41) para 98. See also *Hitachi* (n 98) and *Polynt* (n 98). Here, faced with a similar complaint, the Court examined only cursorily whether the comments submitted by the applicants and the other interested parties (also producers) in the public consultations had been considered, concluding that 'it is apparent from the responses to the comments submitted by the first applicant and other interested parties that all the comments in question were taken into consideration during the identification procedure' (para 86 of both judgements).

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scientific assessment methods chosen by the administration. Methodology cases are characterised by a dense intertwinement of scientific and legal considerations, whereby the Court reviews whether the chosen assessment method is allowed by the relevant legislation and correctly applied. They are often ambiguous and unpredictable in terms of standard of review,[130] but overall they confirm the Court's exclusive reliance on the evidence invoked by the applicants.

Bilbaìna v Commission[131] epitomises the pitfalls of methodology review and is one of the few cases resulting in the annulment of the contested measure, in so far as the Commission erred in the choice of the assessment method. Several producers sought the annulment of the Commission's classification of pitch, coal tar, high-temp (CTPHT), as a substance of very high concern under the Regulation on the classification, labelling, and packaging of substances and mixtures (CLP Regulation) due to its aquatic toxicity. They challenged the method applied to the assessment of the substance's properties, which allegedly resulted in an unreasonably unfavourable assessment.[132] The Court upheld the complaint, because the Commission had 'failed to comply with its obligation to take into consideration all the relevant factors'. These included elements, such as 'the proportion in which the 16 polycyclic aromatic hydrocarbon (PAH) constituents are present in CTPHT and their chemical effects,' namely their low water solubility, which were suggested by the applicants, but not mentioned by the regulation.[133] As a result, the Court found the Commission's assessment to be 'non realistic'.[134] *Bilbaìna v Commission* clearly shows, that the Court's modern approach can result in an intrusive review with the Court close to substituting its assessment to that of the Commission. It also shows that such intrusive scrutiny results from the litigants' operationalisation of the duty of care, to which the Court responds.

'Methods review' cases invite the Court to engage with the quality of the risk assessment process. Instead of taking a comprehensive view of the decision-making process and its deliberative qualities, its scrutiny remains firmly anchored within the applicant-administration binomial. At most, the Court widens the circle of information providers slightly – and rarely – by referring to peer-reviewed scientific literature, but comments and studies submitted by third parties in the context of public consultations remain out of the Court's sight. Therefore, regrettably, the Court's engagement with the risk assessment process does not catalyse deliberation, at least not in its proper sense of including all those concerned.[135] The Court is satisfied with the fact that the relevant scientific committee, which often includes industry representatives, bases its opinion 'on the results of a number of tests carried out using different methods, confirmed by information taken from specialist publications'.[136] There is no apparent concern for the process including a wider range of relevant voices. This is problematic, in light of the epistemic power exerted by economic actors in the regulatory phase and of the intensified review of risk regulation

[130]See GC Leonelli, 'A. Court of Justice The Fine Line between Procedural and Substantive Review in Cases Involving Complex Technical-Scientific Evaluations: Bilbaìna' 55 (4) (2018) Common Market Law Review 1217.

[131]*Bilbaína v Commission* (n 45), confirmed on appeal in *Commission v Bilbaìna* (n 107). See also the antecedent (and with opposite outcome) *Bilbaìna v ECHA* (n 98), confirmed on appeal in Case C-287/13 P *Bilbaìna v ECHA* ECLI:EU:C:2014:599.

[132]In order to establish its aquatic toxicity, ECHA analysed the substance as a mixture, ie based on the properties of its constituents, individually considered (according to the 'summation method'), rather than as a whole. According to the applicants, this approach failed to consider the low water solubility (and therefore limited availability to aquatic organisms) of some of CTPHT components, thus resulting in an excessively unfavorable assessment of its aquatic toxicity (*Bilbaìna* (n 45) para 7).

[133]*Bilbaína* (n 45) para 30 ff.

[134]Ibid., para 34.

[135]The importance of inclusiveness as a condition for deliberation has been repeatedly highlighted in the literature: see for example Holst and Molander (n 7), 243; E Korkea-aho, *Adjudicating New Governance: Deliberative Democracy in the European Union* (Routledge 2015), 70.

[136]*EnviroTech* (n 115) para 141, referring to Case C-425/08 *Enviro Tech (Europe)* ECLI:EU:C:2009:635 para 64. The case concerned the classification of nPB (n-propyl bormide) as having certain dangerous properties (eg flammability). In particular, the producer contested the methodological choices made in the context of an expert group, which 'also welcomes representatives of the industry concerned by the products at issue who may make observations at the beginning of the meeting, followed by a question and answer session' (Ibid., para 29).

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measures in the adjudicative phase. In other words, the Courts' more stringent review mostly benefits those actors, ie the regulated industry, who already enjoy a dominant position in the regulatory process.

It is important to note that the judicial emphasis on process values is not only a reaction to industry-led litigation, but also a consequence of the Court's attempt to compensate for the difficulty of substantive review in highly technical matters.[137] This results in a narrowing down of the function of principle of duty of care in procedures of general rulemaking, a point to which we will return at the end of this paper.

C. Case law 2010–2020: To whom does the EU administration owe justification?

The duty to state reasons, as enshrined in Article 296 TFEU, entails that 'legal acts shall state the reasons on which they are based.' The duty to state reasons has a threefold dimension: protective (giving 'an opportunity to the parties to defend their rights'), control (allowing 'the Court to exercise its supervisory functions') and of objective procedural guarantee (giving 'an opportunity to Member States and to all interested nationals of ascertaining the circumstances in which the Commission has applied the Treaty').[138] In its objective dimension, the duty to state reasons provides 'the basis for efficient and fair administrative decision-making by ensuring that officials perform their tasks free from outside interference and arrive at decisions in a rational way'.[139] More generally, reason giving fulfils a broader democratic function by allowing the public to understand and scrutinise the exercise of public power.[140] It applies to all EU legal acts, regardless of their individual or general application.

Like the duty of care, the duty to state reasons is invoked by litigants to support allegations of unsoundness, incompleteness, or inconsistency of the administration's assessments. Rephrasing the same complaints in terms of reason-giving, economic actors argue that the administration has not sufficiently articulated the reasons for why it omitted their comments or studies,[141] or for drawing certain conclusions rather than others from the evidence submitted.[142] Thereby they again invite the Court to probe the scientific basis of contested measures.

While responding to similar complaints by the applicants, reason-giving review of administrative rulemaking is overall less intrusive than the plausibility review under the duty of care.[143] In terms of standard of review under the duty to state reasons, the Court consistently holds that the statement of reasons 'must be appropriate to the act at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question'.[144] In the case of acts of general application, this is limited to explaining the general objectives

[137]S Rose-Ackerman, *Democracy and Executive Power, Policymaking Accountability in the US, the UK, Germany and France* (Yale University Press 2021).

[138]Case C-24/62 *Federal Republic of Germany v Commission of the European Economic Community* ECLI:EU:C:1963:14, para 69. See also J Mendes, 'Executive Rule-Making: Procedures in between Constitutional Principles and Institutional Entrenchment' in C Harlow, P Leino-Sandberg and G della Cananea (eds), *Research Handbook in EU Administrative Law* (Edward Elgar 2017) 390.

[139]H Hofmann et al, *Administrative Law and Policy of the European Union* (Oxford University Press 2012) 143. According to Türk (n 84) 133, it 'forces the administration to reflect rationally on its reasoning'.

[140]See Rose-Ackerman (n 137), 4.

[141]*Dow agrosciences* (2011) (n 86) para 239; *Dextro energy* (2016) (n 45) para 122; *Agrochem* (n 86) para 68.

[142]*Polyelectrolyte v Commission* (2013) (n 98) para 100; *ICL-IP* (n 41) para 43.

[143]For an example of a lax application of reason giving requirements, see *Agrochem* (n 86) para 83 'that divergence between the rapporteur Member State and EFSA, even if it actually required additional reasoning from the Commission, cannot in itself lead the Court to uphold the first plea and annul the contested regulation on the ground of an infringement of the obligation to state reasons, since, in any event, both the rapporteur Member State and EFSA concluded that oxasulfuron should not be renewed given the numerous data gaps'.

[144]See *Agrochem* (n 86) para 68; *Xeda* (2012) (n 45) para 144; *Sepro Europe* (n 45) para 101; *Health food manifacturers* (n 110) para 105; *Dextro Energy* (n 45) para 123.

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the measure is intended to achieve and the general situation which led to its adoption, since 'it would be excessive to require a specific statement of reasons for the various technical choices made.'[145] Hence, the administration's statement of reasons does not need to address all the relevant facts and points of law, but only those 'having decisive importance in the context of the decision'.[146] In general, the Court's approach to reason giving has not so far resulted in a significant intensification of the justificatory threshold the administration is expected to meet. Furthermore, it signals an attempt to separate (substantive) challenges based on alleged errors of assessment and (procedural) challenges based on the duty to state reasons, the former targeting 'the substantive legality of a decision', the latter alleging 'absence of reasons or inadequacy of the reasons stated'.[147] This general trend is however qualified by cases in which the Court engages in a detailed scrutiny of the reasons provided in scientific opinions: here, procedural and substantive scrutiny conflate, and reason-giving review largely replicates the manifest error of assessment test.[148]

Like with duty of care, the Court stresses the protective individual nature of the reason-giving requirement also in procedures of general rulemaking. The Court conceives the purpose and beneficiaries of the principle of reason-giving in very narrow terms. In *ICL-IP*, it made clear that

> The purpose of the obligation to state the reasons on which an act adversely *affecting an individual* is based, which is a corollary of the principle of respect for the rights of the defence, is (i) to provide *the person concerned* with sufficient information to make it possible to ascertain whether the act is well founded or whether it is vitiated by a defect which may permit its legality to be contested before the Courts of the European Union and (ii) to enable the latter to review the legality of that act.[149]

The Court therefore focuses exclusively on the individual applicant, who should be given sufficient elements to understand and eventually challenge the measure affecting its individual sphere. The Court sees reason-giving and participation rights as closely related. The possibility to participate in the decision-making process has implications for the level of detail required of reason-giving, to the effect that 'where the persons concerned are involved in the process by which a measure comes about, the requirement to state reasons may be circumscribed, since they acquire information through their involvement.'[150] Because of its exclusive focus on the applicant, the Court is satisfied with the latter's actual participation in the administrative process, which then lowers the threshold for the exhaustiveness of reason giving. Conversely, the Court neglects the objective procedural nature of the principle of reason giving and its potential to open decision-making, if only *ex post*, to a broader range of actors.[151] Reasons are due to those who already have access to the decision-making process, but not to

[145] *Agrochem* (n 86) para 59; see also *Health Food Manufacturers* (n 110) para 110.

[146] *Sepro Europe* (n 45) para 99; here, the Court found that a 'succint' statement of reasons was sufficient. See also *Dow Agrosciences* (2011) (n 86) para 246; *Health Food Manufacturers* (n 110) para 105; *Dextro Energy* (n 45) para 123; *Agrochem* (n 86) 59.

[147] *Dow Agrosciences* (n 86) para 245; *Polyeletrolyte* (n 98) para 106; *Sepro Europe* (n 45) para 107; *Dextro Energy* (n 45) para 125; *Agrochem* (n 86) para 55.

[148] See for example *ICL-IP* (n 41) paras 49–56.

[149] *ICL-IP* (n 41) para 45. See also *Dow Agrosciences* (n 86) para 246; *Xeda* (n 45) para 144; *Polyelectrolyte v Commission* (n 98) para 101; *Health Food Manufacturers* (n 110) para 105; *Dextro Energy* (n 45) para 124; *Agrochem* (n 86) para 59.

[150] *Polyelectrolyte v Commission* (n 98) para 101. See also para 105: 'In any event it is also apparent from the first applicant's letter of 18 June 2010 that it had, in its capacity as the representative of the sector concerned, been involved in the process of preparing the measure for many years'. See also *Health Food Manufacturers* (n 110) para 105; *ICL-IP* (n 41) para 46; *Agrochem* (n 86) para 59.

[151] See in more detail Sections 5 and 6.

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those who are excluded from it. This is a missed opportunity in a field of high techno-scientific complexity, where judicial review could indirectly play the role of a translator, facilitating public understanding of the reasons underpinning complex measures.

D. Case law 2010–2020: Whose voice ought to be heard by the EU administration?

The rights of the defense (ie the right to be heard and the right to a fair hearing) are the third ground of review routinely invoked by litigants challenging EU risk regulation measures. Economic actors invoke violations of these rights in three main scenarios, which resemble closely those considered in relation to the duty of care and to the duty to state reasons. Litigants claim that 1) they have not been involved in the procedure in a way to would have enabled them to effectively defend their case; 2) they were not able to provide the necessary information; or 3) the relevant agency did not accurately consider the data submitted.[152]

In the EU legal order, the right to be heard forms part of the right to a good administration as enshrined in Article 41 CFR. It entails 'the right of every person to be heard before any individual measure which would affect him or her adversely is taken'. In the Court's case law, the right to be heard applies, as a general principle, only to individual acts, and not to acts of general application.[153] In *Vecco*, the Court clarified that the procedure for the inclusion of substances in Annex XIV REACH 'cannot be regarded as "proceedings initiated against" the applicants' and neither ECHA nor the Commission are therefore required 'to hear an individual who might be concerned by the disputed measure'.[154] In the case of individual acts, the right to be heard can be invoked by 'the addressees of decisions which significantly affect their interests'.[155] Therefore, where authorisation decisions are addressed at an economic actor, such as with medicines, the latter can invoke the right to be heard before the Court. This, however, is not the case for other affected actors, even where those actors were consulted during the administrative procedure. In *Olivieri*, the applicant (a scientist) had participated in the procedure by submitting on her own initiative her views on the safety and efficacy of the medicinal product being authorised. The Court acknowledged that

> None of the provisions of the applicable Community rules prohibits the Commission, prior to granting a marketing authorisation for a medicinal product, from following a procedure during which persons other than the applicant for marketing authorisation are able to submit their observations so as to enable it to fulfil its duty to check, in the interest of public health, that all the information relating to the scientific evaluation of the product in question, whether it be favourable or unfavourable to the product, has indeed been made available to it.[156]

Yet this did not suffice to consider the applicant as a 'formally concerned' party in the administrative procedure, which resulted in the inadmissibility of her action.[157]

[152] *Sepro Europe* (n 45) para 63; Case T-360/13 *Vecco and Others v Commission* ECLI:EU:T:2015:695 para 80 ff; *Xeda* (2014) (n 45) paras 104–105; *Polynt* (n 104) para 93; *Bayer* (2018) (n 97) para 430; *Probelte* (n 45) para 82.

[153] Türk (n 84) 129; J Mendes, *Participation in EU Rule-Making: A Rights-Based Approach* (Oxford University Press 2011) 192 ff. See also Section 3.

[154] *Vecco* (n 152), para 82, on the procedure for the inclusion of substances in Annex XIV REACH; see also *Health Food Manufacturers* (n 110) para 52 'The right to be heard in an administrative procedure affecting a specific person cannot be transposed to the context of a legislative process leading to the adoption of general laws'.

[155] *Probelte* (n 45) para 86 and case law cited.

[156] Case T-326/99 *Fern Olivieri v Commission and EMEA* ECLI:EU:T:2003:351, para 73.

[157] In *Olivieri* (n 156), the Court declared the action inadmissible due to lack of interest in bringing proceedings, since the information submitted by Dr. Olivieri had been taken into consideration; in subsequent case law (Case T-611/18 *Pharmaceutical Works Polpharma v EMA* ECLI:EU:T:2021:241) this line of reasoning led to the establishment of the lack of individual (paras 116–21) and direct concern (paras 122–48). According to Craig (n 51) 297, in this way the Court 'signals

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Despite the right to be heard being confined to individual acts, the Court has applied it to acts of general application on several occasions. The condition for this, however, remains tied to the requirement that only persons who are directly and individually concerned by the act in question can benefit from the right to be heard. In this way, the Court's approach to the right to be heard mirrors that to legal standing, and both must be considered together. Take, for example, Commission implementing decisions addressed to the Member States concerning the inclusion of active substances in so-called positive lists of authorised products.[158] These acts result from procedures initiated by economic actors, who, although not the addressees of the final decision (addressees being the Member States), are found to be directly and individually concerned due to their prior formal procedural involvement. Here, regulatory design meets the Court's doctrine on standing, closing the circle between participation in the administrative and the adjudicative phase. The circularity is evident in *SeproEurope*, where the Court acknowledged that the applicant is not an addressee of the act, but granted standing based on their being individually and directly concerned by it:

> as the applicant is the person who made the request under Article 13 of Regulation No 33/2008 aimed at the inclusion of flurprimidol in Annex I to Directive 91/414, the contested decision, in which the Commission refused to include that substance in the annex in question, is of direct and individual concern to the applicant.[159]

When moving on to consider the applicants' right to be heard, the Court found that the applicant (although not being the formal addressee of the act) was entitled to the rights of the defense in so far as the contested measure 'refuses [their] request that flurprimidol should be included in Annex I to Directive 91/414 and, consequently, prohibits the applicant from marketing plant protection products containing that active substance'.[160]

Therefore, because of their special procedural position as applicants, economic actors have both legal standing and the right to be heard in procedures for acts of general application. The same does not apply to other parties, even where they participated in the procedure via a public consultation on an act of general application. In *PAN Europe*, one of the environmental non-governmental organisations (NGOs) acting as applicants, had participated in the expert consultation envisaged by Article 12 of the Pesticides regulation. It had submitted written observations on the draft assessment report on the substance undergoing authorisation. According to the Court, however, 'such participation does not support the conclusion that the act in question directly affects an applicant,'[161] leading to the denial of legal standing. Likewise, participation in public consultations 'does not grant the interested parties specific procedural rights,' but only provides for the right to submit comments.[162] Since the latter alone cannot ground legal standing nor the right to be heard, third parties other than the industry applicants will rarely be able to have the right to submit comments reviewed by the Court.[163]

The effect of this case law is that economic actors are structurally privileged even in procedures of general standard-setting, in which the right to be heard, in principle, does not apply. More

to the Union institutions that they can provide de facto consultation secure in the knowledge that if this is not legally required in accord with the Courts' jurisprudence it will not afford any legal rights to those taking part'.

[158]See for example Commission Implementing Decision 2011/328/EU of 1 June 2011 concerning the non-inclusion of flurprimidol in Annex I to Council Directive 91/414/EEC, OJ L153/192.

[159]*Sepro Europe* (n 45) para 30.

[160]Ibid., para 67; see also *Xeda* (n 45) para 109.

[161]*Pesticide Action Network Europe* (n 70), paras 43–4.

[162]*Vecco* (n 152) para 81.

[163]See *Probelte* (n 45) paras 94–112, where the Court reviewed the compliance with the industry applicant's procedural right to be consulted under Art 12(1) Pesticides Regulation (n 20).

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generally, the legal approach to standing and right to be heard is in contrast with the legislative acknowledgement of the value of public participation in risk regulatory procedures.[164] REACH is the flagship framework for inclusive governance in risk regulation,[165] explicitly envisaging consultations with stakeholders;[166] the Pesticides regulation provides for the already mentioned possibility of public consultations, in which environmental NGOs regularly participate.[167] The 2019 reform of the General Food Law has mainstreamed public consultations into EFSA's scientific assessments.[168] The pharmaceuticals regulation does not expressly provide for participatory avenues, but the EMA has a well-developed system of public consultations and stakeholder involvement.[169] Yet while all stakeholders can participate in public consultations, only few, mostly the economic actors, can challenge the outcomes and invoke their procedural rights before the Court.[170]

Concerning the standard of review, of the three procedural principles considered here, the right to be heard results in least intrusive scrutiny. The first scenario in which the right to be heard is invoked, is when applicants lament their inadequate involvement in the procedure. The Court generally considers how and in which context they have been invited to formulate comments.[171] In *Bayer*, for example, it reviewed the decision-making process and found that

> 'the applicants were invited to make comments and that they did make them, both in writing and, through the organisations representing them, at a meeting with the Commission's services. In those circumstances, the Commission was fully entitled to regard itself as being sufficiently apprised of the applicants' point of view and, in particular, it was not obliged to act on Bayer's requests to meet Commission staff responsible for reviewing the substances covered'.[172]

While the Court sometimes engages in a more detailed review,[173] it does not generally question the quality of the applicants' involvement, being satisfied with the fact that such involvement took place.

The second scenario concerns the applicants' submission of additional data to address data gaps emerged during the risk assessment. The Court consistently acknowledges the possibility for the administration to deny the admissibility of such additional data, based on the argument that the public interest in the immediate implementation of the measure prevails over the 'applicants' interest in having the time necessary to generate the missing data'.[174] The opposite solution 'would amount to granting the applicants the right to unduly delay the adoption of a decision to withdraw or amend the approval'.[175] In this context, legislative objectives operate

[164]See Section 3.

[165]Korkea-aho (n 135) 114 ff; Heyvaert (n 46).

[166]Art 64(2) and (3) REACH (n 40).

[167]Art 12(2) Pesticides Regulation (n 20).

[168]See the 'new' Art 32(b) and (c) GFL (n 20), introduced by the GFL reform (n 12).

[169]For an overview of the EMA's consultation system, see <https://www.ema.europa.eu/en/news-events/open-consultations> accessed 21 July 2022; see also European Medicines Agency (2018) *Criteria to be Fulfilled by Patient, Consumer and Healthcare Professional Organisations Involved in European Medicines Agency (EMA) Activities*, EMA/24913/2005 – rev. 3.

[170]Dispersed interests and catalytic subgroups wanting to challenge the substance of risk regulation measures are left with the harder and arguably less effective avenues of preliminary references on validity and appeals against internal review procedures. See for a rights-based critique of the current case law on participation rights, Mendes (n 153).

[171]*Sepro Europe* (n 45) paras 68, 74–6; *Xeda* (n 45) para 109; *Polynt* (n 98) paras 97–9; *Hitachi* (n 98) para 99 ff; *Bayer* (n 97) para 435; *Probelte* (n 45) paras 96–8, 101.

[172]*Bayer* (n 97) para 436; see also *Xeda* (n 45) para 111.

[173]For example in *Xeda* (n 45) paras 150–180.

[174]*Bayer* (n 97) para 443; similarly in *Xeda* (n 45) paras 116–117.

[175]*Bayer* (n 97) 454.

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as a shield for administrative discretion. The third and final scenario is that in which, when reviewing whether the evidence submitted has been accurately considered, the Court refers cursorily to its reasoning under the duty of care and does not further engage with allegations of inaccuracy under the right to be heard.[176]

E. CJEU review – substantively intrusive and procedurally exclusive

Our case law analysis leads to two important conclusions regarding intensity of review and interpretation of principles of administrative procedure respectively. Firstly, the three procedural principles considered above trigger different degrees of review intensity concerning technical discretion. The duty of care triggers high intensity, whereby the Court closely reviews the quality of the scientific information and reasoning following the plausibility test. Here the Court comes close to the substitution of the assessment of the agency with its own assessment. The duty to state reasons triggers a medium-level intensity, whereby the Court reviews the clarity and consistency of the reasons adduced by the Commission or the agency, not expecting them to be exhaustive but rather to focus on the decisive elements of the decision. Review under the right to be heard results in the least engagement with scientific information and reasoning.

Secondly, despite the different nature of these principles in administrative procedure, the Court interprets their function in a similar narrow way even in procedures of general rulemaking. All three play out within the bilateral relationship between the applicant as the (quasi-)addressee and the EU administration. All three are seen as compensating for the limits of substantive review and are used to protect the individual applicant from arbitrary decisions. All three principles, therefore, serve a narrow circle of (quasi-)addressees of the regulatory act, and hence in most cases the industry applicant. If the judicial protection of these principles does enhance the deliberative quality of regulatory decision-making, the result is an impoverished version of deliberation confined to the EU administration and the regulated industry. Given the epistemic imbalances characterising EU risk regulation, this amplifies the latter's epistemic power over the regulatory process.

Our analysis sheds new light on the Court's modern approach to reviewing risk regulation. Intensified scrutiny and the use of procedural principles to review administrative discretion remain two consistent features of the case law. The third feature we identified is the exclusivity of the Court's approach. Instead of catalysing inclusive procedures that open regulatory science to public scrutiny, as some scholars had hoped, the Court's approach fosters an *exclusive* bilateral exchange between the administration and the industry applicant. Our findings call into doubt the widely shared idea that, overall, the Court manages to strike a reasonable balance between effective judicial protection and the need to respect administrative discretion; and that it performs a 'substantially deferential, but procedurally activist'[177] review. Instead, we observe a certain blurring between procedure and substance.[178] While the Court formally states its intention to keep procedural and substantive considerations separate,[179] the two often collapse into a more searching review.[180] As some authors have noted, this leads to the Court sometimes approaching a substantive review of the merits of scientific opinions, risking to overstep its institutional competence by

[176]*Xeda* (n 45) para 120; *Polynt* (n 98) para 100; *Bayer* (n 97) para 76; see however *Dow Agrosciences* (n 45) para 43, where the two heads of claim are considered together.

[177]Corkin (n 99) 383. See also Vos (n 84) 151.

[178]Leonelli, 'The fine line between procedural and substantive review' (n 130); Dabrowska (n 84). See also Scott and Sturm (n 4) who are similarly critical of the procedure/substance distinction, and Türk (n 84) 126–42.

[179]With regard to reason giving: *Dow Agrosciences* (n 45) paras 246–51; *Polyelectrolyte v Commission* (n 98) para 106; *Dextro* (n 45) para 125; with regard to the duty of care: *Polynt* (n 98) para 52; *Bilbaína v ECHA* (n 98) para 76; *ICDA* (n 86) para 45, where the Court states that it cannot substitute its assessment to that of the administration.

[180]See Sections 4B and 4C.

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behaving as a super expert, with *Bilbaìna v Commission* being one of the most problematic examples.[181]

This begs the question, whether the Court really respects administrative discretion, as a 'scope for assessment and judgement left open to the decision-maker by terms of his authority'.[182] There seems to be little clarity in the case law about the conceptual meaning of administrative discretion.[183] While the Court seems to distinguish different types of situations, in which discretion exists (technical assessments, factual determinations[184] or political assessments),[185] this is without consequence for the applicable standard of review, as all types of discretion are reviewed according to the manifest error of assessment standard.[186] Moreover, post-*Pfizer* the expected level of scrutiny the Court will apply in any given case is difficult to predict.[187] The manifest error review has changed meaning over time and is applied inconsistently, sometimes with more and sometimes with less intensity,[188] without the Court explaining what the actual standard is and how it arrives at the conclusion that it is (not) met. Hence the manifest error formula is rightly said to conceal more than it reveals.[189]

The fact that the Court so far has failed to define a principled approach to the standard of review[190] raises doubts as to whether the Court recognises technical discretion at all. Some authors have indeed argued that there is no constitutional basis for judicial self-restraint regarding factual determinations or scientific assessments as opposed to political assessments.[191] The Court therefore would have the last say on technical discretion and reserve the right to intervene defining the intensity of review case-by-case.[192] Although we do not share this view, and although it seems to contradict the Court's statements, it would explain the inconsistent levels of intensity in the case law.

The lack of clarity and consistency in the case law makes it difficult to formulate a convincing theory of judicial review of administrative rulemaking in the field of EU risk regulation as well

[181]A-M Janssen and M van Asselt, 'Handling Uncertain Risks: An Inconsistent Application of Standards? The Precautionary Principle in Court Revisited' 1 (7) (2016) European Journal of Risk Regulation 146. See also Vos (n 84) 157–9; M van Asselt and E Vos, 'The Precautionary Principle and the Uncertainty Paradox' 9 (2006) Journal of Risk Research 313; Korkea-aho (n 135) 143.

[182]A Fritzsche, 'Discretion, Scope of Judicial Review and Institutional Balance in European law' 47 (2) (2010) Common Market Law Review 362.

[183]For critical views see S Lefèvre and M Prek, '"Administrative Discretion", "Power of Appraisal" and "Margin of Appraisal" in Judicial Review Proceedings before the General Court' 56 (2) (2019) Common Market Law Review 339; Mendes (n 159); Fritzsche (n 182) 361; Craig (n 51).

[184]Pfizer (n 2) para 168. See, also, *Enviro Tech (Europe)* (n 115) para 62. For a critical view see Lefèvre and Prek (n 183) 355.

[185]Fritzsche (n 182) who distinguishes four categories: the weighing of interests and policies, expert assessments, the appraisal of complex economic matters, and complex value judgements. Sometimes Advocate Generals have attempted to clarify the categories by distinguishing between technical and political discretion, see Opinion of AG Léger in Case C-40/03 P *Rica Foods v Commission*, ECLI:EU:C:2005:93 para 45; see also his Opinion in Case C-26/00 *Netherlands v Commission* ECLI:EU:C:2005:90 para 45, as well as the Opinion of AG Poiares Maduro in Case C-136/03 *Dörr and Ünal* ECLI:EU:C:2004:651 paras 46 ff.

[186]Lefèvre and Prek (n 183) 344–5.

[187]The only thing one can say is that the standard is more than the decision being self-evidently wrong, see Craig (n 51) 436.

[188]For an example of high intensity review, see *Bilbaína* (2015) (n 45); for a case of low intensity review: *Agrochem* (n 86) para 90.

[189]Craig (n 51) 436; also critical of the Court on this point, Türk (n 84), 139; Fritzsche (n 182) 379–80.

[190]See Craig (n 51).

[191]Lefèvre and Prek (n 183); opposing view Mendes (n 153).

[192]This is confirmed by Fritzsche (n 182) 380, citing AG Cosmas, Opinion in Case C-83/98P *French Republic v Ladbroke Racing Ltd and Commission* ECLI:EU:C:1999:577 p 3278, footnote 3: 'In reality, however, the intention of the [Remia formula, quoted above at note 72] is not to restrict absolutely the scope for the Community judicature to intervene in the substance of the case, but to recognise that the Community judicature has the power to remain master of its tasks, defining itself the depth to which its investigation will go on each occasion.' However, the AG misses the opportunity to reason why he thinks the courts have the power to determine their scope of review in every single case.

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as to normatively evaluate the Court's approach. The Court rarely explicates the higher normative principles driving its review. The repeated emphasis on the need to respect administrative discretion, and to resist substitution of judgement[193] does not *per se* explain the normative reasons that require deference to the administrative decision-maker or that would explain differing levels of intensity in judicial review. A mere reference to the nature of complex assessments fails to justify, in normative-constitutional terms, when and why review should be limited. It has rightly been pointed out that the 'complexity formula has become a rhetorical façade substituting a real discourse about the courts' powers under the Treaty.'[194] A proper justification of judicial review of complex assessments would require a reflection on broader questions, such as on the Court's institutional role vis-à-vis the EU administration[195] as well as, more generally, on the legitimacy of public administration in the EU polity.[196]

5. The role of judicial review in expert accountability

How could the Court play a more constructive role in enhancing the accountability of EU regulatory science? In the following we argue that EU judicial review must be able to adequately respond to the concerns around epistemic capture which we identified in this paper. At present, there seems to be little awareness of this problem in the case law. It is true that the Court threads carefully and cannot be accused of siding with industry applicants. In fact, in most cases, the outcome of litigation favours the EU administration.[197] Yet, as we have shown, the Court's reasoning entrenches certain ideas about legal standing and the administrative process that benefit the regulated industry, while reducing the discretion of the EU administration. Moreover, the current approach seems to ignore the reality of modern risk regulation. The latter is dominated by administrative rulemaking of high salience for health and the environment affecting a broad range of actors, which arguably should make wide access to the Court and the enforcement of epistemically inclusive procedures a priority.[198] The Court also

[193]See *Polynt* (n 98) para 52: 'where the authorities of the European Union have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts [. . .], review by the European Union judicature is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion. In such a context, the European Union judicature cannot substitute its assessment of scientific and technical facts for that of the authorities of the European Union on which alone the FEU Treaty has placed that task'.

[194]Fritzsche (n 182) 380–1.

[195]Ibid.

[196]On the different models of public administration and the respective modes of legitimation, see for example C Harlow and R Rawlings, *Law and Administration*, 25 ff (red light v. green light model); E Fisher, *Risk Regulation and Administrative Constitutionalism* (Bloomsbury Publishing 2007), 28 ff (rational-instrumental v. deliberative-constitutive model); M Weimer and G Pisani, 'Expertise as Justification: The Contested Legitimation of the EU "Risk Administration"' in Weimer and de Ruijter (n 13) 167, 170 (control model v. deliberative model); see also B Emmerson, *The Public's Law* (Oxford University Press 2019). On legitimacy assets see J Mendes and I Venzke, 'Introducing the Idea of Relative Authority' in J Mendes and I Venzke (eds) *Allocating Authority. Who Should Do What in European and International Law?* (Bloomsbury Publishing 2018) 12. In EU governance, both ideational traditions are present (Fisher, ivi, 238 ff; C Anderson, 'Contrasting Models of EU Administration in Judicial Review of Risk Regulation' 51 (2014) Common Market Law Review 2, 425, 447. See also the literature on deliberation and new governance in the EU (C Joerges and J Neyer, 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology' 3 (1997) European Law Journal 3, 273; C Sabel and J Zeitlin, *Experimentalist Governance in the European Union: Towards A New Architecture* (Oxford University Press 2012); Korkea-Aho (n 135)). However, the Court's review of risk regulation, as our analysis shows, predominantly follows the *positivist-liberal* model.

[197]Private applicants have only succeeded in 8 out of the 68 cases they initiated.

[198]Craig (n 51) 295 makes a similar argument in relation to standing under Art 263 (4) calling it a normative choice. We show that this is also true for the Court's review of process-based review of fact and discretion, Section 4.

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ignores that the industry applicants are not merely the initiators and addressees of regulation but also key information providers.[199]

In this section, we discuss the role of the Court from the perspective of political epistemology,[200] which studies the role of experts in modern democracies.[201] We are particularly interested in the institutional turn in these studies, in which the question of 'truth-sensitive' institutional design is central. While recognising the role of politics, power, and social structure in the production of policy-relevant knowledge, this research also acknowledges the crucial role of experts in democratic problem-solving. Therefore, the focus is on the institutional mechanisms that enable expert decision-making to reconcile the 'independence requirement of reliable expertise and the responsiveness requirement of democratic governance'.[202] While this literature studies the accountability of expert bodies from a broader institutional perspective, law and judicial review are increasingly seen as playing an important part in the mix of institutional mechanisms holding expert bodies to account. Courts can contribute to addressing the epistemic concerns around the use of specialised expertise in regulation.[203] In other words, they can hold experts to account for the epistemic quality of their decision-making, which in turn is crucial for both upholding the rule of law and democratic problem-solving.

A particular concern in this regard is the risk of cognitive error and bias in the production of policy-relevant science, which is closely interlinked with the risk of a minoritarian bias, discussed at the beginning of this paper. Studies show that experts can make cognitive errors, are prone to over-confidence, and can suffer from cognitive or ideological bias.[204] In fact, scientific experts have been shown to suffer from the same biases as lay people and moreover show 'a strong affiliation bias, with those experts working in industry having a more benign view of the relevant risks that those experts working outside it'.[205]

Bias can also result from special interests distorting the production of high-quality expert advice. This does not have to be through direct manipulation of scientific data or findings, but in a more subtle way. As Christiano puts it

> It seems to me that one principal source of domination of and parochialism in science is domination by class or ethnic interests. The reason for this is based in the simple facts of cognitive bias. Those facts suggest that beliefs and science can easily come to reflect the narrow backgrounds and interests of those who produce them. So, if science and expertise are funded by one particular group in the society there is a significant danger that that expertise will reflect the interests and backgrounds of those persons.[206]

[199]See also Mendes (n 191) 454.

[200]Which cuts across disciplines and comprises political sociology, political epistemology, studies of regulation and governance, science and technology studies as well as law: see Lentsch and Weingart (n 7); S Turner, *The Politics of Expertise* (Routledge 2015); Holst and Molander (n 7); S Jasanoff, 'Serviceable Truths: Science for Action in Law and Policy' 93 (2015) Texas Law Review 7, 1723; Jasanoff, *The Fifth Branch* (n 1); S Jasanoff, 'Quality Control and Peer Review in Advisory Science' in Lentsch and Weingart (n 7) 19, 26; Weimer and de Ruijter (n 13); Arcuri, 'Three Dimensions of Accountability' in Arcuri and Coman-Kund (n 3), with further references.

[201]This body of literature studies both the epistemic and political-democratic challenges arising from the use of specialised expertise in public decision-making, see Holst and Molander (n 7) for an overview.

[202]E Krick and C Holst, 'The Socio-Political Ties of Expert Bodies. How to Reconcile the Independence Requirement of Reliable Expertise and the Responsiveness Requirement of Democratic Governance' 20 (2019) European Politics and Society 1, 117.

[203]See Holst and Molander (n 7) who differentiate between epistemic and democratic concerns.

[204]Ibid.

[205]N Kraus et al, 'Intuitive Toxicology: Expert and Lay Judgments of Chemical Risk' 12 (2) (1992) *Risk Analysis* 15.

[206]T Christiano, 'Rational Deliberation among Experts and Citizens' in J Parkinson and J Mansbridge (eds), *Deliberative Systems Deliberative Democracy at the Large Scale* (Cambridge University Press 2012) 27.

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As we explained earlier, EU risk regulation is not immune to such concerns, as the industry applicants fund and provide most of the evidence based on which market authorisations are granted. EU agencies review such evidence and are supposed to do so in an independent way and considering other scientific sources. However, there are ongoing concerns about both the independence and quality of agency assessments,[207] which moreover take place within often underfunded institutions.[208]

There are several institutional mechanisms to tackle parochial and biased production of knowledge.[209] Some scholars differentiate between mechanisms targeting expert *behaviour*, expert *judgement*, and the conditions for expert *inquiry*.[210] Others distinguish between ex-ante and ex-post mechanisms of accountability.[211] In one way or another, all these mechanisms aim at extending expert accountability obligations from peer-accountability (peer-review among equally qualified experts in epistemic communities) to public accountability, ie to *an obligation to explain and justify expert judgements to public fora*.[212]

> In a process of democratic decision-making, the testing of judgments and arguments must also be extended for epistemic reasons to other relevant disciplines and other relevant expert fora, for example, to fora comprising bureaucrats and competent stakeholders, to the legislature and even to the public sphere at large. In all these fora, experts can be asked to account for critical assumptions, explain models used, specify their limits and present alternative models.[213]

Such an obligation is justified with the need for cognitive or *epistemic diversity*, the latter being an important pre-condition of successful deliberation, and thus of high epistemic quality of expert decision-making. Deliberating groups are less prone to cognitive bias, group think or distortions based on conflicts of interests, enlarging the pool of ideas and information on which scientific advice is based.[214] This emphasises the importance of epistemic pluralism within the EU administrative process. The quality of EU risk assessments crucially depends on epistemic diversity and the input of all relevant expertise. In fact, these ideas are already reflected in most of the EU risk regulatory frameworks[215] and in many EU soft law documents.[216] If deliberation and pluralism are recognised values of the EU regulatory process, this should, in our view, also be reflected in the procedural review of that process by the CJEU.

[207] Robinson et al, 'Achieving a high level of protection' (n 41). See also the European Parliament's resolution on pesticides authorisations, based on the work of the PEST committee, established in the context of the glyphosate reauthorisation: European Parliament, Union's authorisation procedure for pesticides, European Parliament resolution of 16 January 2019 on the Union's authorisation procedure for pesticides (2018/2153(INI)) (Pesticides Resolution) and our introduction. It should be kept in mind, however, that cognitive bias can afflict all expert work, including publicly funded academic work or NGO studies.

[208] See European Parliament, Pesticides Resolution Ibid., in particular para 70.

[209] Holst and Molander (n 7).

[210] Ibid.

[211] Arcuri 'Three Dimensions of Accountability' in Arcuri and Coman-Kund (n 3), 62.

[212] Ibid., who explains the ways in which regulatory science exercises regulatory authority. There are also challenges to this approach, see Holst and Molander (n 7), essentially resulting from the expert-lay person problem, which points at the difficulty for non-experts to hold experts to account. However, it is mostly suggested that such challenges are addressed through institutional design rather than doing away with public scrutiny of regulatory expertise, see Lentsch and Weingart (n 7).

[213] Holst and Molander (n 7) 14.

[214] Ibid.

[215] See Korkea-Aho (n 135).

[216] See European Commission, Communication from the Commission on the Collection and Use of Expertise by the Commission: Principles and Guidelines. Improving the Knowledge Base for Better Policies, COM (2002) 713 final; European Ombudsman, Recommendation of the European Ombudsman in her strategic inquiry OI/6/2014/NF concerning the composition of Commission expert groups, 14 November 2017.

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This brings us back to the Court's role in ensuring expert accountability. We propose that judicial review can be an important mechanism of expert accountability, in two ways. Firstly, courts *directly* provide a public forum, in which expert judgements are reviewed. This is what the CJEU review of risk regulation already does, when reviewing the reasonableness of science-based decisions against the background of the information submitted by the litigant challenging those decisions. However, while a useful starting point, this pathway is not sufficient for meaningful expert accountability. As we have seen, by narrowing down the circle of persons who, as litigants, can bring counter-expertise to challenge EU regulation, the Court's approach fails to strengthen epistemic diversity and deliberation. Instead, it entrenches the position of the regulated industry as a dominant information provider throughout the regulatory and litigation cycle. Moreover, for reasons of institutional balance and required technical expertise, we believe that judicial review of regulatory science should in principle be limited and becomes problematic where the Court oversteps the boundary of procedural reasonableness review.

Therefore, secondly, a more promising avenue is for judicial review to *indirectly* improve expert accountability within the regulatory process. This is where our work connects to the 'courts as catalysts' literature, which suggests that beyond legality review, courts should also fulfil a quasi-regulatory function by promoting the adherence to certain procedural standards which enhance the legitimacy of the regulatory process.[217] The idea of a catalyst function of judicial review chimes in with the insights on expert accountability presented above. It also places the issue of expert accountability within the broader discourse on the role of deliberation in democratic decision-making and corresponding conceptions of the role of judicial review.[218] According to such conceptions, the CJEU can help ensure deliberation as an important legitimising principle of EU governance, deliberation being understood as a process in which 'a wide variety of actors are encouraged to come forward to present reasons and interrogate those of others, with a view to solving problems and providing norm guidance after an exchange of opinions and views.'[219] The Court's role should be to uphold standards that ensure that decisions are reasoned (ie are justified by reference to reasons acceptable to those affected by those decisions); oriented towards problem-solving by allowing for contestation and divergent views in the decision-making process; and preceded by participation of all affected actors.[220]

In our view, embracing such normative ideas in CJEU review of risk regulation would help address the risk of epistemic capture. However, in contrast to some of the previous literature on this topic, we do not find evidence of the Court embracing these ideas in the risk regulation case law over the last decade.[221] Instead, we show that as long as the procedural values of duty of care, reason-giving and participation (ie the right to be heard), are not interpreted with the value of epistemic diversity and inclusive deliberation in mind, they fail to catalyse meaningful expert accountability mechanisms.

[217]Scott and Sturm (n 4), Corkin (n 99), Vos (n 84).

[218]One of the most elaborated accounts of deliberative democracy as applied to EU governance and judicial adjudication is provided by Korkea-Aho (n 135); see also Scott and Sturm (n 4); in the US context, C Sabel and W Simon, 'Destabilizing Rights: How Public Law Litigation Succeeds' 117 (2004) *Harvard Law Review* 1016; more generally, on the democratic functions of Courts, see also S Rose-Ackerman, 'Democratic Legitimacy and Executive Rule-Making' in Mendes and Venzke (n 196) 29.

[219]Korkea-aho (n 135).

[220]Ibid.

[221]Some authors have been more optimistic with regard to the Pfizer case law. Corkin (n 99) has argued that CJEU review is prompting EU decision-makers to accommodate both scientific and lay voices and to involve affected parties; Scott and Sturm (n 4) have argued that the Court acts as an 'information catalyst' seeking to ensure that the evidence underpinning risk decisions is of high epistemic quality.

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6. What way forward for CJEU review of regulatory science?

The above formulated normative expectations towards judicial review raise the question whether we are possibly expecting too much from the Court. On the one hand, the mandate of the Court is stated to be one of 'observing the law,'[222] which could be seen as supporting the focus on legality in the case at hand rather than broader institutional questions. On the other hand, even if one agrees that judicial review can and should have broader catalytic effects on governance processes,[223] one should perhaps be careful to place responsibility for institutional change on the Court's shoulders alone. After all, other governance actors, above all the EU legislature and the EU administration, are responsible for ensuring a legitimate administrative process,[224] which is conducive to producing excellent, independent, and transparent advice. It could be argued that it is up to those other institutional actors to provide for stronger participation rights and to ensure epistemic diversity is safeguarded. The Court acts within the parameters set by those institutions.

While these arguments are valid, we see room for improvement. First, legal norms in risk regulation are often broadly formulated with their legal determination depending on scientific arguments. Legal and scientific rationality are enmeshed. Therefore, ensuring that the law is observed in areas of high techno-scientific complexity requires mechanisms of expert accountability, to which the Court should contribute. Second, as we discussed above, judicial review is an important mechanism for ensuring the high epistemic quality of regulatory science, next to other institutional mechanisms. Third, we acknowledge that the Court should contribute to EU expert accountability not in isolation, but *together* with other actors. This means that legislative and administrative action will at times be required before the Court can fully unfold its catalyst function.

A comparison to the CJEU case law on transparency and access to documents provides a useful example.[225] Here the Court, relying on a clear legislative mandate, has been able to strengthen access rights vis-à-vis regulatory science, at least around access to environmental information.[226] On the one hand, applicants who are denied access to information are expressly granted standing,[227] without having to fulfil the Court's test under Article 263(4) TFEU for regulatory acts. As a result, public interest groups, as well as individuals, can challenge the EU administration's decisions granting confidentiality to industry studies. This leads to a significantly more balanced litigation pattern, whereby 10 out of 19 cases over the period of 10 years (2010–2020) have been initiated by public interest applicants, the majority of which (7) successfully. On the other hand, following the wording of the Transparency regulation's recitals, the Court explicitly interprets transparency in light of epistemic diversity, public participation, and the

[222]Art 19 (1) TEU.

[223]In a similar vein Alemanno (n 75), how Courts shaped EU risk regulation. See also Scott and Sturm (n 4).

[224]On legitimacy assets of different institutions, see Mendes and Venzke (n 196).

[225]See the Transparency Regulation (n 52) and Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (2006) OJ L264/13 (Aarhus Regulation).

[226]Granting access to the scientific studies underpinning risk regulation measures is crucial, in particular in light of the fact that they are often generated and owned by economic actors (see Section 2) See E Korkea-Aho and P Leino, 'Who Owns the Information Held by EU Agencies? Weed Killers, Commercially Sensitive Information and Transparent and Participatory Governance' 54 (4) (2017) Common Market Law Review 1059. Recent developments show a change of paradigm in the EU's approach to transparency in risk regulation: Hickey and Weimer (n 12); see also M Morvillo, 'The General Court Orders Disclosure of Glyphosate-related Scientific Studies: Tweedale, Hautala, and the Concept of Environmental Information in the Context of Plant Protection Products' 10 (2) (2019) *European Journal of Risk Regulation* 419. In other areas, the Court's case law has been more progressive regarding access to legislative documents as compared to administrative documents; for a critical discussion Hickey and Weimer, Ibid.

[227]Art 8(1) Transparency Regulation (n 52); Art 12 Aarhus Regulation (n 225).

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democratic legitimacy of EU institutions.[228] This has led to new judicial approaches to transparency, in particular in the field of environmental protection.[229] The contrast between access to documents litigation and risk regulation litigation as discussed in this paper creates a paradoxical result: public interest groups and citizens can go to court to enforce their access to the scientific information held by EU agencies, but they do not have standing to challenge decisions based on that information.

This example shows that the Court can catalyse better procedures in interaction with the legislature and the administration.[230] Choices made by other EU actors therefore influence how far the Court can go in strengthening certain procedural values.[231] Participation rights in the administrative process are especially sensitive. It could be argued that the Court is mindful not to encroach upon the powers of the legislature, and therefore refuses to provide participation rights beyond the rights of defense in individual procedures.[232] Participation rights for acts of general application, as those often found in risk regulation, should therefore be grounded in legislation. EU legislation, however, currently does not provide robust and enforceable participation rights beyond the weaker right to be consulted in public consultations. While regulatory frameworks provide for consultation of all stakeholders, enforcement of consultation rights is reserved for individuals who have standing, because they are directly and individually concerned by the contested measure, namely the industry applicants.[233]

Absent legislative intervention, what could the Court do to enable a more meaningful expert accountability and to address the epistemic power imbalances in the production of EU regulatory science? The gist of our proposal is twofold: On the one hand, we believe that there is room for a different, more generous judicial interpretation of legal standing as well as of the administrative principles discussed in this paper. Such interpretation should embrace the values of inclusive deliberation and epistemic diversity thereby overcoming the current exclusive focus on the bilateral relationship between the applicant and the administration. On the other hand, if the Court maintains its current narrow interpretation, more deference and a less intrusive review of technical discretion are warranted.

Within the scope of this paper, we are not able to comprehensively discuss how exactly the Court's new interpretation of legal standing and administrative procedure should look like. The aim of our analysis has been to reveal the ways in which the CJEU doctrine interacts with the epistemic power of economic actors with potentially problematic consequences for the epistemic quality and public interest orientation of EU regulation. However, beyond critique we would also like to point to normative approaches that might counteract the problematic dynamics, which we identified in this paper. We are moreover aware of the doctrinal complexity of administrative legal concepts as developed in EU case law, which demands a more thorough analysis of our proposals than we can offer in this final outlook. Such analysis will have to be reserved to future research building on existing EU administrative law scholarship.

We have shown that to counter the epistemic power of the regulated industry, the Court's approach to both legal standing and procedural review should change. While the legal standing

[228]Case T-716/14, *Anthony C Tweedale v European Food Safety Authority*, ECLI:EU:T:2019:141, in particular paras 54 and 91; Case C-57/16 P, *ClientEarth v Commission* ECLI:EU:C:2018:660, para 75; Case C-673/13 P, *Commission v Stichting Greenpeace Nederland and PAN Europe* ECLI:EU:C:2016:889, para 80.

[229]See in particular *Tweedale* (n 228) and Case T-329/17, *Heidi Hautala and Others v European Food Safety Authority*, ECLI:EU:T:2019:142.

[230]See S Shapiro, E Fisher and W Wagner, 'The Enlightenment of Administrative Law: Looking Inside the Agency for Legitimacy' 47 (2012) *Wake Forest Law Review* 463.

[231]To take another example, the principle of risk analysis, today a fundamental procedural principle of EU risk regulation, was embraced by the Court in reaction to the Commission Communication on the Precautionary Principle, in which the Commission committed to and elaborated such principle. It was later codified in EU secondary law.

[232]See Section 4D above; for a rights-based critique see Mendes (n 153).

[233]See for an example *Probelte* (n 45).

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test privileges the regulated industry as a challenger of regulation, the current interpretation of procedural principles enables, to varying degrees, an intensified scrutiny of the scientific basis of regulation based only on claims brought by the industry.

Concerning legal standing, the Court's approach to direct and individual concern under Article 263 (4) TFEU, justified by the famous, yet often criticised, reasoning that the EU's system of judicial protection is based on a complete system of remedies,[234] seems to be too entrenched to expect the Court to significantly change course. As discussed in Section 3, the Court has maintained its approach despite widespread and persistent criticism. More recently, in the light of the climate emergency, such criticism has gained even more weight in the field of environmental protection.[235] The Court's narrow and individualised understanding of the circle of affected interests seems to significantly clash with the collective nature of environmental harm. It also falls behind the ambition of the EU's Green Deal of a society-wide green transition. At the international level, the Aarhus Convention Compliance Committee has recently declared the EU to be in violation of its international commitments concerning access to justice in environmental matters. None of these arguments, we believe, are likely to change the Court's position, which is based not only on a formalistic understanding of the Treaty text, but also on a deep-seated systemic understanding of the interplay between EU and national courts as well as on practical considerations – never explicitly stated – pertaining to issue of case load and the functioning of the Court.[236] While we support a broader interpretation of legal standing at least in the field of environmental and health protection, we acknowledge that change is more likely to come from EU legislature.[237]

Assuming access to litigation remains restricted, how much would be gained from a re-interpretation of the rights of administrative procedure? And would it be possible given that the Court's understanding of who may challenge administrative acts is directly linked to the question of who may derive such procedural rights? In the following, we differentiate between the right to be heard on the one hand, and the duty of care and reason-giving on the other hand, for two reasons. Firstly, in the absence of change on legal standing, a broader interpretation of the right to be heard is not only less likely,[238] but also less impactful, because it will continue to benefit a small circle of industry applicants. Secondly, in the case law the invocation of the right to be heard does not lead to intensified review in contrast to the invocation of the other two principles. The Court's interpretation of the duty of care enables the most intensive review of technical discretion. Therefore, under the current institutional framework, the most impactful change would be a re-interpretation of the principles of the duty of care and of reason-giving. At the same time, from the Court's perspective, a broader interpretation of both principles might be easier to embrace as compared to a change of course on the right to be heard.

To begin with the duty of care, this principle has not only been key in enabling more judicial engagement with questions of epistemic quality but is also a procedural guarantee with a strong public interest dimension,[239] which resonates with ideas of inclusive deliberation and epistemic

[234]See also Leonelli, 'Access to the EU Courts' (n 73) and Hadjiyianni (n 62).

[235]See van Wolferen and Eliantonio (n 62), Leonelli, 'Access to the EU Courts' (n 73).

[236]For a discussion of such arguments see D Curtin and M Weimer, 'The Court of Justice of the European Union: Supranational Adjudicator and Accountability Forum' in PJ Kuijper et al (eds), *Law of the European Union* (Kluwer Law International 2018) 357.

[237]For example in the form of a measure regulating collective redress at EU level. See also the recently adopted reform of the Aarhus regulation, which however only broadens access to internal administrative review, and not to judicial review (see n 73).

[238]Scholars have nonetheless offered alternative interpretations. In a comprehensive analysis, Mendes criticises the Court's formalistic interpretation of participation rights and the exclusion of such rights in the case of normative acts (general rule-making procedures). She offers a rights-based understanding whereby 'participation rights should be granted whenever an act, irrespective of its status or legal qualification, affects substantively the rights and interests of certain persons.' (Mendes (n 153) 228).

[239]Türk (n 84) 133.

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diversity. While the principle of duty of care can sometimes be seen as a rule protecting individual interests,[240] its primary function is that of an objective procedural guarantee arising from an absolute obligation on the part of the EU administration to examine carefully and impartially all the relevant aspects of the individual case. This is particularly the case for general rulemaking,[241] where its protective function for individuals diminishes as compared to individual decisions. Scholars have emphasised the potential of this principle to induce more deliberation in administrative procedures concerned with the gathering of highly technical yet publicly salient information.[242] Nothing in the Court's reasoning indicates that there are principled reasons to reduce the scope of relevant information to be duly considered by the administration in the process of scientific assessment to only the information submitted by the applicant. Rather, such reduction currently happens in the case law because the Court responds to the arguments brought by the litigant. It is thus an indirect result of the legal standing requirement. It is also a result of the Court's emphasis that the duty of care compensates for limited substantive review and thereby protects the interests of the applicant. Yet in contrast to the right to be heard, in the Court's reasoning, the duty of care does not depend on the test of individual and direct concern. Indeed, it is understood that other actors participating in the regulatory process, eg third parties via the public consultation procedures, are also providing relevant information, which, if prompted, the Court would consider.[243]

An example from the Court's case law on tobacco control may help clarify our argument. In *Pillbox* the Court decided a request for a preliminary ruling challenging the validity of EU *legislation* on electronic cigarettes.[244] The main disputed legal issue pertained to the quality of the scientific basis of the legislation as part of the proportionality test. More specifically, it was contested whether there was sufficient evidence of health risks arising from e-cigarettes that would justify the introduction of restrictions. The way in which the Court responded to the challenge of the scientific basis of the Directive mounted by the industry before the national court was by examining the quality not so much of the evidence as such, but of the process whereby the EU legislature collected such evidence. Before adoption, EU legislature undertook extensive consultations with experts and concerned parties to consider all information. The Court recognised that this did not remove scientific uncertainty. Nonetheless, the fact that the European Parliament, the Council and the Commission 'took account of the available scientific evidence and the opinions of the interested parties' and that 'a number of consultations and meetings was organised precisely in order to collect the necessary information on the options available to the EU legislature' including industry and consumers representatives, scientists, national and international authorities,[245] allowed the Court to conclude that the measure rested on a sound epistemic basis. By emphasising the inclusiveness of the consultation process the Court implicitly emphasised the value of epistemic diversity in the legislative process, which also served as a defense against the applicant's challenge amidst scientific complexity.

The *Pillbox* approach to procedural review[246] has no equivalent in relation to administrative acts, albeit of general application, such as those considered in this paper. Despite the different legal

[240]To what extent individual rights can be derived from this principle is not entirely clear from the case law. See for a recent discussion by AG Szpunar in the context of non-contractual liability, Joined cases C-65/21 P C-73/21 P C-74/21 P and C-75/21 P *Química del Nalón SA v Commission* ECLI:EU:C:2022:78.

[241]See Mendes (n 153) 259.

[242]Scott and Sturm (n 4) 585–6.

[243]See for example the (rare) cases in which CSOs are granted leave to intervene in the proceedings (n 71).

[244]See *Pillbox* (n 50). The referring judge asked the Court to rule on the validity of validity of Art 20 of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ 2014 L127/1.

[245]Ibid., para 66.

[246]Which took place within the framework of the precautionary principle as part of proportionality analysis.

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context, we believe that an analogous approach should apply when the Court applies the principle of the duty of care in administrative rulemaking. At present, in industry-led litigation, the Court confines its review to inquiring whether the information invoked by the applicant was duly considered in the administrative process. We suggest that, in the light of the values of epistemic diversity and the objective procedural nature of the principle of duty of care, the Court should instead look at how inclusive the process of information gathering was, and whether the administration considered *all* relevant information, including those submitted by other stakeholders.[247] Of course, considering the current litigation patterns outlined in Section 3, it would mostly not be prompted to do so by the litigants but would have to do so *ex officio*. The application of the duty of care in state aid cases indicates the existence of an obligation to look beyond the issues raised by the applicant.[248] From an external perspective, this would allow the Court to alleviate the epistemic asymmetries in EU risk regulation. Judicial review could thus catalyse procedures in which agency experts explain and justify their judgements not only vis-à-vis the regulated industry, but also vis-à-vis other stakeholders and affected actors. From an internal perspective, this could serve as a normative benchmark against which to measure the intensity of judicial review. The finding that the administration gathered and duly considered information from different sources and stakeholders should justify less intensive review and more deference – the lack thereof a more intensive engagement with the scientific information.[249]

A similar understanding should inform the reason-giving requirement, which, as we discussed, also has a strong objective procedural dimension.[250] It serves as 'an indicator of substantive defects in the decision to be examined'.[251] The requirement of reason-giving flanks the application of the principle of duty of care,[252] both reinforcing the reasoned nature of the decision-making and ensuring that all the relevant circumstances were duly considered in the decision-making process. Reason-giving, therefore, should be directed at a broader range of stakeholders, refer to all relevant information submitted by them, display all relevant arguments and how they have been weighted against each other, and how disagreement has been handled.[253] At present, however, the Court understands the requirements of reason-giving to be a corollary to the right to be heard, understood as a right of defense of the 'adversely affected individual'.

In the absence of legislative or interpretative change, the normative value of the Courts' intensified review of technical discretion, as developed post-*Pfizer*, should be questioned.[254] As long as only a small group of powerful economic actors has access to litigation and benefits from process rights, such review tends to aggravate the epistemic power imbalances and related legitimacy concerns affecting EU risk regulation.

7. Conclusion

Post-*Pfizer*, the CJEU approach to reviewing both administrative discretion and administrative process has often been understood as a welcome response to a maturing and expanding EU

[247]In a similar vein see the arguments on the role of judiciary by Korkea-Aho (n 135).

[248]See *Sytraval* (n 128).

[249]See also Korkea-Aho (n 135).

[250]See Mendes (n 153) 248.

[251]J Schwarze, *European Administrative Law: Revised First Edition* (Sweet and Maxwell 2006) 1403.

[252]See Cases T-371 and 394/94, *British Airways plc and British Midland Airways Ltd v Commission* ECLI:EU:T:1998:140, para 95.

[253]Korkea-Aho (n 135) 51 and 54.

[254]Due to both the risk of substitution of judgement and disregard of the administration's discretionary space and of the limited range of actors that can ask the Court to review the epistemic bases of risk regulation measures. In this context, other avenues seem more promising, such as the European Ombudsman or internal boards of agencies. J Mendes, 'Discretion, Care and Public Interests in the EU Administration: Probing the Limits of Law' 53 (2) (2016) Common Market Law Review 419–45 and Krajewski (n 39).

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administrative state. The two interlinked features of the modern approach – ie intensified scrutiny of the scientific basis of administrative decisions and procedural review based on the principles of duty of care, reason-giving and participation – promised to achieve a *Goldilocks* balance between the Court's task of ensuring judicial protection amidst scientific complexity, on the one hand, and its duty to respect the administration's prerogatives as decision-maker, on the other hand. Moreover, the Court has been described as an 'information catalyst' promoting inclusive procedures which generate deliberation among all relevant experts, thereby enhancing the informational basis behind EU regulatory measures.

In this paper, we have questioned these established accounts offering a critique of the case law since *Pfizer* on both doctrinal and socio-legal grounds. From a doctrinal perspective, effective judicial protection is seriously undermined by the lack of consistency and conceptual clarity in the case law. Moreover, the blurring of substantive and procedural review and the resulting intensification of scrutiny of scientific information calls into question the principle that in situations of high techno-scientific complexity the administration enjoys a wide discretion.

From a socio-legal perspective, we drew attention to the often-overlooked role of economic actors as information providers in both the EU regulatory process and litigation; as well as to the ways in which CJEU doctrinal approaches interact with the epistemic power of economic actors. We have shown that economic actors exert epistemic power over EU regulation, both through lobbying and as key information providers via legislative design. By feeding information to regulators, economic actors shape the epistemic basis of EU risk regulation, giving rise to the risk of a minoritarian bias, ie the industry's over-representation in the assemblage of scientific knowledge underpinning regulation, and particularly administrative standard-setting.

Such risk of overrepresentation exists also at the stage of litigation due to the CJEU judicial interpretations of legal standing and administrative procedural guarantees. For both access to the Court and procedural guarantees, the Court significantly reduces the circle of beneficiaries to actors who as (quasi-)addressees and procedural applicants can claim a special bilateral relationship with the EU administration. The Court also reduces the function of principles of administrative procedure to a protective function whereby they serve to compensate for the limits of substantive review and to protect the individual applicant from arbitrary decisions. All three principles, therefore, serve a narrow circle of (quasi-)addressees of the regulatory act, and hence in most cases the industry applicant. This narrow compensatory understanding applies also to procedures of general rulemaking, thereby undermining the objective public interest nature of the principles of duty of care and reason-giving.

Therefore, instead of catalysing inclusive procedures that would open regulatory science to public scrutiny by a wide range of actors, as some scholars had hoped, the Court's approach fosters an *exclusive* bilateral exchange between the administration and the industry applicant. Care, reasoned justification and right to be heard are owed primarily to the industry applicants. Thus, the Court scrutinises the scientific basis of administrative rulemaking from the vantage point of resourceful economic actors. Seen together with their epistemic influence in EU regulation and a legal doctrine on standing that grants economic actors almost exclusive access to litigation, the Court's modern approach fails to address, and arguably further entrenches, the epistemic power imbalances inherent in EU risk regulation.

What is the way forward for CJEU review of EU regulatory science? We have argued that the Court should play a more constructive role in enhancing the accountability of EU regulatory science by paying more attention to the risk of epistemic capture. There is, we believe, room for a different, more generous judicial interpretation of legal standing as well as of the administrative principles discussed in this paper. Given that the Court's approach to legal standing and to participation rights (both being closely intertwined) is unlikely to change soon, we argue that under the current institutional framework, the most impactful change would be a re-interpretation of the principles of the duty of care and of reason-giving, which currently lead to the most intrusive level of review. In our view, the Court should stronger emphasise the objective procedural nature of

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these principles when reviewing the scientific basis of EU general rulemaking. In so doing, it should embrace the values of inclusive deliberation and epistemic diversity thereby overcoming the current narrow and exclusive focus on (quasi-)addressees. This would allow the Court to look beyond the claims of the applicant and to consider the overall inclusiveness of the process of information gathering. Instead of only scrutinising whether the EU administration has duly considered the information submitted by the industry applicant, the Court should also scrutinise, *ex officio*, whether the administration has considered *all* relevant information, including those submitted by other stakeholders. Judicial review would thus catalyse procedures in which agency experts explain and justify their judgements not only vis-à-vis the regulated industry, but also vis-à-vis other stakeholders and affected actors.

In the absence of either legislative or interpretative change regarding access to the Court and rights of administrative procedure, more deference and a less intrusive review of technical discretion are warranted. The intensified standard of review as developed post-*Pfizer* is open to critique both because it lacks proper doctrinal justification and because of its problematic socio-legal effects. As long as only a small group of powerful economic actors has access to litigation, and benefits from procedural guarantees, such review risks aggravating the epistemic power imbalances and related legitimacy concerns affecting EU risk regulation at present.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/elo.2022.34

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